

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

MYLAN PHARMACEUTICALS INC., DR. REDDY'S LABORATO-
RIES, INC., DR. REDDY'S LABORATORIES, LTD, SUN PHARMA-
CEUTICAL INDUSTRIES LTD., AND SUN PHARMACEUTICAL IN-
DUSTRIES, INC.

Petitioner

v.

NOVO NORDISK A/S,
Patent Owner

Case IPR2023-00724
Patent 10,335,462

**PATENT OWNER'S MOTION FOR SANCTIONS
PURSUANT TO 37 C.F.R. §§ 42.11 and 42.12**

LIST OF EXHIBITS

Exhibit	Description
EX2001	U.S. Patent No. 9,764,003 File History
EX2002	U.S. Patent No. 9,764,003
EX2003	Excerpt of Amended Joint Claim Construction Chart, <i>In re: Ozempic (Semaglutide) Patent Litigation</i> , No. 1:22-cv-01040-CFC, Dkt. 101 (D. Del. May 23, 2023)
EX2004	Miller, M., et al., “Low Viscosity Highly Concentrated Injectable Nonaqueous Suspensions of Lysozyme Microparticles,” <i>Langmuir</i> , Author Manuscript (2011), PMC 2011 (Feb 17)
EX2005	Knight, A., “Systematic Reviews of Animal Experiments Demonstrate Poor Contributions Toward Human Healthcare,” <i>Reviews on Recent Clinical Trials</i> , Vol.3, Issue 2, 89-96 (2008)
EX2006	Arrowsmith, J., “Phase II failures: 2008–2010,” <i>Nature Reviews, Drug Discovery</i> , Vol. 10 (May 2011)
EX2007	Excerpt of Novo Nordisk’s Initial Responses to Defendants’ Initial Invalidity Contentions Regarding U.S. Patent Nos. 8,129,343; 8,536,122; 8,114,833; 8,920,383; 9,775,953; 9,457,154; and 10,335,462, <i>In re: Ozempic (Semaglutide) Patent Litigation</i> , No. 1:22-cv-01040-CFC, (D. Del. Dec. 21, 2022)
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EX2010	Declaration of Julio Rosenstock, M.D.
EX2011	Declaration of George L. Bakris, M.D.
EX2012	Rossing, P., et al., “The rationale, design and baseline data of FLOW, a kidney outcomes trial with once-weekly semaglutide in people with type 2 diabetes and chronic kidney disease,” <i>Nephrol Dial Transplant</i> , Vol.38, 2041-2051 (2023)
EX2013	Heerspink, H., et al., “Effects of Semaglutide on Albuminuria and Kidney Function in People with Overweight or Obesity With or Without Type 2 Diabetes: Exploratory Analysis from the STEP 1, 2 and 3 Trials,” <i>Diabetes Care</i> , Vol.46, Issue 4, 801-810 (2023)
EX2014	Weeda, E., et al., “Medication adherence to injectable glucagon-like peptide-1 (GLP-1) receptor agonists dosed once weekly vs once daily in patients with type 2 diabetes: A meta-analysis,” <i>Int J Clin Pract.</i> , Vol.75 (2021)
EX2015	Shaman, A., et al., “Effect of the Glucagon-Like Peptide-1 Receptor

	Agonists Semaglutide and Liraglutide on Kidney Outcomes in Patients With Type 2 Diabetes: Pooled Analysis of SUSTAIN 6 and LEADER,” Circulation, Vol.145, 575-585 (2022)
EX2016	Mehdi, S., et al., “Glucagon-like peptide-1: a multi-faceted anti-inflammatory agent,” Frontiers in Immunology, Vol. 14 (2023)
EX2017	Novo Nordisk Company Announcement (October 10, 2023)
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EX2019	Transcript of January 5, 2024 Deposition of William J. Jusko, Ph.D.
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EX2060	Rosenstock, J., et al., “The Fate of Taspoglutide, a Weekly GLP-1 Receptor Agonist, Versus Twice-Daily Exenatide for Type 2 Diabetes,” <i>Diabetes Care</i> , Vol.36, 498-504 (March 2013)
EX2061	Nordqvist, C., “Experimental Diabetes Drug Taspoglutide Late-Stage Trials Suspended,” available at https://www.medicalnewstoday.com/articles/200893#1 (September 13, 2010)
EX2062	Rosenstock, J., et al., “Potential of Albiglutide, a Long-Acting GLP-1 Receptor Agonist, in Type 2 Diabetes,” <i>Diabetes Care</i> , Vol.32, Issue 10, 1880-1886 (October 2009)
EX2063	OPTUMRx, “Tanzeum® (albiglutide) – Drug Discontinuation,” available at https://professionals.optumrx.com/content/dam/optum3/professional-optumrx/news/rxnews/drug-recalls-shortages/drug-withdrawal-tanzeum-2017-0801.pdf (2017)
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EX2067	Evaluation and Licensing Division, Pharmaceutical and Food Safety Bureau, Ministry of Health, Labour and Welfare, “Report on the Deliberation Results,” available at https://www.pmda.go.jp/files/000153180.pdf (December 3, 2009)
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EX2075	Madsbad, S. et al., “Improved Glycemic Control With No Weight Increase in Patients With Type 2 Diabetes After Once-Daily Treatment With the Long-Acting Glucagon-Like Peptide 1 Analog Liraglutide (NN2211),” <i>Diabetes Care</i> , Vol.27, Issue 6, 1335-1342 (June 2004)
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EX2078	Blüher, M. et al., “Dose-response effects on HbA1c and bodyweight reduction of survodutide, a dual glucagon/GLP-1 receptor agonist, compared with placebo and open-label semaglutide in people with type 2 diabetes: a randomized clinical trial,” <i>Diabetologia</i> (2023), available at https://link.springer.com/content/pdf/10.1007/s00125-023-06053-9.pdf
EX2079	United States Patent and Trademark Office, Consolidated Trial Practice Guide, Appendix B Default Protective Order (November 2019)
EX2080	Dhruv Khullar, “The Year of Ozempic,” <i>New Yorker</i> , December 14, 2023, available at https://www.newyorker.com/culture/2023-in-review/the-year-of-ozempic (last visited January 13, 2024)
EX2081	Dani Blum, “What’s Next for Ozempic,” <i>New York Times</i> , December 20, 2023
EX2082	M.S. Capehorn <i>et al.</i> , “Efficacy and safety of once-weekly semaglutide 1.0 mg vs once-daily liraglutide 1.2 mg as add-on to 1-3 oral antidiabetic drugs in subjects with type 2 diabetes (SUSTAIN 10),” <i>Diabetes & Metabolism</i> 46 100-109 (2020)
EX2083	V. Aroda <i>et al.</i> , “Efficacy and safety of once-weekly semaglutide versus once-daily insulin glargine as add-on to metformin (with or without sulfonylureas) in insulin-naïve patients with type 2 diabetes (SUSTAIN 4): a randomized, open-label, parallel-group, multicentre, multinational, phase 3a trial,” <i>Lancet Diabetes Endocrinol</i> 5:355-66 (2017)
EX2084	R. Pratley <i>et al.</i> , “Semaglutide versus dulaglutide once weekly in patients with type 2 diabetes (SUSTAIN 7): a randomized, open-label, phase 3b trial,” <i>Lancet Diabetes Endocrinol</i> 6:275-86 (2018)

EX2085	A. Ahmann <i>et al.</i> , “Efficacy and Safety of Once-Weekly Semaglutide Versus Exenatide ER in Subjects with Type 2 Diabetes (SUSTAIN 3): A 56-Week, Open-Label, Randomized Clinical Trial,” <i>Diabetes Care</i> 2018;41:258-266
EX2086	Abdul-Ghani, M., <i>et al.</i> , Cardiovascular Disease and Type 2 Diabetes: Has the Dawn of a New Era Arrived?, <i>Diabetes Care</i> , 40:813-820 (2017).
EX2087	ADA Standards of Medical Care., Cardiovascular Disease and Risk Management: Standards of Medical Care in Diabetes, <i>Diabetes Care</i> 45(Suppl. 1):S144–S175 (2022)
EX2088	American College of Cardiology, “Clinical Topics, Diabetes and Cardiometabolic Disease,” https://www.acc.org/Clinical-Topics/Diabetes-and-Cardiometabolic-Disease (last visited Jan. 16, 2024).
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EX2090	Cosentino, F. <i>et al.</i> , ESC Guidelines on diabetes, pre-diabetes, and cardiovascular diseases developed in collaboration with the EASD, <i>Eur. Heart J.</i> , 41:255-323 (2019)
EX2091	Das, S.R., <i>et al.</i> , ACC Expert Consensus Decision Pathway on Novel Therapies for Cardiovascular Risk Reduction in Patients with Type 2 Diabetes and Atherosclerotic Cardiovascular Disease, <i>J. Am. Coll. Cardiol.</i> , 72: 3200-3223 (2018)
EX2092	Das, S.R., <i>et al.</i> , Expert Consensus Decision Pathway on Novel Therapies for Cardiovascular Risk Reduction in Patients with Type 2 Diabetes, <i>J. Am. Coll. Cardiol.</i> , 76: 1117-1145 (2020)
EX2093	Davies, M.J., <i>et al.</i> , Cardiovascular outcomes trials: a paradigm shift in the current management of type 2 diabetes, <i>Cardiovasc. Diabetol.</i> , 21:144 (2022)
EX2094	Eckel, R.H. and Blaha, M.J., Cardiometabolic Medicine: A Call for a New Subspecialty Training Track in Internal Medicine, <i>Am. J. Med.</i> , 132(7):788-790 (2019).
EX2095	Evans, L.M., <i>et al.</i> , A population-adjusted indirect comparison of cardiovascular benefits of once-weekly subcutaneous semaglutide and dulaglutide in the treatment of patients with type 2 diabetes, with or without established cardiovascular disease, <i>Endocrinol. Diab. Metab.</i> 2021;4:e00259 (2021)
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EX2097	García-Casares, N., <i>et al.</i> , Effects of GLP-1 receptor agonists on neurological complications of diabetes, <i>Rev. Endocr. Metab. Disord.</i> , 24:655-672 (2023)
EX2098	Jha, K.K., <i>et al.</i> , Transitioning to GLP-1 RAs and SGLT2 Inhibitors as the First Choice for Managing Cardiometabolic Risk in Type 2 Diabetes, <i>Curr. Atheroscler. Rep.</i> , 24:925-937 (2022)
EX2099	Kleindorfer, D.O., <i>et al.</i> , Guideline for the Prevention of Stroke in Patients With Stroke and Transient Ischemic Attack, <i>Stroke</i> , 52:e364–e467 (2021)
EX2100	Leiter, L.A., <i>et al.</i> , Cardiovascular risk reduction with once weekly semaglutide in subjects with type 2 diabetes: a post hoc analysis of gender, age, and baseline CV risk profile in the SUSTAIN 6 trial, <i>Cardiovasc. Diabetol.</i> , 18:73 (2019)
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EX2104	Maskery, M.P., <i>et al.</i> , Glucagon-like peptide-1 receptor agonists as neuroprotective agents for ischemic stroke: a systematic scoping review, <i>J. Cereb. Blood Flow Metab.</i> , 41:14-30 (2020)
EX2105	Nauck, M.A., <i>et al.</i> , Cardiovascular Actions and Clinical Outcomes With Glucagon-Like Peptide-1 Receptor Agonists and Dipeptidyl Peptidase-4 Inhibitors, <i>Circulation</i> , 136: 849-870 (2017)
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EX2110	Verges, B. and Charbonnel, B., After the LEADER trial and SUSTAIN-6, how do we explain the cardiovascular benefits of some GLP-1 receptor agonists? <i>Diabetes Metab.</i> 43: 2s3-2s12 (2017)
EX2111	Verma, S., <i>et al.</i> , Effects of glucagon-like peptide-1 receptor agonists liraglutide and semaglutide on cardiovascular and renal outcomes across body mass index categories in type 2 diabetes: Results of the LEADER

	and SUSTAIN 6 trials, <i>Diabetes Obes. Metab.</i> , 22:2487-2492 (2020)
EX2112	Terry, T., <i>et al.</i> , Does aggressive glycemic control benefit macrovascular and microvascular disease in type 2 diabetes? Insights from ACCORD, ADVANCE, and VADT, <i>Curr. Cardiol. Rep.</i> , 14(1):79-88 (2012).
EX2113	Victoza® FDA Approval Letter (Jan. 25, 2010)
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EX2351	National Institute of Diabetes and Digestive Kidney Diseases, “What is Diabetes,” https://www.niddk.nih.gov/health-information/diabetes/overview/what-is-diabetes , last reviewed April 2023.
EX2352	Mayo Clinic, “Diabetes – Symptoms & causes,” https://www.mayoclinic.org/diseases-conditions/diabetes/symptoms-causes/syc-20371444 , last updated Sept. 15, 2023.
EX2353	Mayo Clinic, “Hyperglycemia in diabetes – Symptoms & causes,” https://www.mayoclinic.org/diseases-conditions/hyperglycemia/symptoms-causes/syc-20373631 , last updated Aug. 20, 2022.
EX2354	Centers for Disease Control and Prevention, “Gestational Diabetes,” https://www.cdc.gov/diabetes/basics/gestational.html , last reviewed Dec. 30, 2022.
EX2355	National Institute of Diabetes and Digestive Kidney Diseases, “Dictionary Definition: insulin,” https://www.niddk.nih.gov/Dictionary/I/insulin .
EX2356	Centers for Disease Control and Prevention, National Diabetes Statistics Report 2020: Estimates of Diabetes and Its Burden in the United States (2020).
EX2357	National Institute of Diabetes and Digestive Kidney Diseases, “Type 2 Diabetes,” https://www.niddk.nih.gov/health-information/diabetes/overview/what-is-diabetes/type-2-diabetes , last reviewed May 2017.
EX2358	Mayo Clinic, “Type 2 diabetes – Diagnosis & Treatment,”

	https://www.mayoclinic.org/diseases-conditions/type-2-diabetes/diagnosis-treatment/drc-20351199 , last updated March 14, 2023.
EX2359	Moses, R.G., Combination Therapy for Patients with Type 2 Diabetes: Repaglinide in Combination with Metformin, Overview of Oral Antidiabetic Medications, https://www.medscape.com/viewarticle/722513_3
EX2360	Quianzon, C. C.L. and Cheick, I.E., History of current non-insulin medications for diabetes mellitus, <i>J. Community Hosp. Intern. Med. Perspect.</i> 2012 Oct. 15; 2(3). Doi: 10.3402/jchimp.v2i3.19081.
EX2361	National Institute of Diabetes and Digestive and Kidney Diseases, “Low Blood Glucose (Hypoglycemia),” https://www.niddk.nih.gov/health-information/diabetes/overview/preventing-problems/low-blood-glucose-hypoglycemia , last reviewed July 2021.
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EX2367	Sirtori, C.R. and Pasik, C., Re-evaluation of a biguanide, metformin: mechanism of action and tolerability, <i>Pharmacol. Res.</i> 1994 Oct-Nov; 30(3):187-228.
EX2368	Tomkin, G.H., Treatment of type 2 diabetes, lifestyle, GLP1 agonists and DPP4 inhibitors, <i>World J. Diabetes</i> , 2014 Oct. 15; 5(5):636-650.
EX2369	U.S. Food & Drug Administration, Drugs@FDA, Glucophage®
EX2370	White, Jr., J.R., A Brief History of the Development of Diabetes Medications, <i>Diabetes Spectr.</i> 2014;27(2):82-86.
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Consistent with the Director’s *Interim Procedure for Discretionary Denials*, 7 (June 21, 2022) (“*Fintiv* Guidance”), Mylan made a promise to the Board and Patent Owner (“PO”) as a *quid pro quo*: a *Sand Revolution* stipulation to avoid discretionary denial under *Apple Inc. v. Fintiv, Inc.*, IPR2020-00019, Pap.11 (Mar. 20, 2020) (prec.). But despite promising **not** to pursue instituted IPR grounds in litigation, Mylan is actively violating that promise—taking the unsupported position it **can** (or “**must**”) litigate three identical grounds in court until dispositive motions or trial. This harms the Board’s efficient operation, the system’s integrity, and PO—which must simultaneously defend Mylan’s duplicative attacks while Mylan educates its litigation co-defendants and apparently funds their experts on the overlapping grounds. Unless the Board enforces petition promises and punishes these blatant violations, petitioners will be free to make and break their *Fintiv* stipulations.

I. Factual Background

In its Petition, Mylan Pharmaceuticals Inc. (“Mylan”) promised the Board and PO that it **would not litigate any of the same IPR grounds** in the co-pending district court action, *In re: Ozempic (Semaglutide)*, No. 1:22-md-03038-CFC (D. Del.) (“parallel litigation”), from the moment this IPR was instituted.¹ Relying on that

¹ Pap.1, 66 (“if the Board institutes, **Petitioner will not pursue** in [parallel litigation] any instituted grounds,” citing *Sand Revolution II, LLC v. Continental Intermodal*

stipulation, PO did not brief *Fintiv* in its POPR (Pap.6). Mylan got what it wanted: the Board, noting Mylan's stipulation, declined to invoke its discretion and, instead, instituted trial on October 4. Pap.10, 16. Mylan's promise took effect that day, but Mylan broke it: ***Mylan is actively litigating three identical instituted IPR grounds in district court***—flouting its representation to the Board and PO, engaging in the harassing, duplicative litigation the *Fintiv* policies exist to prevent, and ensuring the harm to PO cannot now be undone. ***After*** institution:

- Mylan coordinated and educated its litigation co-defendants to continue pressing these same three identical grounds in court.
- In the midst of the co-defendants developing their litigation invalidity theories, Mylan shared its three IPR experts with each of the four other defendant groups, uniting them all in forming and refining their arguments and evidence on these core invalidity positions in litigation expert reports.

Grp.–Trucking LLC, IPR2019-01393, Pap.24, 12 (June 16, 2020) (informative)).

Unless stated, statutory and regulatory citations herein are to 35 U.S.C. or 37 C.F.R., as context indicates, internal citations omitted, and emphases/annotations are added.

- Represented by the same counsel,² Mylan itself actually served the three litigation reports on behalf of Mylan and every other defendant on March 19, 2024, making the very arguments Mylan is barred from pursuing. And, as detailed below, Mylan’s violations continue.

These Mylan-coordinated **litigation** reports were from the same three experts Mylan hired for its **IPR**—Jusko (EX1006/EX2551), Bantle (EX1004/EX2537), and Dalby (EX1008/EX2538)—and include three invalidity grounds **identical** to those already instituted here, asserting ’462’s litigated claims are: (1) “invalid as anticipated by WO ’421” (just as in Mylan’s IPR Ground 1), (2) “invalid as anticipated by Lovshin 2009” (IPR Ground 2), and (3) “obvious over WO ’537 in view of Lovshin 2009” (IPR Ground 4). *E.g.*, EX2551, ¶¶1, 206, 227, 331; EX2537, ¶¶1, 286-304, 323-339, 414-438; EX2538, ¶¶1, 178-181; EX2539, 1-2. The reports contain not only swaths of these experts’ original IPR declarations to argue the very grounds Mylan gave up for institution,³ but also refinements responding to and road-mapping from specific

² Mylan is represented by many of the same Perkins Coie LLP attorneys in both this IPR and the parallel litigation. *Compare, e.g.*, Pap.45, with EX2544, at 2-3.

³ *See, e.g.*, EX2563, 40:9-13. Despite Mylan’s contrary suggestions (*e.g., id.*, 35:12-17; Pap.69, 4), its stipulation doesn’t permit Mylan to pursue insitituted grounds through “public” materials.

arguments PO made in this IPR. *E.g.*, *compare* POR (Pap.29), 51 (identifying **failure to show REOS**), *with* EX2551, ¶¶340-42 (**adding REOS arguments** after ¶340 in ¶¶341-42 (missing after similar EX1005, ¶255 (Ground (“Gr.”) 4)); POR, 35 (“Jusko opined (**without data**)”), *with* EX2551, ¶350 (**adding data** missing from similar EX1005, ¶262 (Gr. 4)); *compare*, Pap.29(POR), 33-34 (criticizing “0.1, 0.2, and 0.4 mg [doses as] ***not show[ing] statistically significant improvement***”), *with* EX2551, ¶349 (adding assertion (missing from similar EX1005, ¶261(Gr. 4)) that “these doses [0.1, 0.2, and 0.4 mg]... ***would still provide some degree of efficacy***”).

As even the publicly-available record⁴ confirms, Mylan began sharing its IPR experts with the other defendants on these overlapping grounds only ***after*** Mylan’s promise took effect. When copycat petitioners Dr. Reddy’s Laboratories and Sun Pharmaceuticals filed their petitions and joinder motions within a month of Mylan’s institution, each submitted declarations from their own ***alternate experts***, expressing uncertainty about whether Mylan would allow them to retain Mylan’s.⁵ *See, e.g.*,

⁴ PO is separately seeking discovery regarding Mylan’s violation. *See* Pap.69, 5-6.

⁵ Dr. Reddy’s and Sun joined this proceeding as silent understudies, agreeing, *inter alia*, to be bound by Mylan’s agreements about taking testimony. *E.g.*, IPR2024-00009, Pap.3, 2, 6-7 (DRL); IPR2024-00107, Pap.2, 7-8 (Sun). Both knew of Mylan’s stipulation, which they copied in their copycat petitions, and each knew

EX2545, 4-5 (“[I]n the event that Mylan does not agree to allow DRL to retain... Mylan[’s] Declarants”); EX2546, 4-6. But the reports Mylan served in March for all defendants say Mylan’s experts are *now expressly testifying for every co-defendant*—petitioners Mylan, DRL and Sun, as well as Zydus and Rio—for purposes of attacking PO’s ’462 Patent. EX2551, ¶1; EX2537, ¶1; EX2538, ¶1.

After PO served a proposed motion for sanctions on June 10, 2024, the parties engaged in an extended meet-and-confer pursuant to §42.11(d)(2). But Mylan never acknowledged a problem with its conduct and *never disputed the underlying facts*. EX2654, 1-5, 7-9. Mylan also *refused to answer basic questions about its conduct*, and *would not commit to stop* pursuing the identical grounds in litigation.⁶ Instead,

of, participated in, and benefitted from Mylan’s violation of its stipulation, having joined the March 19 expert reports knowing Mylan was forbidden from doing so. *E.g.*, IPR2024-00009, Pap.18, 1-2 (DRL); IPR2024-00107, Pap.14, 1-2 (Sun).

⁶ *E.g.*, EX2654, 9 (unanswered from June 25: “can Mylan represent that... Mylan had no substantive involvement in the preparation, discussion, or other development of the” foresworn invalidity theories in the March reports), 8 (same: “Does Mylan agree that, going forward, it will not pursue these grounds, whether alone or in collaboration (openly or “behind the scenes”) with its codefendants?”); Pap.69, 4 (“Mylan...would not acknowledge whether it was involved”); EX2536, 13:1-15,

Mylan first sought to *limit* its stipulation—editing it from *any pursuit* of the forbidden grounds *from institution* (Pap.1, 66), to *pursuit only later, by dispositive “motion or at trial.”* EX2654, 10. And on July 2, after meeting and conferring, Mylan first hypothesized it was *required* to pursue the forbidden grounds to *preserve* them in case the law changed—in other words, Mylan had to *break* its promise in case the law later changed (in some unspecified way) to free it from its promise. EX2655, 2.

Mylan’s active misconduct continues. On July 16, Mylan and its codefendants again served joint expert reports. This time, *DRL* and *Sun* (now instituted and joined here) acknowledged *they* were bound by their *Sotera* stipulations. But in sharp contrast, *Mylan* continued to press its unsupportable position that its own *Sand Revolution* stipulation does *not* limit Mylan’s full-bore litigation of these overlapping grounds against PO in court—through expert discovery and pretrial—until a dispositive “motion or trial.” The three July reports (again from Bantle, Jusko, and Dalby) each include footnotes like the following:

¹ I understand that Dr. Reddy’s and Sun do not adopt my opinions as they relate to anticipation or obviousness of the ’462 patent, *see also* Op. Rpt. §§ IX.A and IX.B, because they stipulated in related proceedings not to pursue such arguments in this case. I also understand that Mylan Pharmaceuticals Inc. will not pursue by motion or at trial in this litigation anticipation of the claims of the ’462 patent by WO ’421 or Lovshin or obviousness of the claims of the ’462 patent by WO ’537 in view of Lovshin, *see also* Op. Rpt. §§ IX.A.1, IX.A.3, and IX.B.3, unless a change in law otherwise permits.

EX2650, ¶1n.1; EX2651, ¶1n.1; EX2652, ¶1nn.1-2. And Mylan further argues it

20:9-22:21, 39:21-40:17.

can't, as a practical matter, follow its stipulation because it chose to *share* experts:

“[Y]ou cite no authority for your argument that Mylan may “fund[] and shar[e] experts *only on permissible topics*,” and offer no explanation as to how exactly that would work in practice or what, exactly, is a “permissible topic[.]” ...Apparently Patent Owner believes Mylan must parse and divide expert bills according to whether an expert was reading WO421 with one ground in mind or another or was describing it generally or in the context of certain grounds but not others. Patent Owner also appears to believe, for example, that when the district court defendants prepare an expert for deposition, Mylan may discuss WO421 with the expert for some purposes but not others. As these examples illustrate, at no point have you attempted to explain how your unsupported position could be carried out in practice....

EX2655, 3 (emph. orig.); EX2656, 2; EX2536, 21:21-22:9, 35:12-36:1. While this is certainly revealing (both about Mylan's past conduct and its intent going forward) it offers no excuse: parties regularly pay and direct their experts on separate tasks (as Sun's⁷ and DRL's footnotes confirm), and Mylan's convenience doesn't trump its promise to the Board and PO.

⁷ While acknowledging its stipulation, Sun has confessed its own view that Mylan has inextricably embedded its three estopped IPR Grounds into the co-defendants' litigation positions. EX2543, 1 (declining to confirm it would forgo indirect pursuit of stipulated grounds, as it “*may not be the case*” that issues can be isolated).

II. Argument

The Board (and patentees) are entitled to rely on petitioners to keep their promises—indeed, the orderly functioning of PTAB proceedings *requires* it. To do otherwise would gut the Office’s *Fintiv* policies and Congress’s intent for the PTAB. *See also* §42.11(a)-(c) (describing duty of candor). Given Mylan’s clear, continuing violations, sanctions are needed to protect the integrity and efficient functioning of the PTAB, as well as to begin to address the prejudice to PO.

The Board has broad powers to sanction misconduct. §42.12(a). Whether sanctionable misconduct has taken place is a “fact-based inquiry” into whether a party’s conduct “demonstrates an abuse of process or conduct that otherwise thwarts, as opposed to advances, the goals of the Office and/or the AIA.” *E.g., Patent Quality Assurance, LLC v. VLSI Tech. LLC*, IPR2021-01229, Pap.102, 38–39 (Dec. 22, 2022) (prec.) (“*PQA*”). §42.12(b) identifies particular sanctions, including sanctions sought here, although the Board may also issue other non-listed sanctions. *Apple Inc. v. Voip-Pal.com, Inc.*, 976 F.3d 1316, 1323-24 (Fed. Cir. 2020). In determining appropriate sanctions, the Board generally considers: (1) whether the party’s conduct warrants sanctions; (2) whether that conduct caused harm (to, *e.g.*, another party, the proceedings, or the USPTO); and (3) whether the sanctions are proportionate to the harm. *PQA* at 36–37; *OpenSky Indus., LLC v. VLSI Tech. LLC*, IPR2021-01064, Pap.102, 26 (Oct. 4, 2022) (prec.). As explained below, Mylan’s misconduct requires

that the Board (1) enter adverse judgment on the Grounds Mylan has improperly continued to pursue in IPR and litigation—Grounds 1, 2, and 4⁸—or, alternatively, preclude argument and exclude evidence as to those Grounds (*see* §42.12(b)),⁹ and (2) order Mylan pay compensatory expenses, including PO’s attorney fees (*id.*).

A. Mylan’s Violation of Its Stipulation Warrants Sanctions

Mylan’s disregard of its promised estoppel is sanctionable conduct. In making and then blatantly breaking its promise not to pursue *any* instituted IPR grounds in parallel litigation, Mylan first “[a]dvanc[ed] a misleading or frivolous argument” to avoid discretionary denial, (Pap.1, 66), and then “[a]buse[d the Board’s] process” and “improper[ly] use[d this] proceeding” to harass PO and waste the resources of both PO and the Board with improper duplicative attacks against the ’462 Patent that risk inconsistent results. *See* §42.12(a)(2), (6), (7). The same is true of Mylan’s baseless assertions to the Board and PO that it can now limit its stipulation to dispositive “motion[s] or trial,” or that Mylan “must” break its promise to “preserve” its options. *E.g.*, EX2656, 2; EX2536, 13:9-15:3, 20:9-21:13; *see Samsung Elec’s America, Inc.*

⁸ While Ground 3 is also substantially identical to a fourth ground urged by the defendants in litigation (WO421 in view of the ’833 Patent), PO reserves for the district court whether Mylan’s stipulation extends to that ground.

⁹ For the reasons *supra* (*see* n.5), silent understudies DRL and Sun are also bound.

v. RFCyber Corp., IPR2021-00980, Pap.11, 17-18 (Dec.15, 2021) (rejecting argument that *Sotera* stipulation caveat “unless a change in the law allows otherwise” created an “‘out,’ in reality [that] would... allow[] Petitioner to continue its prior-art based invalidity arguments in district court”). Mylan wants to have its cake and eat it, too: while failing to acknowledge its *actual* stipulation in district court (even after DRL and Sun made court filings acknowledging *their* IPR stipulations¹⁰), Mylan actively broke that promise by personally serving invalidity arguments Mylan was barred from making, and improperly continues actively litigating these duplicative grounds in both forums. And, by sharing its experts and working with other defendants on reports urging these same overlapping grounds, Mylan has improperly ensured the other defendants are fully and improperly educated and armed **by Mylan** with Mylan’s detailed views and Mylan-prepared experts to continue pursuing (for all defendants) the arguments Mylan is forbidden from pursuing—embedding

¹⁰ Mylan’s counsel was informed via ECF in **February** and again in **May** that co-defendants DRL and Sun had both filed stipulations in the parallel litigation about post-institution estoppel. EX2541; EX2542; EX2550; EX2547; EX2548; EX2549. And PO had **reminded** Mylan of its *Sand Revolution* stipulation (which DRL and Sun copied into their own petitions) in **November**—proposing Mylan upgrade it to a *Sotera* stipulation to avoid certain disputes (Mylan declined). EX2540, 1-2.

Mylan’s ongoing participation in a way that cannot now be undone. This renders the Board’s precedents and policies meaningless, and frustrates these stipulations’ very purpose: to avoid burdensome, duplicative efforts across litigation and the PTAB, and potentially conflicting decisions. This, alone, supports sanctioning Mylan.

More fundamentally, Mylan’s misconduct is sanctionable as an improper use of this AIA proceeding as part of a wrongful, duplicative, and burdensome attack on PO and the ’462 Patent. AIA proceedings, such as Mylan’s IPR, “do not exist in isolation but are part of a larger patent and innovation ecosystem” which “Congress intended ... to be a less-expensive alternative to district court litigation to resolve certain patentability issues.” *PQA* at 39. At the same time, AIA proceedings are not “intended to be tools of patent owner harassment.” *Id.* AIA’s intent, expressed by Congress, is to “consider . . . the integrity of the patent system [and] the efficient administration of the Office.” *Id.* (citing § 316(b)). Having “recognized the potential for inefficiency and gamesmanship in AIA proceedings, given the existence of parallel proceedings between the Office and district courts,” it is precisely to pursue this purpose of the AIA that the Board has designated *Fintiv*, *Sotera*, and *Sand Revolution* as precedential or informative. *Fintiv Guidance*, 1, 7–8; *Sand Revolution*, 12.

B. Mylan Has Harmed the Office, the Patent System, and PO

Harm to the Office and System. *Fintiv* exists to police the “potential for inefficiency and gamesmanship in AIA proceedings” running in parallel to related

litigations, particularly when overlapping issues raise “concerns of inefficiency and [potentially] conflicting decisions.” *Fintiv* Guidance at 1, 7. *Sand Revolution* stipulations, like Mylan’s, are meant to mitigate those concerns and “help ensure that an IPR functions as a **true alternative** to litigation in relation to grounds that could be at issue in an IPR.” *Sand Revolution*, 12 & n.5. Mylan’s invoking *Sand Revolution* to win institution, only to break its promise later when it benefited Mylan, violates these policy goals, undermines the Office’s safeguards against inefficiency and gamesmanship, and invites distrust of the patent system. Mylan’s active two-forum litigation on its IPR grounds after promising to choose just one undercuts Congress’s goal of a more efficient “alternative to district court litigation....” *PQA*, 39.

Harm to PO. Mylan’s intentional disregard of its promised stipulation has also harmed, and continues to harm, PO. PO relied on Mylan’s explicit promise in the Petition and, given the Office’s precedent weighing such stipulations, did not pursue *Fintiv*-related issues or arguments. The Board did not question Mylan’s stipulation, either, and to the contrary cited it in instituting this IPR. Pap.10, 16. Because Mylan is, in fact, pursuing overlapping grounds in litigation and directing and organizing its co-defendants to do the same, PO is now forced to carry the needless, wasteful burden of defending its patent simultaneously against Mylan and the same invalidity grounds in two different forums—including in expert discovery and depositions *against Mylan* in the parallel litigations—as well as the costs of responding

to and seeking to remedy Mylan's violation. PO's quiet title is further prejudiced by potentially-conflicting decisions between the PTAB and district court. Mylan is improperly using AIA proceedings as "tools of patent owner harassment." *PQA*, 39.

This harm cannot be undone. By setting up all the defendants to pursue the same overlapping grounds in parallel litigation using Mylan's IPR experts and their opinions crafted at Mylan's behest and now refined with Mylan's participation, Mylan has made permanent the inefficiencies of duplicative litigation Mylan promised the Board it would avoid. Pap.1, 66. Even if Mylan now formally "withdraws" from those reports and arguments, its IPR grounds (as shaped, revised, and argued by Mylan) will be carried forward by the co-defendants, now fully informed on Mylan's invalidity theories and armed with Mylan's experts. *See also supra* n.7; EX2536, 21:21-22:9, 35:12-36:1.

C. PO's Requested Sanctions Are Proportional to the Harm

PO's requested sanctions are reasonable in light of the severity of Mylan's ongoing misconduct, and also necessary to ensure compliance with the Board's rules, deter others, and begin addressing the prejudice to PO. *See Apple Inc. v. Voip-Pal.com, Inc.*, IPR2016-01198, Pap.70, 9–10 (Dec. 21, 2018) (citing § 42.11(d)(4)).

1. Adverse Judgment or, Alternatively, Preclusion and Exclusion

As detailed above, the harm to PO cannot be fully remedied because Mylan

has assured late compliance with its stipulation will be meaningless. To begin addressing Mylan's wrongdoing, an appropriate sanction would be entry of adverse judgment against Petitioners on duplicative Grounds 1, 2, and 4, leaving them free to pursue in the IPR any non-overlapping grounds. §42.12(b)(8); n.9. Such an order is necessary and proportionate because of the severity of Mylan's misconduct: while Mylan has continued pressing them in this IPR *and* parallel litigation, Mylan has also irreversibly tainted the litigation by directing, sharing, and furnishing the experts and arguments for the duplicative grounds to Mylan's litigation co-defendants.

Any remedy short of adverse judgment would encourage future petitioners to proffer sham stipulations in exchange for institution, safe in the knowledge they need only comply if they are forced to do so later. Allowing Mylan to brush off its stipulation without consequence would render *Sand Revolution* stipulations meaningless and undercut the Board's policies regarding discretionary denial and *Fintiv*—encouraging use of AIA proceedings as a tool for PO harassment, inefficient litigation, and gamesmanship. Indeed, the Office has confirmed the value and importance of avoiding the pursuit of identical grounds in litigation by specifying in its *Fintiv* Guidance that petitioners may avoid discretionary denial by promising *not* to pursue overlapping grounds in litigation. *Fintiv* Guidance at 7. To protect these policy interests, ensure parties keep their promises to the Board, and deter others from following Mylan's bad example, adverse judgment is needed. *See, e.g., One World*

Techs., Inc. v. Chervon (HK) Ltd., IPR2020-00884, Pap.27, 5 (Feb. 11, 2021) (“[W]e need to take steps to ensure that a party... knows that it can rely on our rules and orders.”) (authorizing sanctions motion). Declining to enforce a petitioner’s promise made to achieve institution will only invite further bad behavior. It is “incumbent on... the USPTO to protect against... harm” to AIA proceedings. *PQA*, 55.

If the Board decides not to enter adverse judgment, PO submits that, for the same reasons above, the Board should enter an order precluding Petitioners from contesting the patentability of the claims in this IPR based on Grounds 1, 2, and 4, or at minimum preclude Petitioners from relying on any evidence in support of those Grounds (including without limitation from the three experts Mylan has prepared and then shared with its litigation co-defendants). §42.12(b)(2), (3), (5).

2. Compensatory Expenses, Including Attorney Fees

PO also respectfully requests the Board award reasonable attorney fees to cover PO’s costs for having to undertake this motion and address Mylan’s violation of its stipulation. §42.12(b)(6). These monetary sanctions are necessary to compensate PO for the resources it has wasted in response to Mylan’s misconduct.

III. Conclusion

PO respectfully requests that the Board impose the requested sanctions.

Respectfully submitted: /J. Steven Baughman/

July 31, 2024

CERTIFICATE OF PAGE COUNT

The undersigned certifies that the foregoing PATENT OWNER'S MOTION FOR SANCTIONS PURSUANT TO 37 C.F.R. § 42.12 complies with the Board's July 26, 2024 (Pap.69) limiting this motion to 15 pages.

Dated: July 31, 2024

Respectfully Submitted,

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CERTIFICATE OF SERVICE

The undersigned hereby certifies that a copy of PATENT OWNER’S MOTION FOR SANCTIONS PURSUANT TO 37 C.F.R. § 42.12 have been served in their entirety on July 31, 2024, by causing the aforementioned documents to be electronically mailed to the following attorneys of record for the Petitioner listed below.

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