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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. 9549918 — Response to Assertion of Infringement

Dear Counsel,

We acknowledge receipt of your correspondence asserting infringement of U.S. Patent No. 9549918 (the "9549918 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

An analysis of U.S. Patent 9,549,918 reveals a focus on improving the stability of the immunosuppressant drug tacrolimus in pharmaceutical formulations. As of the current date, there is no indication of active litigation involving this patent before the Court of Appeals for the Federal Circuit (CAFC) in 2026.
Summary of U.S. Patent 9,549,918
• Title: Stabilized tacrolimus composition
• Assignee: Veloxis Pharmaceuticals Inc.
• Inventors: Nikolaj Skak, Per Holm
• Filing Date: February 17, 2011
• Issue Date: January 24, 2017
• Abstract: The patent describes a stable pharmaceutical composition of the drug tacrolimus. The invention involves a solid dispersion of tacrolimus within a "vehicle"…

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 9549918 Patent:

Analysis of Prior Art for U.S. Patent 9,549,918

The core invention of U.S. Patent 9,549,918 is a stabilized solid oral dosage form of tacrolimus. The key features claimed are the use of a solid dispersion of tacrolimus within a specific vehicle composed of polyethylene glycol (PEG) and poloxamer, stabilized by tartaric acid to maintain a low pH and limit the formation of degradation products, especially 8-epitacrolimus. The claims further specify sustained-release properties and define acceptable levels of degradation products over time.
An analysis of the prior art cited by the patent examiner reveals several key references that, while relevant to tacrolimus formulations, do not appear to fully anticipate the specific combination and stability requirements claimed in the '918 patent. The novelty of the '918 patent seems to lie in the identification of 8-epitacrolimus as a major degradation product and the use of tartaric acid in a specific polymeric matrix to control its formation.
Here are the most relevant prior art references and their potential relation to the claims of US…

3. Obviousness under 35 U.S.C. § 103

Independent of § 102, we believe the asserted claims are obvious in view of combinations of prior art that a person having ordinary skill in the art would have been motivated to combine:

Based on the provided prior art analysis, here is an assessment of the obviousness of US patent 9,549,918 under 35 U.S.C. § 103.
Obviousness Analysis Under 35 U.S.C. § 103
Under United States patent law, an invention is considered obvious if the differences between the invention and the prior art are such that the invention as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art (PHOSITA). This analysis considers the scope of the prior art, the differences between the prior art and the claims, and the level of ordinary skill in the relevant art.
Person Having Ordinary Skill in the Art (PHOSITA)
At the time of this invention (priority date 2008-05-30), a PHOSITA would be a pharmaceutical scientist or formulation chemist with a graduate degree in a relevant field (e.g., pharmaceutics, chemistry) and several years of experience in developing oral dosage forms, particularly for poorly soluble and chemically sensitive compounds. This individual would be familiar with solid dispersion technology, common pharmaceutical…

4. Litigation History of the Patent

Public records reflect that the 9549918 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. — 1:25-cv-00458 · U.S. District Court for the District of Delaware · filed 2025-04-14 · ongoing

• Veloxis Pharmaceuticals Inc. v. Sun Pharmaceutical Industries Ltd. — U.S. District Court for the District of Delaware · settled

• Veloxis Pharmaceuticals, Inc. v. Accord Healthcare, Inc. et al. — 1:22-cv-00909 · U.S. District Court for the District of Delaware · filed 2022-07-07 · outcome not detailed

5. 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]