

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

HANGSEN INTERNATIONAL GROUP LTD.,

Petitioner

v.

ZANOPRIMA LIFESCIENCES, LTD.,

Patent Owner.

IPR2023-00503

U.S. Patent No. 10,913,962

PETITIONER'S REPLY TO PRELIMINARY RESPONSE

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TABLE OF AUTHORITIES

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Cases

<i>Apple Inc. v. Fintiv, Inc.</i> , No. IPR2020-00019, Paper 11 (P.T.A.B. Mar. 20, 2020)	1, 2, 4
<i>Sotera Wireless, Inc. v. Masimo Corp.</i> , No. IPR2020-01019, Paper 12 (P.T.A.B. Dec. 1, 2020)	1, 3, 4, 5

EXHIBIT LIST

Exhibit No.	Description¹
1001	U.S. Patent No. 10,913,962
1002	Declaration of Jeffrey D. Winkler, Ph.D. (“Winkler”)
1003	U.S. Patent No. 8,367,837 (“Divi”)
1004	Tom Moody, “Biocatalysis: Genes to GMP,” Speciality Chemicals Magazine, pp. 12-14 (January 2016) (“Moody”)
1005	Declaration of Andrew Warmington, Ph.D.
1006	Enzymicals, 2017 Portfolio (“Enzymicals”)
1007	Declaration of Nathaniel E. Frank-White from the Internet Archive
1008	U.S. Patent No. 9,556,142 (“Arnold”)
1009	Dennis Wetzl et al., “Expanding the Imine Reductase Toolbox by Exploring the Bacterial Protein-Sequence Space,” <i>ChemBioChem</i> 2015, 16, 1749-1756 (“Wetzl”)
1010	Declaration of Sylvia D. Hall-Ellis, Ph.D., with attachments 1a-1f, 2a-2c, and 3a-3g.
1011	Stefan Velikogne et al., “Sequence-Based <i>In-silico</i> Discovery, Characterization, and Biocatalytic Application of a Set of Imine Reductases,” <i>ChemCatChem</i> 2018, 10, 3236-3246 (“Velikogne”)
1012	<i>Reserved</i>
1013	International Patent Application Publication WO 2014/174505 (“Sheldon”)

¹ Descriptions are for convenience only and are not admissions or evidence.

Exhibit No.	Description ¹
1014	October 30, 2020, Response to Office Action
1015	Complaint from <i>Zanoprima Lifesciences, Ltd. v. Hangsen Int’l Grp. Ltd.</i> , No. 6:22-cv-00268-ADA (W.D. Tex.)
1016	“Chemical and physical basics of routine formaldehyde fixation,” <i>J. of Oral and Maxillofacial Pathology</i> , Vol. 16, Issue 3, pp. 400-405 (Sep. – Dec. 2012).
1017	Dictionary Definition of “polyoxymethylene” from <i>McGraw-Hill Dictionary of Scientific and Technical Terms</i>
1018	Dictionary Definition of “excipient” from <i>McGraw-Hill Dictionary of Scientific and Technical Terms</i>
1019	August 7, 2020, Office Action
1020	United States District Courts — National Judicial Caseload Profile
1021	Curriculum Vitae of Dr. Jeffrey D. Winkler.
1022	Francis A. Carey, <i>Organic Chemistry</i> (6th ed. 2006), Chapter 7
1023	Letter from Tony Corsini of the British Library Regarding the Public Availability of January 2016 Issue of <i>Speciality Chemicals Magazine</i>
1024	Motion to Stay Pending IPR Statistics – Waco Division of the Western District of Texas – Report Generated from Docket Navigator
1025	Stipulation to Not Raise Printed Publication Invalidity Grounds Presented in the IPR and Those that Reasonably Could Have Been Raised in IPR
1026	Katherine K. Vidal, Memorandum to Members of the Patent Trial and Appeal Board, Interim Procedure for Discretionary Denials in AIA Post-Grant Proceedings with Parallel District Court Litigation

I. INTRODUCTION

Hangsen International Group, Ltd. (“Hangsen”) replies to Patent Owner’s argument that the *Fintiv* factors favor discretionary denial. They do not. Regardless, Hangsen’s invalidity case is compelling, and Hangsen has provided a *Sotera* stipulation to Patent Owner in the co-pending district court case agreeing not to pursue the grounds of invalidity raised in this *inter partes* review (“IPR”) and any printed-publication grounds of invalidity that reasonably could have been raised in this IPR should this IPR petition be instituted. The Board should institute IPR.

II. ARGUMENT

On a request for discretionary denial of IPR in light of a parallel district court action, the Board considers the following factors:

1. Whether the district court granted a stay or evidence exists that one may be granted if a proceeding is instituted;
2. The proximity of the district court’s trial date to the Board’s projected statutory deadline for a final written decision;
3. The investment in the parallel proceeding by the district court and the parties;
4. Overlap between issues 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.

Apple Inc. v. Fintiv, Inc., No. IPR2020-00019, Paper 11 at 6 (P.T.A.B. Mar. 20, 2020) (precedential). The factors weigh against a discretionary denial.

A. The District Court Often Stays Cases Pending IPR (Factor 1).

The parallel litigation is pending in the Western District of Texas, Waco Division. The Waco Division grants motions to stay pending IPR significantly more often than not. Exhibit 1024 is a report generated from Docket Navigator showing the results of motions to stay pending IPR in the Waco Division of the Western District of Texas. In 2019, the court granted five and denied one. In 2020, the court granted nine and denied three. In 2021, the court granted eight and denied one. In 2022, the court granted 28, denied 12, and had three other dispositions. Thus far in 2023, the court granted 13 motions to stay pending IPR and denied five.

The evidence shows that the court grants a stay pending IPR in the large majority of cases. This factor weighs in favor of institution.

B. The District Court's Trial Date Is Not Definitively Set (Factor 2).

The trial date is listed as the "[w]eek of January 29, 2024, or at the Court's convenience." The Scheduling Order thus envisions that circumstances, including the court's docket, could bump the start of trial to an unknown date. The lack of a firm trial date weighs in favor of institution.

C. The Parties’ and the District Court’s Investments Are Not Exceptional (Factor 3).

The parties and the district court have made investments typical of civil litigation. Patent Owner filed suit on March 12, 2022. Through January 20, 2023, the parties were engaged in claim construction²; fact discovery did not open, and initial disclosures were not served, until January 24, 2023. And the pleadings were amended (by each party) on May 16, 2023. Opening expert reports are not due until September 5, 2023. The litigation has proceeded efficiently and without atypical investment by the parties or the court. This factor is neutral.

D. There Is No Overlap Between the Issues Raised in the Petition and in the District Court Action (Factor 4).

On June 26, 2023, Hangsen stipulated to not raise any ground of invalidity based on printed-publication prior art that was presented in this IPR or that reasonably could have been presented in this IPR, if the IPR is instituted. This stipulation was filed with the district court on June 26, 2023.

When a petitioner files such a stipulation, it “mitigates any concerns of duplicative efforts between the district court and the Board, as well as concerns of potentially conflicting decisions.” *Sotera Wireless, Inc. v. Masimo Corp.*, No. IPR2020-01019, Paper 12 at 18–19 (P.T.A.B. Dec. 1, 2020) (precedential).

² The parties are still waiting for the district court’s written decision explaining its claim construction decision rendered from the bench.

Hangsen’s stipulation thus “weighs strongly in favor of not exercising discretion to deny institution.” *Id.* at 19.

Moreover, on June 21, 2022, the Director of the USPTO issued a memorandum to the Members of the Patent Trial and Appeal Board concerning discretionary denials with parallel district court litigation. Ex. 1026. The Director has stated that “the PTAB will not discretionarily deny institution of an IPR or PGR in view of parallel district court litigation where,” as here, “a petitioner stipulates not to pursue in a parallel district court proceeding the same grounds as in the petition or any grounds that could have reasonably been raised in the petition.” *Id.* at 7.

In view of Hangsen’s stipulation, there is no risk of “inconsistent outcomes between the PTAB and the district court” and the PTAB can “review grounds that the parallel district court litigation will not resolve.” *Id.* at 8. Under the Board’s *Fintiv* and *Sotera* precedents, and under the Director’s order, the Board should not exercise discretion to deny institution.

E. The Parties’ Identity Favors Institution Given the IPR Raises Issues that Will Not Be Considered in the District Court Action (Factor 5).

As discussed above, Hangsen has entered a *Sotera* stipulation agreeing not to pursue the grounds of invalidity raised in this IPR and any printed-publication grounds of invalidity that reasonably could have been raised in this IPR if this IPR is instituted. Ex. 1025. The parties in this IPR are the same as the parties in the

district court litigation. As such, and in view of the *Sotera* stipulation, the grounds in the IPR necessarily will not be considered in the district court. The identity of the parties thus weighs in favor of not exercising discretion to deny institution.

F. The Merits of the Petition Are Compelling (Factor 6).

The Director has stated that “compelling, meritorious challenges are those in which the evidence, if unrebutted at trial, would plainly lead to a conclusion that one or more claims are unpatentable by a preponderance of the evidence.” Ex. 1026 at 4. The Petition presents a compelling case of invalidity.

The Petition presents prior art teaching the reaction mechanism for converting myosmine to nornicotine to nicotine. It also presents numerous publications teaching the availability of imine reductase enzymes to stereoselectively reduce imines like myosmine to amines like nornicotine. And imine reductase enzymes characteristically have stereoselective products. During prosecution, Patent Owner emphasized that the claims recite a “stereoselective synthesis” and that “Arnold at least fails to disclose or suggest step (i) of claim 1, that is, reduction of myosmine using an enzyme with imine reductase activity.” *Id.* The Petition is directed to the exact point of alleged inventiveness identified in prosecution.

III. CONCLUSION

For the foregoing reasons, Hangsen respectfully requests that the Board institute IPR.

Date: June 27, 2023

Respectfully submitted,

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CERTIFICATE OF SERVICE

Under 37 C.F.R. § 42.6(e), the undersigned hereby certifies that on June 27, 2023, a copy of the Petitioner's Reply to the Preliminary Response and supporting exhibits was served via electronic mail and Priority Mail Express® on counsel of record for Patent Owner:

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