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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. 12083103 — Response to Assertion of Infringement

Dear Counsel,

We acknowledge receipt of your correspondence asserting infringement of U.S. Patent No. 12083103 (the "12083103 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

Patent Summary: US 12,083,103 B2

Title: Tacrolimus for improved treatment of transplant patients

Assignee: Veloxis Pharmaceuticals Inc.

Inventors: Robert D. Gordon, Per Holm, Anne-Marie Lademann, Tomas Norling

Filing Date: August 4, 2021

Issue Date: September 10, 2024

Abstract:

The patent describes an extended-release oral dosage form of tacrolimus, an immunosuppressive drug used in transplant patients. The formulation is designed for once-daily administration and aims to provide improved bioavailability and a better pharmacokinetic profile compared to conventional tacrolimus formulations. This is achieved by releasing the active substance over a prolonged period, which is intended to...

4. Litigation History of the Patent

Public records reflect that the 12083103 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. Sun Pharmaceutical Industries Ltd. — 1:24-cv-00726 · U.S. District Court for the District of Delaware · filed 2024-06-19 · active
- Veloxis Pharmaceuticals, Inc. v. Alkem Laboratories Ltd. — 1:24-cv-00784 · U.S. District Court for the District of Delaware · filed 2024-07-03 · active

3. 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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