From:	Hackman, Blaine
To:	Director_PTABDecision_Review
Cc:	Zolgensma-Dechert-All IPRs; john.livingstone@finnegan.com; jeffrey.smyth@finnegan.com; amanda.murphy@finnegan.com; Helm, Katherine; Antons, Amanda
Subject:	IPR2023-01044 | Patent Owner"s Request for Rehearing by the Director
Date:	Tuesday, January 23, 2024 3:45:20 PM

CAUTION: This email has originated from a source outside of USPTO. **PLEASE CONSIDER THE SOURCE** before responding, clicking on links, or opening attachments.

Honorable Director Vidal,

Patent Owner Genzyme Corporation respectfully submits its "Patent Owner's Request for Hearing by the Director" in IPR2023-01044. As provided by Section 3.A of the Revised Interim Director Review Process (July 24, 2023), Patent Owner provides a brief explanation of the issue for which it seeks Director review.

The Board's Decision Granting Institution of *Inter Partes* Review in IPR2023-01044 ("Decision") was based on *an erroneous conclusion of law* resulting from the Board's reliance on a defunct version of Rule § 42.108(c), rescinded three years ago, to improperly view the "testimonial evidence … ***in the light most favorable to the petitioner***." Decision, 25 (quoting former Rule 37 C.F.R. § 42.108(c)). The text of Rule § 42.108(c) that the Board relied on for its analysis of each Ground was eliminated in a 2020 rule change, so petitioners are no longer entitled to this presumption. PTAB Rules of Practice, 85 FR 79120, 79122 (Dec. 9, 2020) ("Eliminating the Presumption at Institution Favoring Petitioner as to Testimonial Evidence"). Currently applicable Rule § 42.108(c) requires that "any testimonial evidence submitted with a patent owner's preliminary response will be taken into account as part of the totality of the evidence." *Id.* at 79122. The Board did not do so here.

With its Patent Owner Preliminary Response ("POPR"), Patent Owner presented evidence, including expert testimony, demonstrating that the Petition had several deficiencies fatal to Petitioner's proofs for its anticipation (Ground 1) and obviousness (Grounds 2 and 3) grounds. The Board, however, discounted the POPR's evidence, "determin[ing] that the information presented by Patent Owner ***creates genuine issues of material fact***," and then resolving those issues in favor of Petitioner for purposes of institution, solely on the basis of the presumption in favor of Petitioner that has been eliminated from Rule § 42.108(c). Decision, 25, 31, 33, 39. Citing the now-defunct version of Rule § 42.108(c), the Board relied on an erroneous conclusion of law to support institution by improperly "view[ing] the material fact[s] in the light most favorable to Petitioner" (*id.* at 25, 39), a presumption that Petitioner is not entitled to receive, and which "conflicts with the decision of Congress to place the burden of proof on the petitioner." *Id.* at 79125 (citing 35 U.S.C. § 314(a)).

When properly considered without reliance on the improper presumption in favor of Petitioner, the Petition failed to meet its burden for institution. For these reasons, and those in the currently filed Request for Rehearing by the Director, Director Review should be granted, the Board's Decision should be vacated, and institution denied.

Respectfully submitted,

/Blaine M. Hackman/
Reg. No. 67,479
Attorney of Record for Patent Owner of Genzyme Corporation

Blaine M. Hackman
Counsel

Dechert LLP
+1 917 388 8306 Direct
+1 646 552 5261 Mobile
blaine.hackman@dechert.com
dechert.com

This e-mail is from Dechert LLP, a law firm, and may contain information that is confidential or privileged. If you are not the intended recipient, do not read, copy or distribute the e-mail or any attachments. Instead, please notify the sender and delete the e-mail and any attachments. Thank you.