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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. 11878049 — Response to Assertion of Infringement

Dear Counsel,

We acknowledge receipt of your correspondence asserting infringement of U.S. Patent No. 11878049 (the "11878049 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 11878049 Summary
Title: Mitapivat therapy and modulators of cytochrome P450
Assignee: Agios Pharmaceuticals Inc.
Inventors: Varsha Venkatachalam Iyer, Chandra Agarwal Prakash, Hua Yang
Filing Date: 2020-06-12
Issue Date: 2024-01-23
Abstract: The patent describes methods for treating diseases, disorders, or conditions using mitapivat or its pharmaceutically acceptable salts. These methods involve either co-administering mitapivat with a cytochrome P450 3A4/5 (CYP3A4/5) inducer, a CYP3A4/5 inhibitor, or a p-glycoprotein (p-gp) inhibitor, or administering mitapivat in the absence of such modulators. The disclosure provides for adjusting the mitapivat dosage to manage drug-drug…

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 11878049 Patent:

The most relevant prior art for US patent 11878049, based on its citations and the stated priority date of June 14, 2019, are patents and publications that disclose the use of mitapivat (also

known as AG-348) for the treatment of pyruvate kinase deficiency (PKD), sickle cell disease (SCD), and thalassemia. These references establish the foundational knowledge upon which US11878049 builds, specifically concerning the therapeutic application of mitapivat.
However, for a prior art reference to anticipate a claim under 35 U.S.C. § 102, it must disclose every single element of that claim, either explicitly or inherently. The distinguishing features of US11878049's independent claims involve methods of treating these diseases by either:
1. Co-administering mitapivat with an effective amount of a CYP3A4/5 inducer, a CYP3A4/5 inhibitor, or a p-glycoprotein (p-gp) inhibitor.
2. Administering mitapivat in the absence of such modulators.
3. Implying that these approaches are specifically for managing drug-drug interactions and optimizing mitapivat exposure.
While the prior art listed below…

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:

The obviousness analysis under 35 U.S.C. § 103 requires determining whether the differences between the claimed invention and the prior art would have made the invention as a whole obvious to a person having ordinary skill in the art (POSITA) before the effective filing date. The patent specifies a prior art date of June 14, 2019.
Prior Art Context from the Patent Itself:
The patent US11878049B1, in its "Definitions" and "Non-clinical studies" sections, provides critical information that is pertinent to the state of the art before the filing date. Specifically, it states:
• "Non-clinical studies described in Example 1 show that the PKR activator, mitapivat, is primarily metabolized by the cytochrome P450 3A4 (CYP3A4) or 3A5 (CYP3A5) enzymes (i.e., >90%), with minor contributions from other detoxification enzymes, namely CYP2C8, CYP2C9, and CYP1A2."
• "It has also been found that in a clinical trial, total exposure of mitapivat increased in the presence of itraconazole, a strong CYP3A4A and p-gp inhibitor, compared with dosing of mitapivat sulfate alone."
• "It has further been…

4. 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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