

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

SAREPTA THERAPEUTICS, INC.,
Petitioner,

v.

GENZYME CORPORATION,
Patent Owner.

Case No. IPR2025-01195
Patent No. 7,704,721

**PATENT OWNER'S REPLY TO PETITIONER'S OPPOSITION TO
PATENT OWNER'S REQUEST FOR DISCRETIONARY DENIAL**

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<i>Tessell, Inc. v. Nutanix, Inc.</i> , IPR2025-00322, Paper 14 (PTAB June 12, 2025)	1
<i>Therasense, Inc. v. Becton, Dickinson & Co.</i> , 649 F.3d 1276 (Fed. Cir. 2011)	2

PATENT OWNER’S UPDATED EXHIBIT LIST

Exhibit No.	Description
2001	Declaration of Katherine A. Helm
2002	Complaint, <i>Genzyme Corporation v. Sarepta Therapeutics, Inc., and Sarepta Therapeutics Three, LLC</i> , D.I. 1 (1:24-cv-00882-UNA)
2003	Second Amended Complaint, <i>Genzyme Corporation v. Sarepta Therapeutics, Inc., and Sarepta Therapeutics Three, LLC</i> , D.I. 81, (1:24-cv-00882-UNA)
2004	Second Amended Complaint, Ex. K, <i>Genzyme Corporation v. Sarepta Therapeutics, Inc., and Sarepta Therapeutics Three, LLC</i> , D.I. 81-2 (1:24-cv-00882-UNA)
2005	Second Amended Complaint, Ex. M, <i>Genzyme Corporation v. Sarepta Therapeutics, Inc., and Sarepta Therapeutics Three, LLC</i> , D.I. 81-3 (1:24-cv-00882-UNA)
2006	<i>Collabo Innovations, Inc. v. Sony Corp.</i> , 15-cv-1094-RGA, D.I. 43 (D. Del. Jan. 5, 2017)
2007	<i>Ansell Healthcare Prods. LLC v. Reckitt Benckiser LLC</i> , 15-cv-915-RGA, D.I. 105 (D. Del. Dec. 1, 2016)
2008	<i>RainDance Techs., Inc. v. 10X Genomics, Inc.</i> , 15-cv-152-RGA, D.I. 27, 37 (D. Del. Feb. 29, 2016)
2009	Notice of Service of Plaintiff’s Initial Claim Chart, <i>Genzyme Corporation v. Sarepta Therapeutics, Inc., and Sarepta Therapeutics Three, LLC</i> , D.I. 59 (1:24-cv-00882-UNA)
2010	Notice of Service of Stipulation to Extend Time, <i>Genzyme Corporation v. Sarepta Therapeutics, Inc., and Sarepta Therapeutics Three, LLC</i> , D.I. 68 (1:24-cv-00882-UNA)
2011	So Ordered re 77 Joint Stipulation to Amend Scheduling Order, <i>Genzyme Corporation v. Sarepta Therapeutics, Inc., and Sarepta Therapeutics Three, LLC</i> , D.I. 78 (1:24-cv-00882-UNA)
2012	Notices of Service for Interrogatories and Requests for Production, <i>Genzyme Corporation v. Sarepta Therapeutics, Inc., and Sarepta Therapeutics Three, LLC</i> , D.I. 28 (1:24-cv-00882-UNA)

Exhibit No.	Description
2013	A.R. Kucernak et al., <i>Avoid Using Phosphate Buffered Saline (PBS) as an Electrolyte for Accurate OER Studies</i> , 9 ACS Energy Lett. 3939–3946 (2024)
2014	Oral Order on April 5, 2016 Denying Motion to Stay, <i>RainDance Technologies, Inc. et al v. 10X Genomics, Inc.</i> (1-15-cv-00152)
2015	A.E. Smith, “ <i>Gene Therapy: Where Are We</i> ,” 354 The Lancet SI1 (July 1999)
2016	<i>Remington: The Science and Practice of Pharmacy</i> , Nineteenth Ed., Vol. I, Chapters 17, 18, 23, and 36 (1995).
2017	<i>Remington: The Science and Practice of Pharmacy</i> , Nineteenth Ed., Vol. II, Chapter 87(1995).
2018	Carpenter, J. F. & Manning, M.C. (Eds.), <i>Rational Design of Stable Protein Formulations: Theory and Practice</i> , Vol. 13 (2002).
2019	Gatlin, L., Chapter 17, “Formulation and Administration Techniques to Minimize Injection Pain and Tissue Damage Associated with Parental Products,” in <i>Injectable Drug Development: Techniques to Reduce Pain and Irritation</i> , (eds. P. Gupta and G. Brazeau), pp. 401-421 (1999).
2020	International Patent Pub. No. WO 99/41416 to Frei, et al.
2021	Croyle, et al., “Development of Formulations That Enhance Physical Stability of Viral Vectors for Gene Therapy,” <i>Gene Ther.</i> , 8:1281-1290 (2001).
2022	Adadevoh, K. et al., “A Short-Term Field Use and Shipping Stability Study of a Wild Type Ad5 Adenoviral Reference Material,” <i>BioProcessing</i> 1(2) 62-69 (2002).
2023	Declaration of Martyn Davies
2024	Curriculum Vitae of Martyn Davies
2025	Ayache, J. et al., <i>Sample Preparation Handbook for Transmission Electron Microscopy</i> . (2010).
2026	Arista-Romero, M. et al., “Towards a Quantitative Single Particle Characterization by Super Resolution Microscopy: From Virus Structures to Antivirals Design.” (2021).

Exhibit No.	Description
2027	Chu, J. et al., “A bright cyan-excitable orange fluorescent protein facilitates dual-emission microscopy and enhances bioluminescence imaging in vivo.” <i>Nat Biotechnol.</i> 2016 July ; 34(7): 760–767 (2016).
2028	Aaron, K. et al., “Selection of Viral capsids and promoters affects the efficacy of rescue of Tmprss3-deficient cochlea.” <i>Molecular Therapy: Methods & Clinical Development</i> (2023).
2029	Jia, F. et al., “A nonviral minicircle vector for deriving human iPS cells” <i>Nature Methods</i> (2010).
2030	[Reserved]
2031	J.O. Konz et al. “Development of a Purification Process for Adenovirus: Controlling Virus Aggregation to Improve the Clearance of Host Cell DNA,” 21 <i>Biotechnol. Prog.</i> 466 (2005)
2032	Booy, F. P., et al. “Electron microscopy of influenza virus: a comparison of negatively stained and ice-embedded particles.” <i>Journal of Molecular Biology</i> 184.4 (1985): 667-676.
2033	Emails between the Parties and the Trials@USPTO.gov, IPR2023-00608 and IPR2023-00609 - Novartis v. Genzyme, Aug. 11, 2023 to Aug. 21, 2023

Genzyme has presented an exceedingly strong settled expectations case—the ’721 patent was in force for fifteen years and is now expired. Through its continuation, U.S. Patent No. 9,051,542 the (“’542 patent”), its key limitations faced two failed IPRs. (Paper 8 (“Br.”), 3-8). Backed into a corner by these dispositive facts, Sarepta asks the Board to approve a massive and dangerous expansion of the Board’s narrow “unfair dealing” decision in *Tessell, Inc. v. Nutanix, Inc.*, IPR2025-00322, Paper 14 (PTAB June 12, 2025). Doing so would turn the discretionary denial process into a name-calling exercise and thwart the Director’s important role in allocating resources to worthy IPRs. In any case, there was no misrepresentation in the prior IPRs, and any inequitable conduct allegations belong in district court.

I. The Board Should Decline to Expand the Doctrine of “Unfair Dealings.”

In *Tessell*, the Board was faced with a unique circumstance. The petitioner hired the inventors of a patent and then asked the PTAB to institute an IPR to revoke it. The PTAB reasoned that “[a]lthough assignor estoppel does not apply in [IPRs] ... the Office may consider unfair dealings as a factor when determining whether to exercise discretion to deny institution under 35 U.S.C. § 314(a).” *Id.* The Board then denied institution on the ground that “[i]t is not an appropriate use of Office resources where the inventors applied for and were issued a patent, but, as is the case here, now advocate for its unpatentability.” *Id.*

From this sensible and narrow decision involving unfair dealings by a

petitioner, Sarepta now seeks to expand the ruling to cover all manner of alleged “misrepresentations” by a *patent owner* to defeat discretionary denial. *Tessell*’s limited holding provides no support for doing so, and accepting Sarepta’s position would vastly expand the scope of discretionary denial disputes. Discretionary denial decisions should remain focused on settled expectations and the best use of Board resources. If the Board does not nip this tactic in the bud, it risks a reprise of the development of inequitable conduct law, where recognition of the defense led to “an absolute plague” of defendants making similar accusations. *Therasense, Inc. v. Becton, Dickinson & Co.*, 649 F.3d 1276, 1289 (Fed. Cir. 2011) (quoting *Burlington Indus., Inc. v. Dayco Corp.*, 849 F.2d 1418, 1422 (Fed. Cir. 1988)).

II. Sarepta’s Allegations of “Misrepresentation” are Unfounded.

The crux of Sarepta’s position is the allegation that the earlier IPRs of the ’542 patent failed because Genzyme misrepresented the Potter reference. Paper 10 (“Opp.”), 3-6, 11-12.¹ Potter was a minor reference that was not included in any ground for institution, and Sarepta does not point to any flaw in the Board’s discussion of Potter. As explained in the POPR, Genzyme and Dr. Davies accurately

¹Sarepta accuses Genzyme of “gamesmanship” for deferring its discussion of Potter to its POPR. Genzyme was simply following guidance that advises directing “attention to [the] anticipated POPR and evidence for a discussion of the merits.”

See <https://www.uspto.gov/patents/ptab/interim-director-discretionary-process>.

responded to Novartis’ arguments regarding the cited disclosure in Potter. POPR, 60-61. Novartis is an experienced litigant that surely would have pointed out any material misrepresentation had there been one.

Sarepta’s attack here is typical of serial IPR practice—the late filing petitioner elevates a minor reference to a primary reference and then repackages a previously rejected attack. Sarepta points to a different section of Potter than Novartis did, and the parties have a substantive dispute about its import, as the POPR explains. That is neither a “misrepresentation,” nor grounds for assuming the Board was misled.

III. Sarepta’s Inequitable Conduct Allegations Favor Discretionary Denial.

An IPR is the wrong forum to adjudicate inequitable conduct (Opp., 2). *Symantec Corp. v. Finjan, Inc.*, IPR2015-01895, Paper 7 (PTAB Feb. 16, 2016). In the prior IPRs, Novartis raised inequitable conduct at the institution stage, and the Board denied institution. Ex. 2033. Sarepta’s attempt to raise inequitable conduct should be rejected here too. Opp., 6-7. If anything, the assertion of inequitable conduct favors discretionary denial. Sarepta has pled the defense in parallel district court litigation and no doubt will try to press the issue regardless of the outcome of the IPR. It would be far more efficient to have the district court resolve *all* validity and enforceability issues.

Dated: October 20, 2025

/Blaine M. Hackman/

Blaine M. Hackman, Reg. No. 67,479
Counsel for Patent Owner

CERTIFICATE OF SERVICE

Pursuant to 37 C.F.R. § 42.6(e), I certify that today in

Sarepta Therapeutics, Inc., v. Genzyme Corporation, IPR2025-01195

I caused to be served a copy of:

**PATENT OWNER'S REPLY TO PETITIONER'S OPPOSITION TO
PATENT OWNER'S REQUEST FOR DISCRETIONARY
DENIAL**

EXHIBIT NO. 2033

upon:

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electronic service to the email addresses above.

Date: October 20, 2025

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