

From: [Director Discretionary Decision](#)
To: [Anne Toker](#); [Hackman, Blaine](#); [Director Discretionary Decision](#)
Cc: [Antons, Amanda](#); [Helm, Katherine](#); [Elevidys IPR-Dechert](#); [Robert Wilson](#); [Jim Glass](#)
Subject: RE: PR2025-01194 and IPR2025-01195 - Patent Owner's Request for Reply
Date: Thursday, October 16, 2025 10:17:53 AM

Patent Owner is authorized to file a 3-page reply in IPR2025-01194 and IPR2025-01195 due no later than Monday, October 20, 2025, limited to addressing the arguments raised below. Petitioner is authorized to file a 3-page sur-reply due no later than Wednesday, October 22, 2025.

From: Anne Toker <annetoker@quinnemanuel.com>
Sent: Tuesday, October 14, 2025 7:17 PM
To: Hackman, Blaine <Blaine.Hackman@dechert.com>; Director_Discretionary_Decision <Director_Discretionary_Decision@uspto.gov>
Cc: Antons, Amanda <Amanda.Antons@dechert.com>; Helm, Katherine <khelm@dechert.com>; Elevidys IPR-Dechert <Elevidys-IPR-Dechert@dechert.com>; Robert Wilson <robertwilson@quinnemanuel.com>; Jim Glass <jimglass@quinnemanuel.com>
Subject: RE: PR2025-01194 and IPR2025-01195 - Patent Owner's Request for Reply

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Dear Honorable Director,

Petitioner Sarepta respectfully requests that Genzyme's request to submit a Reply be denied because Genzyme has not demonstrated good cause on either issue:

1. Potter – In its Requests for Discretionary Denial, Genzyme chose not to offer any substantive response to Sarepta's arguments that Genzyme mischaracterized Potter and the state of the art in the Novartis IPR proceedings. Genzyme had full notice of these issues, given that Sarepta set out these arguments in detail in the Petitions and the supporting expert declarations of Professor Kay. Genzyme decided to wait to respond to these issues in its POPRs, and said so expressly in a footnote in each Request for Discretionary Denial. Indeed, Genzyme does not contend that Sarepta's Oppositions to the discretionary denial requests contain any new substantive arguments regarding Potter. Genzyme should not be afforded another opportunity to address these issues as part of the discretionary denial process, when it expressly chose not to do so initially.
2. Inequitable Conduct – the arguments and evidence that Genzyme seeks to submit in a Reply are not responsive to the issues raised in Sarepta's Oppositions. Sarepta, in its Oppositions, sought to provide information about proceedings that occurred in the

district court after the prior Novartis IPR petitions were denied. The district court granted Novartis leave to add inequitable conduct counterclaims, over Genzyme's opposition, several months after the Board issued its decisions denying institution of the Novartis IPRs. Any email correspondence with the Board during the Novartis IPR proceedings is therefore irrelevant to the subsequent events in the district court discussed in Sarepta's Oppositions. As Sarepta explained, the district court proceedings, like Genzyme's mischaracterizations of Potter and the state of the art in the Novartis IPRs, are relevant to questions of unfair dealings that bear on the discretionary denial decision. As Genzyme itself states, Sarepta did not raise inequitable conduct issues in its Petitions, and has not argued that they are relevant to the merits of the Petitions. Instead, these issues regarding Genzyme's pattern of unfair dealings in the Patent Office weigh strongly against discretionary denial.

In the event Genzyme is granted leave to submit a Reply, Sarepta respectfully requests leave to submit a Sur-Reply of equal length. Should the Director wish to discuss Genzyme's request for a Reply, Sarepta is available for a conference call at the Director's convenience.

Respectfully submitted,

Anne S. Toker, Reg. No. 53,692

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From: Hackman, Blaine <Blaine.Hackman@dechert.com>
Sent: Tuesday, October 14, 2025 4:58 PM
To: Director_Discretionary_Decision@USPTO.gov
Cc: Antons, Amanda <Amanda.Antons@dechert.com>; Helm, Katherine <khelm@dechert.com>; Elevidys IPR-Dechert <Elevidys-IPR-Dechert@dechert.com>; Anne Toker <annetoker@quinnemanuel.com>; Robert Wilson <robertwilson@quinnemanuel.com>; Jim Glass <jimglass@quinnemanuel.com>
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[EXTERNAL EMAIL from blaine.hackman@dechert.com]

Dear Honorable Director,

Patent Owner Genzyme respectfully requests a 3-page Reply to address two issues raised in Petitioner Sarepta's Opposition to Genzyme's Request for Discretionary Denial,

filed October 8, 2025, in the subject proceedings. The Parties met and conferred on October 14, 2025 and in that meeting Petitioner Sarepta stated it opposed Patent Owner Genzyme's request. Genzyme has good cause for a reply on the following two issues:

(1) Sarepta alleges that Genzyme and its expert, Dr. Martyn Davies "misrepresented the state of the prior art and, in particular, the disclosures of Potter" in a prior IPR proceeding ('1194 IPR (Paper 10), 3; '1195 IPR (Paper 10), 3-4) and that Genzyme "hope[s] grant of discretionary denial will obviate any further examination of its prior misrepresentations to the Board" ('1194 IPR (Paper 10), 1; '1195 IPR (Paper 10), 1). Genzyme has good cause for a Reply to respond to Sarepta's allegations so that the complete and correct factual record regarding prior Genzyme statements and expert testimony relating to Potter is before the Director. If Sarepta succeeds in reframing the parties' substantive disagreements (see '1194 IPR (Paper 11), 60-61 (citing Ex. 2023, ¶167); '1195 IPR (Paper 11), 60-61 (citing Ex. 2023, ¶163)) as "unfair dealings" or "misrepresentations" in order to avoid discretionary denial, then petitioners may be encouraged to regularly apply this strategy to undermine the Director's bifurcated discretionary denial evaluation process.

(2) Sarepta alleges "inequitable conduct" for the first time in its opposition brief, which provides good cause for a Genzyme Reply. Genzyme also requests authorization to file as an exhibit to the Reply an email from the Board to the parties in IPR2023-00608 and -00608, which is not on P-TACTS, so that the Director has an accurate record of how the Board previously addressed this issue. The email declined a request from Petitioner, Novartis, for "routine and additional discovery" relating to Novartis' inequitable conduct allegations. Here, Sarepta does not tie the inequitable conduct allegations to its prior art grounds, and the Board does not have jurisdiction to address patent enforceability due to inequitable conduct. Inequitable conduct is also pending before the district court in parallel litigation, and so under principles of efficiency this issue weighs in favor of discretionary denial.

If Genzyme is granted a Reply, it will not oppose grant of an equal-length sur-reply to Petitioner. Should the Director wish to discuss the Reply, Genzyme is available for a conference call at the Director's convenience.

Respectfully submitted,
Blaine M. Hackman, Reg. No. 67,479

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