

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

AZURITY PHARMACEUTICALS, INC.,
Petitioner,

v.

HELSINN HEALTHCARE S.A.,
Patent Owner.

Case IPR2025-00946
Case IPR2025-00947
Patent US 9,186,357 B2

STATEMENT REGARDING MULTIPLE PETITIONS

I. INTRODUCTION

Petitioner Azurity Pharmaceuticals, Inc. (“Azurity”) has concurrently filed two petitions for *inter partes* review (“IPR”) to cancel disjoint claim sets of U.S. Patent 9,186,357 (“Trento’357”, EX1002), assigned to Patent Owner (Helsinn). Specifically, a IPR2025-00947 challenges claims 1, 5-10, 17-39, and 43-51, while IPR2025-00946 challenges claims 2-4, 11-16, 40-42, and 52-62. The multiplicity and complexity of the claims, as well as the necessity of addressing applicant-submitted evidence and argument in the prosecution history, makes “more than one petition ... necessary” within the meaning of the PTAB Consolidated Trial Practice Guide (“CTPG”), 59-60 (Nov. 2019). For the reasons provided below, the Director should institute both petitions.

II. RANKING

As the following table shows, the claims do not overlap; hence, Azurity believes ranking petitions for non-overlapping claims is inapplicable except to comply with the TPG.

Rank	IPR2025	Claims	Grounds
1	-00947	1, 5-10, 17	1: Herrstedt (EX1010) & Bös (EX1014)
		18-19, 25-27 & 30-32	2: Herrstedt, Bös & Herrington (EX1016)

		20	3: Herrstedt, Bös, Herrington & ALOXI (EX1015)
		24 & 29	5: Herrstedt, Bös, Hargreaves (EX1012) & Herrington
		28	6: Herrstedt, Bös, Bonadeo (EX1017) & Herrington
		21-23, 33-35, 37-39, 43-44 & 46-51	7: Herrstedt, Bös, Bonadeo, Herrington & ALOXI
		36 & 45	8: Herrstedt, Bös, Bonadeo, Hargreaves, Herrington & ALOXI
2	-00946	2, 3, 4, 11-16, 40, and 52-54 & 56-62	1: Herrstedt & Bös
		41-42	2: Herrstedt, Bös & Herrington
		55	4: Herrstedt, Bös & Hargreaves

III. MATERIAL DIFFERENCES; REASONS FOR INSTITUTION

Trento’357 contains 62 claims with three independent claims: 1, 2, and 4. The petitions have been divided to treat claim 1 and its dependencies in the first petition, and to treat claims 2 and 4 and their dependencies in the other. The second petition is comparable in size (23 claims) to petitions Azurity is concurrently filing against other Helsinn patents, while the first petition by itself is larger (39 claims)

than the others.

As patentee, Helsinn alone controlled the number and complexity of the claims it pursued in a single patent. The claims are both numerous and complex, spanning nearly six columns of the patent, and over 2400 words. *Cf. AliveCor, Inc. v. Apple Inc.*, IPR2023-00948, #8, 24 (2024) (“[T]he claims themselves constitute almost 1,000 words.”); *accord Meta Platforms v. SitNet LLC*, IPR2024-00528, #10, 10 (2024) (“We agree with Petitioner that the claims in the patent are relatively lengthy. Moreover, the overlap of petitions (i.e., the prior art asserted), mitigates the potential that the parallel proceedings may place a substantial and unnecessary burden on the Board or the patent owner or that it could raise fairness, timing, and efficiency concerns.”) (simplified); *see also, e.g., Visa, Inc. v. Cortex MCP, Inc.*, IPR2024-00486, Paper 8 at 41-43 (Aug. 2, 2024) (instituting multiple IPRs; patent with 33 claims totaling 1,691 words has “a relatively high number of claims and the claims are relatively lengthy”); *Novartis Gene Therapies, Inc. v. Genzyme Corp.*, IPR2023-01045, Paper 10 at 3-5 (Jan. 17, 2024) (patent with 34 claims justifies multiple petitions).

Helsinn evinced an intent to cover different inventions in each of its independent claims, which each claim a method of treating chemotherapy-induced nausea and vomiting with:

active ingredient	Claim 1	Claim 2	Claim 4
palonosetron	yes	<i>not required</i>	yes
netupitant	yes	yes	yes
dexamethasone	yes	<i>subtherapeutic</i>	<i>not required</i>

Each set of claims starts with different limitations to be incorporated, and the dependent claims—while often similar—are not identical and indeed often diverge sharply. For example, only the claim-1 family has a dependent claim (28) with a specific impurity limitation. Thus, alternative forms of claim grouping that might work for some patents do not lend themselves to the complex, nonlinear way Helsinn chose to draft its claims here. *Cf.* 37 C.F.R. §1.75(g) (requiring claims to be logically ordered and grouped together). Sixty-two is objectively a large number of claims. *Cf.* 35 U.S.C. 41(a)(2)(ii) (defining “Excess claims” as more than twenty per application); *accord* 37 CFR §42.15(a)(3) (surcharge for more than 20 claims).

Additionally, the petitions address secondary considerations raised during prosecution. Trento’357 issued from a child of an application in which the examiner expressly relied as reason for allowance on declaration testimony purporting to show unexpected results from using netupitant. Helsinn’s declaration and related argument warrant careful analysis supported with expert testimony to show precisely why they were both material to allowance and substantively misleading. EX1009, ¶32 (explaining materiality); *cf. Gilead Sciences v. United*

States, IPR2019-01453, #14, 29 (2020) (denying institution because unexpected results leading to allowance not addressed).

A single IPR covering a subset of claims would not be sufficient. Because no collateral litigation is pending, Azurity cannot predict which claims Helsinn might choose to enforce. *Cf. AliveCor*, IPR2023-00948, #8, 24 (given litigation uncertainty, “it is not unreasonable for Petitioner to challenge all the claims”). If Azurity waited for litigation to file a second IPR, it would face a Catch-22 accusation of having waited and filed a serial petition for tactical advantage. Both Board efficiency and public interest are best served by resolving patentability for all claims now.

Additionally, because Azurity is filing the two IPR petitions simultaneously, they will be able to follow the same schedule post-institution, maximizing the efficiency of depositions, briefing, and oral argument, as well as allowing the Board the option to eliminate any inefficiencies by consolidating the proceedings. *See, e.g., Visa*, IPR2024-00486, #8, 42. Further, the petitions apply consistent claim constructions and are supported by the same expert witness, meaning a single deposition should be sufficient.

IV. CONCLUSION

All Trento’357 claims are unpatentable. Azurity respectfully requests both *inter partes* reviews be instituted so all these claims receive review.

Respectfully submitted,

Dated: 1 May 2025

/Richard Torczon/

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