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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. 12290598 — Response to Assertion of Infringement

Dear Counsel,

We acknowledge receipt of your correspondence asserting infringement of U.S. Patent No. 12290598 (the "12290598 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 12,290,598 reveals the following details regarding the invention and its legal status.

Title: Orally administered corticosteroid compositions

Assignee: Ellodi Pharmaceuticals, L.P.

Inventors:

- Stephen Perrett
- Fredric Jay Cohen
- Gopi M. Venkatesh

Filing Date: January 5, 2022

Issue Date: Based on the information, the patent publication date is May 6, 2025.

Abstract:

The patent describes orally administered corticosteroid compositions designed for treating inflammatory conditions of the gastrointestinal tract. The invention also covers a method for treating these conditions by administering the described pharmaceutical compositions to an individual in need....

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 12290598 Patent:

Analysis of Prior Art Cited for U.S. Patent No. 12,290,598

The following is an analysis of the most relevant prior art for U.S. Patent No. 12,290,598, focusing on references that could potentially anticipate its claims under 35 U.S.C. § 102. The analysis is based on the patent's own description and publicly available patent data.

Patent Family (Prior Applications)

The patent's own text establishes a direct lineage from earlier applications, which constitute significant prior art.

- U.S. Patent No. 8,771,729 (issued Jul. 8, 2014)

Full Citation: US 8,771,729 B2

Filing Date: October 1, 2010

Brief Description: This patent is the parent of a series of continuations and divisionals leading to the '598 patent. It discloses orally administered corticosteroid compositions, including orally disintegrating tablets (ODTs), for treating inflammatory conditions of the gastrointestinal tract.

The core invention of an ODT with a corticosteroid for topical esophageal delivery is described.

Potential Anticipation: As the foundational patent in this family, its disclosure is highly likely to...

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, an analysis of the obviousness of the claims of U.S. Patent 12,290,598 under 35 U.S.C. § 103 indicates a strong likelihood that the key claims would be considered obvious to a person having ordinary skill in the art (POSITA) at the time of the invention.

Obviousness of Claim 1 (Orally Disintegrating Tablet Composition)

Claim 1 is directed to an orally disintegrating tablet (ODT) comprising corticosteroid-containing granules and rapidly dispersing microgranules. The specific limitations involve the composition of these microgranules, which are made from a disintegrant and a sugar alcohol/saccharide with defined particle sizes.

Combination of Prior Art:

1. Primary Reference: U.S. Patent No. 8,771,729 (the parent patent in the '598 family).
2. Secondary Reference: U.S. Patent Application Publication No. US 2005/0232988.

Analysis:

The '729 patent discloses the core inventive concept: an ODT containing a corticosteroid (such as fluticasone or budesonide) for the topical treatment of inflammatory gastrointestinal conditions like eosinophilic...

4. Litigation History of the Patent

Public records reflect that the 12290598 Patent has been the subject of the following litigation, which informs our view of the asserted claims and your client's enforcement posture:

- Dr. Falk Pharma GmbH v. Ellodi Pharmaceuticals, L.P. — PGR2025-00086 · United States Patent and Trademark Office, Patent Trial and Appeal Board (PTAB) · filed 2025-09-19 · Pending

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]

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