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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. 12502357 — Response to Assertion of Infringement

Dear Counsel,

We acknowledge receipt of your correspondence asserting infringement of U.S. Patent No. 12502357 (the "12502357 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

As a senior US patent analyst, I have reviewed the provided information for US patent 12502357. Below is a concise summary based on the authoritative patent text.
Summary of US Patent 12502357
Title: Formulations of enzalutamide
Assignee at Issue:
• Astellas Pharma Inc
• Medivation Prostate Therapeutics LLC
Inventors:
• Douglas Alan Lorenz
• Sanjay Konagurthu
• Randy J. Wald
• Jason A. Everett
• Sheila Matz
• Yuuki Takaishi
• Toshiro Sakai
• Ryousuke Irie
• Shinsuke Oba
• Hiroyasu Toyota

• Koji Nishimura
• Atsushi Kanbayashi
Filing Date: December 4, 2024
Issue Date: December 23, 2025
Abstract:
The patent text does not contain a formal abstract. However, the "Definitions" section…

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 12502357 Patent:

As a senior US patent analyst, I have analyzed the prior art cited against US patent 12502357. My analysis is based on the authoritative patent text provided and a search of the USPTO database.
It is important to note that the provided text for US patent 12502357 does not contain a formal, numbered "Claims" section. The analysis of which claims are anticipated is therefore based on the detailed description of the invention throughout the patent document, which describes pharmaceutical compositions of enzalutamide, particularly solid amorphous dispersions. The potential anticipations noted below are directed at the core inventive concepts described.
Prior Art Analysis for US Patent 12502357
A search of the USPTO database for US patent 12502357 reveals several prior art citations. The most relevant of these are detailed below.
1. US Patent 7,709,517 B2
• Full Citation: US Patent 7,709,517 B2, "Diarylhydantoin compounds"
• Publication/Filing Dates: Publication Date: May 4, 2010; Filing Date: August 12, 2005.
• Brief Description: This patent is the foundational patent for the…

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:

As a senior US patent analyst, I have analyzed the potential obviousness of US patent 12502357 under 35 U.S.C. § 103, based on the previously supplied prior art references.
Obviousness Analysis under 35 U.S.C. § 103
Under 35 U.S.C. § 103, a patent claim is unpatentable if the differences between the claimed invention 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 (PHOSITA). An obviousness analysis requires finding a suggestion or motivation to combine prior art elements with a reasonable expectation of success.
The PHOSITA for US patent 12502357 would be a pharmaceutical scientist or formulation chemist with experience in developing oral dosage forms, particularly for compounds with poor aqueous solubility.
1. The Core Invention and the Known Problem
The core invention of US 12502357 is a pharmaceutical composition comprising a solid amorphous dispersion of the drug enzalutamide and a concentration-enhancing polymer, such as hydroxypropylmethylcellulose acetate…

4. Litigation History of the Patent

Public records reflect that the 12502357 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

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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