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[Your Name]

[Your Title]

[Your Company]

[Street Address, City, State ZIP]

May 14, 2026

[Opposing Counsel Name]

[Firm Name]

[Address]

Re: U.S. Patent No. 12403095 — Response to Assertion of Infringement

Dear Counsel,

We acknowledge receipt of your correspondence asserting infringement of U.S. Patent No. 12403095 (the "12403095 Patent"). After preliminary review, we have substantial concerns about the validity, enforceability, and scope of the asserted claims, summarized below. We reserve all rights and defenses.

1. Subject Patent — Summary

Analysis of U.S. Patent 12,403,095: Stabilized Tacrolimus Composition

Date of Analysis: May 1, 2026

A detailed review of U.S. Patent 12,403,095 has been conducted. This document, titled "Stabilized tacrolimus composition," was issued on September 2, 2025, and is assigned to Veloxis Pharmaceuticals Inc. The inventors are listed as Nikolaj Skak and Per Holm. The patent application was filed on July 5, 2022.

No litigation concerning this patent has been identified in the CAFC dockets for 2026.

Abstract:

The invention relates to a stable pharmaceutical composition comprising a solid dispersion of tacrolimus in a vehicle. The composition further includes a stabilizing agent capable of...

2. Validity Concerns under 35 U.S.C. § 102 — Prior Art

We have identified prior-art references that, in our preliminary view, anticipate one or more asserted claims of the 12403095 Patent:

Analysis of Prior Art for U.S. Patent 12,403,095

An evaluation of the prior art cited in U.S. Patent 12,403,095 has been performed to determine its relevance to the patent's claims under 35 U.S.C. § 102. The following references are

considered the most pertinent.

U.S. Patent Application Publication No. 2008/0132533 A1 (Yeom et al.)

- Full Citation: US 2008/0132533 A1
- Publication Date: June 5, 2008
- Filing Date: November 29, 2007
- Brief Description: Yeom discloses a solid dispersion formulation of tacrolimus with an enteric polymer to enhance stability by reducing recrystallization, particularly under high temperature and humidity. The formulation is designed to release tacrolimus quickly in aqueous media to improve bioavailability.

- Potential Anticipation of Claims:

Claims 1 and 11: Yeom teaches the use of a solid dispersion of tacrolimus to improve stability, which is a core concept of the '095 patent. Specifically, it mentions conducting stability tests at 40°C and 75% relative humidity, directly relevant to the conditions specified in claim 1. However, Yeom's focus...

4. Litigation History of the Patent

Public records reflect that the 12403095 Patent has been the subject of the following litigation, which informs our view of the asserted claims and your client's enforcement posture:

- Veloxis Pharmaceuticals AS v. Zydus Cadila et al. — 1:26-cv-00467 · Delaware District Court · filed 2026-04-23 · Open
- Veloxis Pharmaceuticals, Inc. v. Glenmark Pharmaceuticals Inc., USA — 1:26-cv-00305 · U.S. District Court for the District of Delaware · filed 2026-03-20 · open

4. Request

In light of the foregoing, we request that your client (i) provide a detailed claim chart identifying each accused product or service and mapping every limitation of each asserted claim, (ii) identify any prior art known to your client, including any references cited during prosecution or reexamination, and (iii) substantiate the basis for any damages or licensing demand. We are prepared to discuss the matter further once we have received and reviewed the foregoing.

Sincerely,

[Your Name]

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