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[Your Name]

[Your Title]

[Your Company]

[Street Address, City, State ZIP]

May 25, 2026

[Opposing Counsel Name]

[Firm Name]

[Address]

Re: U.S. Patent No. 8273735 — Response to Assertion of Infringement

Dear Counsel,

We acknowledge receipt of your correspondence asserting infringement of U.S. Patent No. 8273735 (the "8273735 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

US Patent 8,273,735: Process for Preparing Benzazepine Compounds

Title: Process for preparing benzazepine compounds or salts thereof

Current Assignee: Otsuka Pharmaceutical Co Ltd

Inventors: Yasuhiro Torisawa, Kaoru Abe, Yasuaki Muguruma, Shigekazu Fujita, Hidenori Ogawa, Naoto Utsumi, Masahiro Miyake

Filing Date: September 1, 2006

Issue Date: September 25, 2012

Abstract:

The patent describes a process for preparing benzazepine compounds or their salts, particularly 2,3,4,5-tetrahydro-1H-1-benzazepine compounds or their salts. The invention also covers intermediate compounds. The primary goal is to provide an improved industrial process for producing these compounds in high yield and...

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 8273735 Patent:

Most Relevant Prior Art for US Patent 8,273,735

The following patent documents are cited as prior art in US Patent 8,273,735. This analysis focuses on their potential anticipation under 35 U.S.C. § 102.

Cited Patent Documents:

1. JP-A-4-154765

Full Citation: JP 4-154765 A

Publication Date: June 1, 1992 (Filing date: November 27, 1990)

Brief Description: This Japanese patent application describes certain benzazepine compounds and their use as vasopressin antagonists. It is explicitly mentioned in US8273735 as disclosing "a pharmaceutically active benzazepine compound having vasopressin antagonistic activity, e.g. the compounds (10)" and also that "benzoic acid compounds of the above formula (4) are useful as an intermediate for preparing a pharmaceutically active benzazepine compound having vasopressin antagonistic activity".

Potential Anticipation (35 U.S.C. § 102): JP-A-4-154765 likely anticipates the compounds themselves (compounds of Formula (1) and (10), and intermediates of Formula (4)) rather than the processes for preparing them, which is the focus of US8273735....

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 8,273,735 Under 35 U.S.C. § 103

This analysis evaluates the obviousness of US Patent 8,273,735, which describes processes for preparing benzazepine compounds or salts thereof, under 35 U.S.C. § 103, considering the relevant prior art and the established legal precedent from the Federal Circuit.

Person Having Ordinary Skill in the Art (PHOSITA)

A person having ordinary skill in the art (PHOSITA) for US Patent 8,273,735 would likely be an organic chemist or a chemical engineer with experience in pharmaceutical synthesis, particularly in the development and optimization of synthetic routes for nitrogen-containing heterocyclic compounds, such as benzazepines. This individual would possess knowledge of common synthetic methodologies, reaction conditions, catalysts, and purification techniques, as well as an understanding of how to achieve high yields and purity in industrial-scale chemical production. They would also be familiar with literature concerning vasopressin antagonists and their synthesis.

Prior Art References

The following prior art...

4. Litigation History of the Patent

Public records reflect that the 8273735 Patent has been the subject of the following litigation, which informs our view of the asserted claims and your client's enforcement posture:

- Otsuka Pharmaceutical Co., Ltd. v. Lupin Ltd. et al. — 21-900-RGA · U.S. District Court for the District of Delaware · Judgment

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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