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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. 11021437 — Response to Assertion of Infringement**

Dear Counsel,

We acknowledge receipt of your correspondence asserting infringement of U.S. Patent No. 11021437 (the "11021437 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**

Summary of U.S. Patent 11,021,437

A concise summary of U.S. Patent 11,021,437 is provided below, including details on the patent's title, assignee, inventor, key dates, abstract, and a plain-language overview of its independent claims.

Title: Pharmaceutical formulation for sublingual or buccal delivery of epinephrine or a pro-drug thereof.

Assignee: Iono Pharma LLC.

Inventor: Hassan Almoazen.

Filing Date: November 9, 2017.

Issue Date: June 1, 2021.

Abstract: The patent describes a pharmaceutical composition for treating anaphylaxis that is designed for rapid delivery. One embodiment of the invention is a rapidly dissolving film for sublingual (under the tongue) or buccal (in the...)

## **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 11021437 Patent:

## Prior Art Analysis for US Patent 11,021,437

The following analysis details the most relevant prior art cited against US Patent 11,021,437, focusing on potential anticipation of the claimed subject matter under 35 U.S.C. § 102. The analysis is based on the citations listed in the patent's file wrapper.

### Patent Citations

#### 1. US Patent 3,809,714 A ("Hussain '714")

- Full Citation: US Patent 3,809,714, "Novel ester of ((methylamino)methyl) benzyl alcohol," filed by Anwar A. Hussain and James E. Truelove.
- Publication/Filing Dates: Publication Date: May 7, 1974; Filing Date: August 31, 1972.
- Brief Description: The '714 patent discloses novel di-esters of epinephrine, specifically created to be prodrugs with increased lipid solubility. The stated purpose is to enhance penetration through the cornea for the treatment of glaucoma. The patent explicitly describes several compounds that are ester derivatives of epinephrine, including 4-(1-hydroxy-2-(methylamino)ethyl)-1,2-phenylene diacetate (Structure 7A in the '437 patent), 4-(1-hydroxy-2(methylamino)ethyl)-1,2-phenylene...

### 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:

#### Obviousness Analysis of US Patent 11,021,437 under 35 U.S.C. § 103

This analysis assesses the obviousness of the claims of US patent 11,021,437 ('437 patent) in light of prior art available before its priority date of November 13, 2016. The analysis is based on a combination of prior art references cited in the patent itself.

A claim is considered obvious under 35 U.S.C. § 103 if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art (POSA).

#### Person Having Ordinary Skill in the Art (POSA)

For the purposes of this analysis, a POSA would be a medicinal chemist or pharmaceutical formulation scientist with experience in drug delivery, particularly in developing prodrugs and non-invasive dosage forms. This person would be familiar with the challenges of delivering unstable and poorly absorbed molecules like epinephrine.

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Analysis of Independent Claims 1 and 4, and Dependent Claims 2, 3, and 5

Claim 1...

### 4. Litigation History of the Patent

Public records reflect that the 11021437 Patent has been the subject of the following litigation, which informs our view of the asserted claims and your client's enforcement posture:

- Aquestive Therapeutics, Inc. v. Iono Pharma, LLC — IPR2025-00874 · Patent Trial and Appeal Board (PTAB) · filed 2025-05-16 · Denied

## 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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