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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. 8501730 — Response to Assertion of Infringement

Dear Counsel,

We acknowledge receipt of your correspondence asserting infringement of U.S. Patent No. 8501730 (the "8501730 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 8501730, titled "Process for preparing benzazepine compounds or salts thereof," was issued to Otsuka Pharmaceutical Co Ltd.. The patent was filed on May 17, 2012, and granted on August 6, 2013. The inventors listed are Yasuhiro Torisawa, Kaoru Abe, Yasuaki Muguruma, Shigekazu Fujita, Hidenori Ogawa, Naoto Utsumi, and Masahiro Miyake.

Abstract Overview:

The invention provides a method for preparing benzazepine compounds of formula (1) and intermediate benzoic acid compounds of formula (4) with high yield and purity on an industrial scale. These compounds are valuable as intermediates for creating pharmaceutically active 2,3,4,5-tetrahydro-1H-1-benzazepine compounds, which act as...

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 8501730 Patent:

The most relevant prior art for US Patent 8501730, based on its citations and background discussion, includes several US patents and non-patent literature. The patent US8501730 has a priority date of September 2, 2005. References published or effectively filed before this date are relevant for potential anticipation under 35 U.S.C. § 102.

Here is an analysis of the cited prior art:

Patent Citations

1. US 6,468,988 B1

Full Citation: US 6,468,988 B1, "Process for preparing benzazepine compounds," Otsuka Pharmaceutical Co., Ltd., published October 22, 2002.

Publication/Filing Date: Publication date: October 22, 2002.

Brief Description: Based on the title, this patent likely discloses methods for synthesizing benzazepine compounds. Given the common assignee (Otsuka Pharmaceutical Co., Ltd.) and the subject matter, it is expected to detail processes relevant to the core structures found in US8501730.

Potential Anticipation: This reference potentially anticipates aspects of the processes described in Claims 1-6 of US8501730, particularly if it outlines general synthetic routes for...

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 under 35 U.S.C. § 103

This analysis will focus on combinations of prior art that would render the independent claims of US Patent 8501730 obvious to a person having ordinary skill in the art (POSA) as of the priority date of September 2, 2005.

The core of the invention lies in providing improved processes for preparing benzazepine compounds (1), benzoic acid compounds (4), and the pharmaceutically active vasopressin antagonist compounds (10) in high yield and purity on an industrial scale. The patent explicitly states that existing methods for compounds (1) and (4) were not suitable for industrial production due to low yield, low purity, or difficulty in obtaining starting materials.

Motivation to Combine Prior Art

A POSA in the field of pharmaceutical organic chemistry would be motivated to combine known chemical reactions and processes to achieve more efficient, higher-yielding, and purer synthetic routes for pharmaceutically relevant compounds, particularly when existing methods are acknowledged as being industrially unsuitable. The patent itself...

4. Litigation History of the Patent

Public records reflect that the 8501730 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
- Otsuka Pharmaceutical Co. Ltd. v. Par Pharmaceutical Inc. — 1:13-cv-01979 · District of Delaware · filed 2013-11-26
- Otsuka Pharmaceutical Co., Ltd. v. Hetero USA Inc. et al. — 1:14-cv-00421 · District of Delaware · filed 2014-04-04

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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