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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. 12161628 — Response to Assertion of Infringement

Dear Counsel,

We acknowledge receipt of your correspondence asserting infringement of U.S. Patent No. 12161628 (the "12161628 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 No. 12,161,628

Title: Combination therapy

Assignee: Astellas Pharma Inc., Medivation Prostate Therapeutics LLC

Inventors: Jacqueline GIBBONS, Joyce MORDENTI, Michiel DE VRIES, Walter KRAUWINKEL, Taoufik Ouatas

Filing Date: October 4, 2022

Issue Date: December 10, 2024

Abstract: This disclosure provides a dosage regimen for co-administration of enzalutamide and a strong CYP3A4 inducer.

Independent Claims Overview

The patent contains one independent claim, Claim 1. The subsequent claims (2-6) are dependent on Claim 1, narrowing its scope.

Claim 1: Plain-Language Overview

Claim 1 of patent 12,161,628 describes a method for treating prostate cancer. The method...

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 12161628 Patent:

Analysis of Prior Art Cited in U.S. Patent 12,161,628

This analysis examines the patent references cited during the prosecution of U.S. Patent 12,161,628 to determine their relevance and potential to anticipate the patent's claims under 35 U.S.C. § 102. The core of the invention is Claim 1, which details a method for treating prostate cancer by co-administering a 240 mg daily dose of enzalutamide to a patient who is also being treated with rifampin.

For a prior art reference to anticipate Claim 1, it must expressly or inherently disclose every element of the claim in a single document. The key elements are:

1. A method of treating prostate cancer.
2. The patient is administered rifampin.
3. Co-administration of enzalutamide.
4. A specific daily dose of 240 mg of enzalutamide.

The patent's "Patent Citations" section lists two references, which are analyzed below.

1. WO2017027660A1: Combination therapy with apalutamide
 - Full Citation: WO2017027660A1. "Combination therapy with apalutamide." Assignee: Medivation Technologies, Inc. Publication Date: February 16, 2017. Filing...

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 U.S. Patent 12,161,628 under 35 U.S.C. § 103

This analysis evaluates whether the claimed invention in U.S. Patent 12,161,628 would have been obvious to a person having ordinary skill in the art (PHOSITA) at the time the invention was made. The standard for obviousness is whether the differences between the claimed invention and the prior art are such that the subject matter as a whole would have been obvious to a PHOSITA.

A PHOSITA in this context would be a clinical pharmacologist or medical oncologist with experience in prostate cancer therapeutics, pharmacokinetics, and drug-drug interactions, particularly those involving the cytochrome P450 enzyme system.

Claim at Issue

The analysis focuses on independent Claim 1, which recites:

- Claim 1: A method of treating prostate cancer in a patient to whom rifampin is administered, comprising co-administering to the patient a daily dose of 240 mg enzalutamide.

The dependent claims (2-6) narrow the type of prostate cancer and are therefore rendered obvious if Claim 1 is obvious.

Proposed Combination of Prior...

4. Litigation History of the Patent

Public records reflect that the 12161628 Patent has been the subject of the following litigation, which informs our view of the asserted claims and your client's enforcement posture:

- Astellas US LLC et al. v. Dr Reddys Laboratories Ltd — 3:26-cv-04101 · New Jersey District Court · filed 2026-04-17 · Open

- Astellas Pharma Inc. et al. v. Hikma Pharmaceuticals USA Inc. — 3:25-cv-00578 · U.S. District Court for the District of New Jersey · filed 2025-01-16 · Dismissed
- Astellas Pharma Inc. et al. v. Haimen Pharma Inc. et al. — 3:24-cv-09403 · U.S. District Court for the District of New Jersey · filed 2025-01-03 · Ongoing
- Astellas Pharma Inc. et al. v. Zydus Pharmaceuticals (USA) Inc. et al. — 3:24-cv-09748 · U.S. District Court for the District of New Jersey · filed 2024-10-11 · Consolidated
- Astellas Pharma Inc. v. Ascent Pharmaceuticals, Inc. — 3:25-cv-00035 · U.S. District Court for the District of New Jersey · Unknown

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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