

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

RESMED CORP.,
Petitioner,

v.

CLEVELAND MEDICAL DEVICES, INC.,
Patent Owner.

Case IPR2025-00157
U.S. Patent No. 11,602,284

**AUTHORIZED RESPONSE TO REQUEST FOR WAIVER
OF THE DIRECTOR REVIEW REQUEST DEADLINE**

TABLE OF CONTENTS

I.	INTRODUCTION	1
II.	FACTS	1
III.	THERE IS NO GOOD CAUSE TO WAIVE THE DEADLINE FOR REQUESTING DIRECTOR REVIEW IN THIS CASE	2
A.	New Discretionary Denial Factors Are Not Applicable in this Case	2
B.	The DRR Facially Does Not Satisfy the Standard for Granting Director Review	3
C.	Petitioner Failed to Request Authorization to File New Arguments	3
D.	There Was No Intervening Change in the Law	4
E.	Petitioner's Predictability, Efficiency, and Prejudice Arguments Are Wrong and Do Not Implicate or Excuse its Late Action	5

TABLE OF AUTHORITIES

	Page(s)
Cases	
<i>H&S v. Oxbo Int’l</i> , IPR2016-00950, Paper 11 (P.T.A.B. Dec. 7, 2016)	5
<i>Huawei Device Co. v. Optis Cellular Tech. LLC</i> , IPR2018-00816, Paper 19 (P.T.A.B. Jan. 8, 2019)	4
<i>LifeVac, LLC v. DCSTAR Inc.</i> , IPR2025-00454, Paper 11 (P.T.A.B. July 11, 2025)	4, 5
Other Authorities	
Consolidated Trial Practice Guide (Nov. 2019)	2
Director Review Process (July 15, 2025)	3
FAQs for Interim Processes for PTAB Workload Management (Mar. 26, 2025)	3

I. INTRODUCTION

Patent Owner respectfully requests that the Director deny Petitioner's request to waive the 30-day period for requesting Director Review because Petitioner has not established good cause for waiver: (1) new discretionary factors are not applicable to this case because the Preliminary Response (POPR) was filed before March 26, 2025; (2) Petitioner did not request authorization to make new arguments in its Director Review Request ("DRR"); (3) the DRR facially does not meet the standard for Director Review; (4) there was no intervening change of law, guidance, or policy; (5) Petitioner's arguments allegedly establishing good cause for waiver of the deadline are unrelated to its failure to request Director Review in a timely fashion; and (6) parties litigating before the PTAB have a strong interest in consistent application of the USPTO's rules and the finality of its judgments.

II. FACTS

The parties have been litigating patent infringement issues concerning the '284 Patent's family since June 2022, when CleveMed asserted infringement of the ancestral '269 Patent in the District of Delaware. On March 14, 2023, while that litigation was pending, the USPTO issued the '284 Patent. Petitioner filed a Complaint for Declaratory Judgment of Noninfringement of the '284 Patent roughly one week later in the Southern District of California. Because the parties had insufficient ties to that forum, the action was transferred to the District of Ohio.

After losing access to its preferred forum, and on the penultimate day of the nine-month statutory period, Petitioner filed a petition for PGR of the '284 Patent. The Board denied the petition and denied Petitioner's Rehearing Request of that decision because the '284 Patent is a pre-AIA patent and, therefore, not eligible for PGR.

Rather than file this IPR petition concurrently with its PGR petition to hedge against a finding that the '284 Patent is a pre-AIA patent—as the Consolidated Trial Practice Guide contemplates (CTPG at 59-61 (blessing the use of parallel petitions when the patent's priority date is in question))—it waited until it received patent owner's arguments distinguishing the references raised in the PGR and used those arguments as a roadmap to craft a *serial* IPR petition that abandoned the PGR's obviousness grounds. See Institution Decision, Paper 10 ("DI") at 13-14. The Board found that *General Plastic* Factors 1-6 weighed in favor of discretionary denial and that Factor 7 was neutral. Consequently, the Board denied the Petition. *Id.*, at 7-15.

III. THERE IS NO GOOD CAUSE TO WAIVE THE DEADLINE FOR REQUESTING DIRECTOR REVIEW IN THIS CASE

A. New Discretionary Denial Factors Are Not Applicable in this Case

There is no good cause to waive the 30-day rehearing deadline because new discretionary denial factors are not applicable in this case. Because CleveMed filed its Preliminary Response before the *Process Memorandum* issued, the Board was instructed to "address any discretionary considerations and merits and other non-discretionary considerations the parties raise . . . as *enumerated in previously*

existing Board precedent (including *Fintiv*, *General Plastic*, and *Advanced Bionics*).” *FAQs for Interim Processes for PTAB Workload Management*, FAQ 5. Rehearing “based on those new factors” is not available in this case. *Id.* (“The panel **will not address any new factors** outlined in the Process Memorandum, **nor consider a request for rehearing** based on those new factors.”) (emphases added).

This is the procedure the parties and the Board followed, and Petitioner has neither acknowledged this rule nor attempted to establish good cause for the Director to waive it. Indeed, waiver of this rule would amount to inappropriate retroactive application of a rule that expressly **excluded** this case and all similarly situated cases.

B. The DRR Facially Does Not Satisfy the Standard for Granting Director Review

“Requests for Director Review of the Board’s decision on institution . . . or decisions granting rehearing of such a decision, shall be limited to decisions presenting (a) an abuse of discretion, (b) important issues of law or policy, (c) erroneous findings of material fact, or (d) erroneous conclusions of law.” *Director Review Process*, Section 2.B. The DRR does not allege any such issue.

C. Petitioner Failed to Request Authorization to File New Arguments

Petitioner’s request to waive the 30-day deadline for requesting Director Review should also be denied because the new arguments raised in the DRR are “not part of the official record,” and Petitioner did not request authorization to submit new arguments. *Director Review Process*, Section 3.E (a party must request

authorization before submitting “new evidence or arguments” in a Director Review Request); *see also Huawei Device Co. v. Optis Cellular Tech. LLC*, IPR2018-00816, Paper 19 at 3-4 (P.T.A.B. Jan. 8, 2019) (precedential) (expunging new evidence because petitioner did not establish “good cause” prior to submitting the new material or argue “good cause” in the rehearing request itself). Accordingly, not only was *LifeVac, LLC v. DCSTAR Inc.*, IPR2025-00454, Paper 11 (P.T.A.B. July 11, 2025) based on a new discretionary denial factor that cannot be considered in this case, Petitioner did not request authorization to make new arguments, as required.

D. There Was No Intervening Change in the Law

There is also no good cause for waiving the rehearing deadline because there was no intervening change in law, guidance, or policy even if new discretionary denial factors could be considered in this case and the Director excuses Petitioner’s failure to request authorization to file new arguments in its DRR. The crux of Petitioner’s request for waiver of the deadline for requesting Director Review is that the DI “directly conflicts” with *LifeVac*. Waiver Request, 1. However, the DI in this case was based on application of the *General Plastic* opinion, which remains precedential. DI at 7-15. *LifeVac* did not change the precedential nature of *General Plastic* or establish a rule that an IPR petition filed after an unsuccessful PGR petition is *per se* insulated from discretionary denial. Like all discretionary denial

decisions, the Director's decision in *LifeVac* was based on a holistic weighing of factors, none of which is dispositive. See *LifeVac* at 3.

E. Petitioner's Predictability, Efficiency, and Prejudice Arguments Are Wrong and Do Not Implicate or Excuse its Late Action

There is also no good cause to excuse Petitioner's late filing because fully half of Petitioner's Waiver Request is spent on issues that are unrelated to the timeliness of its DRR. Waiver Request, 2 (arguing that "waiver would promote predictability," "efficiency and consistency" and would not prejudice Patent Owner). Indeed, these arguments all *assume* that Petitioner will be successful in (1) convincing the Director to apply new discretionary factors in this case, despite clear guidance that they cannot apply; (2) convincing the Director that its DRR is meritorious, despite the non-dispositive nature of the *LifeVac* decision and key facts distinguishing this case from *LifeVac*; and (3) convincing the Board on remand that no other discretionary denial or merits issues warrant denial of institution.

These arguments also ignore countervailing policy issues, including those articulated in *General Plastic* and the importance of finality of judgments. As the Board has previously recognized, good cause does not exist when a petitioner chose not to request rehearing and only did so based on "arguments in other proceedings." *H&S v. Oxbo Int'l*, IPR2016-00950, Paper 11 at 3 (P.T.A.B. Dec. 7, 2016).

Respectfully submitted,

Dated: July 24, 2025

/James Hannah/

James Hannah (Reg. No. 56,369)
HERBERT SMITH FREEHILLS
KRAMER (US) LLP
333 Twin Dolphin Drive, Suite 700
Redwood Shores, CA 94065
Telephone: (650) 752-1700
Facsimile: (650) 752-1800
James.Hannah@hsfkramer.com

Jeffrey H. Price (Reg. No. 69,141)
Jenna Fuller (Reg. No. 74,212)
Jeffrey Eng (Reg. No. 63,189)
HERBERT SMITH FREEHILLS
KRAMER (US) LLP
1177 Avenue of the Americas
New York, NY 10036
Telephone: (212) 715-7502
Facsimile: (212) 715-8302
Jeffrey.Price@hsfkramer.com
Jenna.Fuller@hsfkramer.com
Jeffrey.Eng@hsfkramer.com

(Case No. IPR2025-00157)

Attorneys for Patent Owner
Cleveland Medical Devices, Inc.

CERTIFICATE OF SERVICE

The undersigned certifies, in accordance with 37 C.F.R. § 42.6(e), and pursuant to agreement by the parties that filing with the Board through the P-TACTS constitutes electronic service if Patent Owner provides the foregoing document (excluding exhibits), service was made on the Petitioner as detailed below.

<i>Date of service</i>	July 24, 2025
<i>Manner of service</i>	Electronic Filing and Electronic Mail (PH-ResMed-CleveMed@paulhastings.com)
<i>Documents served</i>	AUTHORIZED RESPONSE TO REQUEST FOR WAIVER OF THE DIRECTOR REVIEW REQUEST DEADLINE
<i>Persons Served</i>	PAUL HASTINGS LLP Lisa Nguyen David M. Tennant Grace Wang

/James Hannah/
James Hannah
Reg. No. 56,369