

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

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**BEFORE THE PATENT TRIAL AND APPEAL BOARD**

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CSPC MEGALITH BIOPHARMACEUTICAL CO., LTD.,

Petitioner,

v.

SHANGHAI MIRACOGEN INC.,

Patent Owner.

Case No. IPR2025-00685

U.S. Patent No. 10,792,370

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**PATENT OWNER'S OBJECTIONS TO PETITIONER'S EVIDENCE  
PURSUANT TO 37 C.F.R. § 42.64(b)(1)**

Pursuant to 37 C.F.R. § 42.64(b)(1) and the Federal Rules of Evidence, Patent Owner submits the following objections to evidence served by Petitioner. These objections are timely served pursuant to 37 C.F.R. § 42.64(b)(1) within ten business days of the institution of the trial. The Federal Rules of Evidence (F.R.E.) apply to these proceedings according to 37 C.F.R. § 42.62(a), and these rules form the basis of the objections contained herein.

<b>Document Number</b>	<b>Objections</b>
1002	<p><u>Hearsay.</u> F.R.E. 801(c) and 802. Exhibit 1002 relies on documents that constitute or contain inadmissible hearsay, because the documents contain out-of-court statements that are offered for the truth of the matters asserted therein.</p> <p><u>Qualification of Expert Witness.</u> F.R.E. 401, 402, 403, and 702. This exhibit includes testimony not relevant to the instituted review, because, among other things, it has not been shown that the purportedly expert declarant is qualified to testify competently regarding the matters the opinions are said to address, or that the declarant’s testimony is based on sufficient facts or data or arrived at by reliable principles, procedures, or methods reliably applied to the facts of this case, or that the declarant’s opinion will assist the trier of fact to understand the evidence or to determine any fact in issue and does not have a greater potential to mislead than to enlighten.</p> <p><u>Personal Knowledge.</u> F.R.E. 602, 701, 801, and 802 and 37 C.F.R. § 42.61. This exhibit includes testimony that is not shown to be based on first-hand knowledge including of how relied-upon data was generated, is based on speculation, and constitutes and contains inadmissible hearsay.</p> <p><u>Underlying Facts and Data.</u> F.R.E. 401 and 705 and 37 C.F.R. § 42.65. This exhibit does not disclose underlying facts and data</p>

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	<p>and includes testimony on patent law and practice.</p> <p><u>Authentication.</u> F.R.E. 901(a). Exhibit 1002 relies on exhibits for which Petitioner has not produced evidence sufficient to support a finding that the exhibits are what Petitioner claims them to be or the dates on which they were allegedly published.</p>
1005	<p><u>Underlying Facts and Data.</u> F.R.E. 705 and 37 C.F.R. § 42.65. This exhibit does not disclose underlying facts and data for embodiments relied upon by Petitioner.</p> <p><u>Relevance.</u> F.R.E. 401-403. Any probative value of this exhibit is substantially outweighed by unfair prejudice, confusing the issues, and/or misleading the factfinder in that the exhibit contains material errors and insufficiently discloses embodiments relied upon by Petitioner.</p> <p><u>Hearsay.</u> F.R.E. 801(c) and 802. The Petition relies on this exhibit to prove the truth of matters described therein. For example, Petitioner cites to statements in this exhibit to support the argument that “a POSA would recognize [humanized anti-EGFR antibodies] as having lower immunogenicity than murine and chimeric antibodies” Pet., 40. Because the statements were not made by a declarant in this proceeding, the statements are hearsay.</p> <p><u>Personal Knowledge.</u> F.R.E. 602. This exhibit contains testimony regarding matters for which the declarant does not have personal knowledge.</p> <p><u>Improper Opinion.</u> F.R.E. 701. This exhibit contains impermissible opinion testimony that is based on scientific, technical, or other specialized knowledge and is not rationally based on the declarant’s perception. Examples of such impermissible opinion testimony include the hearsay statements described above. Petitioner has not established that the declarant is qualified to provide expert testimony.</p>

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1008	<p><u>Interpreter.</u> F.R.E. 604. Petitioner has not produced evidence sufficient to support a finding that the purported interpreter is qualified to perform this translation. For example, the translation certification does not appear to include the full name of the interpreter.</p> <p><u>Relevance.</u> F.R.E. 401-403. Any probative value of this exhibit is substantially outweighed by unfair prejudice, confusing the issues, and/or wasting time to the extent the translation contained in Exhibit 1008 is inaccurate or unreliable.</p>
1010	<p><u>Hearsay.</u> F.R.E. 801(c) and 802. The Petition relies on this exhibit to prove the truth of matters described therein. For example, Petitioner cites to statements in this exhibit to support the argument that “there are fourteen FDA-approved ADCs available on the market, twelve of which use cleavable linkers.” Pet., 7. Because the statements were not made by a declarant in this proceeding, the statements are hearsay.</p> <p><u>Personal Knowledge.</u> F.R.E. 602. This exhibit contains testimony regarding matters for which the declarant does not have personal knowledge.</p> <p><u>Improper Opinion.</u> F.R.E. 701. This exhibit contains impermissible opinion testimony that is based on scientific, technical, or other specialized knowledge and is not rationally based on the declarant’s perception. Examples of such impermissible opinion testimony include the hearsay statements described above. Petitioner has not established that the declarant is qualified to provide expert testimony.</p> <p><u>Relevance.</u> F.R.E. 401-403. This exhibit is not relevant to any issue in this IPR proceeding, and any probative value of the exhibit is substantially outweighed by unfair prejudice, confusing the issues, and/or wasting time in that the publication date of this exhibit’s content has not been established. Furthermore, the purported publication date does not predate</p>

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	<p>the priority date of the '370 patent.</p> <p><u>Authentication.</u> F.R.E. 901(a). Petitioner has not produced evidence sufficient to support a finding that this exhibit is what Petitioner claims it to be or the date on which it was allegedly published.</p>
1011	<p><u>Hearsay.</u> F.R.E. 801(c) and 802. The Petition relies on this exhibit to prove the truth of matters described therein. For example, Petitioner cites to statements in this exhibit to support the argument that “[f]ully human and humanized antibodies have an even lower risk of inducing an immune response in humans than murine or chimeric antibodies.” Pet., 7. Because the statements were not made by a declarant in this proceeding, the statements are hearsay. Furthermore, reliance on dates stated within the document constitutes hearsay because they are out-of-court statements offered to prove the truth of when the statements in the document were allegedly made.</p> <p><u>Personal Knowledge.</u> F.R.E. 602. This exhibit contains testimony regarding matters for which the declarant does not have personal knowledge.</p> <p><u>Improper Opinion.</u> F.R.E. 701. This exhibit contains impermissible opinion testimony that is based on scientific, technical, or other specialized knowledge and is not rationally based on the declarant’s perception. Examples of such impermissible opinion testimony include the hearsay statements described above. Petitioner has not established that the declarant is qualified to provide expert testimony.</p> <p><u>Relevance.</u> F.R.E. 401-403. This exhibit is not relevant to any issue in this IPR proceeding, and any probative value of the exhibit is substantially outweighed by unfair prejudice, confusing the issues, and/or wasting time in that the publication date of this exhibit’s content has not been established.</p>

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1012	<p><u>Hearsay.</u> F.R.E. 801(c) and 802. To the extent the Petition relies on this exhibit to prove the truth of matters described therein, because the statements were not made by a declarant in this proceeding, the statements are hearsay. Furthermore, reliance on dates stated within the document constitutes hearsay because they are out-of-court statements offered to prove the truth of when the statements in the document were allegedly made.</p> <p><u>Personal Knowledge.</u> F.R.E. 602. This exhibit contains testimony regarding matters for which the declarant does not have personal knowledge.</p> <p><u>Improper Opinion.</u> F.R.E. 701. This exhibit contains impermissible opinion testimony that is based on scientific, technical, or other specialized knowledge and is not rationally based on the declarant's perception. Examples of such impermissible opinion testimony include the hearsay statements described above. Petitioner has not established that the declarant is qualified to provide expert testimony.</p> <p><u>Relevance.</u> F.R.E. 401-403. This exhibit is not relevant to any issue in this IPR proceeding, and any probative value of the exhibit is substantially outweighed by unfair prejudice, confusing the issues, and/or wasting time in that the publication date of this exhibit's content has not been established.</p> <p><u>Authentication.</u> F.R.E. 901(a). Petitioner has not produced evidence sufficient to support a finding that this exhibit is what Petitioner claims it to be or the date on which it was allegedly published.</p>

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1013	<p><u>Hearsay.</u> F.R.E. 801(c) and 802. To the extent the Petition relies on this exhibit to prove the truth of matters described therein, because the statements were not made by a declarant in this proceeding, the statements are hearsay. Furthermore, reliance on dates stated within the document constitutes hearsay because they are out-of-court statements offered to prove the truth of when the statements in the document were allegedly made.</p> <p><u>Personal Knowledge.</u> F.R.E. 602. This exhibit contains testimony regarding matters for which the declarant does not have personal knowledge.</p> <p><u>Improper Opinion.</u> F.R.E. 701. This exhibit contains impermissible opinion testimony that is based on scientific, technical, or other specialized knowledge and is not rationally based on the declarant's perception. Examples of such impermissible opinion testimony include the hearsay statements described above. Petitioner has not established that the declarant is qualified to provide expert testimony.</p> <p><u>Relevance.</u> F.R.E. 401-403. This exhibit is not relevant to any issue in this IPR proceeding, and any probative value of the exhibit is substantially outweighed by unfair prejudice, confusing the issues, and/or wasting time in that the publication date of this exhibit's content has not been established.</p> <p><u>Authentication.</u> F.R.E. 901(a). Petitioner has not produced evidence sufficient to support a finding that this exhibit is what Petitioner claims it to be or the date on which it was allegedly published.</p>
1014	<p><u>Hearsay.</u> F.R.E. 801(c) and 802. To the extent the Petition relies on this exhibit to prove the truth of matters described therein, because the statements were not made by a declarant in this proceeding, the statements are hearsay. Furthermore, reliance on dates stated within the document constitutes hearsay because they are out-of-court statements offered to prove the truth of</p>

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1015	<p><u>Hearsay.</u> F.R.E. 801(c) and 802. The Petition relies on this exhibit to prove the truth of matters described therein. For example, Petitioner cites to statements in this exhibit to support the argument that “cleavable linkers can include chemically labile (<i>e.g.</i>, hydrazones and disulfides) and protease-labile linkers, linkers that can be cleaved under different conditions (<i>e.g.</i>, pH, enzymes, reductive conditions), and linkers with different coupling functional handles.” Pet., 35. Because the statements were not made by a declarant in this proceeding, the statements are hearsay. Furthermore, reliance on dates stated within the document constitutes hearsay because they are out-of-court statements offered to prove the truth of when the</p>

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1016	<p><u>Hearsay.</u> F.R.E. 801(c) and 802. The Petition relies on this exhibit to prove the truth of matters described therein. For example, Petitioner cites to statements in this exhibit to support the argument that “in contrast to a non-cleavable linker, an antibody conjugated with MMAE through a cleavable linker releases more potent MMAE drug, which can diffuse through the cell membrane and induce bystander killing of neighboring target cells.” Pet., 48. Because the statements were not made by a declarant in this proceeding, the statements are hearsay. Furthermore, reliance on dates stated within the document</p>

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1018	<p><u>Hearsay.</u> F.R.E. 801(c) and 802. The Petition relies on this exhibit to prove the truth of matters described therein. For example, Petitioner cites to statements in this exhibit to support the argument that “[a]s of the earliest possible effective filing date of the Challenged Claims, it was known that the MDA MB 231M TNBC tumors tested with Wei’s ADCs are BRAF-mutated tumors.” Pet., 64. Because the statements were not made by a declarant in this proceeding, the statements are hearsay. Furthermore, reliance on dates stated within the document constitutes hearsay because they are out-of-court</p>

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1020	<p><u>Hearsay.</u> F.R.E. 801(c) and 802. The declaration of Dr. Bournazos relies on this exhibit to prove the truth of matters described therein. For example, Dr. Bournazos cites to statements in this exhibit to support the argument that “ADC technology is based on the principle that linking a cytotoxic drug to an antibody specific for an antigen more highly expressed on cancer cells could allow high doses of the cytotoxic drug to be specifically delivered to cancer cells, largely sparing normal tissues.” Ex-1002, ¶34. Because the statements were not made by a declarant in this proceeding, the statements are hearsay. Furthermore, reliance on dates stated within the document constitutes hearsay because they are out-of-court statements offered to prove the truth of when the statements in the document were allegedly made.</p> <p><u>Personal Knowledge.</u> F.R.E. 602. This exhibit contains testimony regarding matters for which the declarant does not</p>

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1021	<p><u>Hearsay.</u> F.R.E. 801(c) and 802. The declaration of Dr. Bournazos relies on this exhibit to prove the truth of matters described therein. For example, Dr. Bournazos cites to statements in this exhibit to support the argument that “Brentuximab vedotin (also known as Adcetris, marketed by Seattle Genetics; a CD30-specific ADC conjugated with vcMMAE, is the first ADC that couples the targetability of monoclonal antibodies (‘mAbs’) with the potent cytotoxicity of small molecule drugs and desirable pharmacokinetic (‘PK’) profiles.” Ex-1002, ¶51. Because the statements were not made by a declarant in this proceeding, the statements are hearsay. Furthermore, reliance on dates stated within the document constitutes hearsay because they are out-of-court statements offered to prove the truth of when the statements in the</p>

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1022	<p><u>Hearsay.</u> F.R.E. 801(c) and 802. The declaration of Dr. Bournazos relies on this exhibit to prove the truth of matters described therein. For example, Dr. Bournazos cites to statements in this exhibit to support the argument that “[f]ully human and humanized antibodies have a lower risk of inducing an immune response in humans than murine or chimeric antibodies.” Ex-1002, ¶38. Because the statements were not made by a declarant in this proceeding, the statements are hearsay. Furthermore, reliance on dates stated within the document constitutes hearsay because they are out-of-court statements offered to prove the truth of when the statements in</p>

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1023	<p><u>Hearsay.</u> F.R.E. 801(c) and 802. To the extent Petitioner relies on this exhibit to prove the truth of matters described therein, because the statements were not made by a declarant in this proceeding, the statements are hearsay. Furthermore, reliance on dates stated within the document constitutes hearsay because they are out-of-court statements offered to prove the truth of when the statements in the document were allegedly made.</p> <p><u>Personal Knowledge.</u> F.R.E. 602. This exhibit contains testimony regarding matters for which the declarant does not</p>

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1025	<p><u>Hearsay.</u> F.R.E. 801(c) and 802. To the extent Petitioner relies on this exhibit to prove the truth of matters described therein, because the statements were not made by a declarant in this proceeding, the statements are hearsay. Furthermore, reliance on dates stated within the document constitutes hearsay because they are out-of-court statements offered to prove the truth of when the statements in the document were allegedly made.</p> <p><u>Personal Knowledge.</u> F.R.E. 602. This exhibit contains testimony regarding matters for which the declarant does not have personal knowledge.</p> <p><u>Improper Opinion.</u> F.R.E. 701. This exhibit contains impermissible opinion testimony that is based on scientific, technical, or other specialized knowledge and is not rationally based on the declarant’s perception. Examples of such impermissible opinion testimony include the hearsay statements described above. Petitioner has not established that the declarant is qualified to provide expert testimony.</p>

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1026	<p><u>Hearsay.</u> F.R.E. 801(c) and 802. The declaration of Dr. Bournazos relies on this exhibit to prove the truth of matters described therein. For example, Dr. Bournazos cites to statements in this exhibit to support the argument that “[t]he vc-PAB linker is hydrolyzed by the cysteine protease cathepsin B in lysosomes following endocytosis.” Ex-1002, ¶50. Because the statements were not made by a declarant in this proceeding, the statements are hearsay. Furthermore, reliance on dates stated within the document constitutes hearsay because they are out-of-court statements offered to prove the truth of when the statements in the document were allegedly made.</p> <p><u>Personal Knowledge.</u> F.R.E. 602. This exhibit contains testimony regarding matters for which the declarant does not have personal knowledge.</p> <p><u>Improper Opinion.</u> F.R.E. 701. This exhibit contains impermissible opinion testimony that is based on scientific, technical, or other specialized knowledge and is not rationally based on the declarant's perception. Examples of such impermissible opinion testimony include the hearsay statements described above. Petitioner has not established that the declarant is qualified to provide expert testimony.</p> <p><u>Relevance.</u> F.R.E. 401-403. This exhibit is not relevant to any</p>

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	<p>issue in this IPR proceeding, and any probative value of the exhibit is substantially outweighed by unfair prejudice, confusing the issues, and/or wasting time in that this exhibit is not cited in the Petition and the publication date of this exhibit's content has not been established.</p> <p><u>Authentication.</u> F.R.E. 901(a). Petitioner has not produced evidence sufficient to support a finding that this exhibit is what Petitioner claims it to be or the date on which it was allegedly published.</p>
1027	<p><u>Hearsay.</u> F.R.E. 801(c) and 802. The declaration of Dr. Bournazos relies on this exhibit to prove the truth of matters described therein. For example, Dr. Bournazos cites to statements in this exhibit to support the argument that “the selected cleavable linker (Val-Cit) displayed very potent efficacy both <i>in vitro</i> and <i>in vivo</i>, as well as favorable safety profile and stability.” Ex-1002, ¶191. Because the statements were not made by a declarant in this proceeding, the statements are hearsay. Furthermore, reliance on dates stated within the document constitutes hearsay because they are out-of-court statements offered to prove the truth of when the statements in the document were allegedly made.</p> <p><u>Personal Knowledge.</u> F.R.E. 602. This exhibit contains testimony regarding matters for which the declarant does not have personal knowledge.</p> <p><u>Improper Opinion.</u> F.R.E. 701. This exhibit contains impermissible opinion testimony that is based on scientific, technical, or other specialized knowledge and is not rationally based on the declarant's perception. Examples of such impermissible opinion testimony include the hearsay statements described above. Petitioner has not established that the declarant is qualified to provide expert testimony.</p> <p><u>Relevance.</u> F.R.E. 401-403. This exhibit is not relevant to any</p>

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1028	<p><u>Hearsay.</u> F.R.E. 801(c) and 802. The declaration of Dr. Bournazos relies on this exhibit to prove the truth of matters described therein. For example, Dr. Bournazos cites to statements in this exhibit to support the argument that “the selected cleavable linker (Val-Cit) displayed very potent efficacy both <i>in vitro</i> and <i>in vivo</i>, as well as favorable safety profile and stability.” Ex-1002, ¶191. Because the statements were not made by a declarant in this proceeding, the statements are hearsay. Furthermore, reliance on dates stated within the document constitutes hearsay because they are out-of-court statements offered to prove the truth of when the statements in the document were allegedly made.</p> <p><u>Personal Knowledge.</u> F.R.E. 602. This exhibit contains testimony regarding matters for which the declarant does not have personal knowledge.</p> <p><u>Improper Opinion.</u> F.R.E. 701. This exhibit contains impermissible opinion testimony that is based on scientific, technical, or other specialized knowledge and is not rationally based on the declarant's perception. Examples of such impermissible opinion testimony include the hearsay statements described above. Petitioner has not established that the declarant is qualified to provide expert testimony.</p> <p><u>Relevance.</u> F.R.E. 401-403. This exhibit is not relevant to any</p>

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	<p>issue in this IPR proceeding, and any probative value of the exhibit is substantially outweighed by unfair prejudice, confusing the issues, and/or wasting time in that this exhibit is not cited in the Petition and the publication date of this exhibit's content has not been established.</p> <p><u>Authentication.</u> F.R.E. 901(a). Petitioner has not produced evidence sufficient to support a finding that this exhibit is what Petitioner claims it to be or the date on which it was allegedly published.</p>
1029	<p><u>Hearsay.</u> F.R.E. 801(c) and 802. The declaration of Dr. Bournazos relies on this exhibit to prove the truth of matters described therein. For example, Dr. Bournazos cites to statements in this exhibit to support the argument that “[t]he payload from non-cleavable linked ADCs remains covalently bonded to the linker via the residues to which the linkers are conjugated.” Ex-1002, ¶54. Because the statements were not made by a declarant in this proceeding, the statements are hearsay. Furthermore, reliance on dates stated within the document constitutes hearsay because they are out-of-court statements offered to prove the truth of when the statements in the document were allegedly made.</p> <p><u>Personal Knowledge.</u> F.R.E. 602. This exhibit contains testimony regarding matters for which the declarant does not have personal knowledge.</p> <p><u>Improper Opinion.</u> F.R.E. 701. This exhibit contains impermissible opinion testimony that is based on scientific, technical, or other specialized knowledge and is not rationally based on the declarant's perception. Examples of such impermissible opinion testimony include the hearsay statements described above. Petitioner has not established that the declarant is qualified to provide expert testimony.</p> <p><u>Relevance.</u> F.R.E. 401-403. This exhibit is not relevant to any</p>

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	<p>issue in this IPR proceeding, and any probative value of the exhibit is substantially outweighed by unfair prejudice, confusing the issues, and/or wasting time in that this exhibit is not cited in the Petition and the publication date of this exhibit's content has not been established.</p> <p><u>Authentication.</u> F.R.E. 901(a). Petitioner has not produced evidence sufficient to support a finding that this exhibit is what Petitioner claims it to be or the date on which it was allegedly published.</p>
1031	<p><u>Hearsay.</u> F.R.E. 801(c) and 802. The declaration of Dr. Bournazos relies on this exhibit to prove the truth of matters described therein. For example, Dr. Bournazos cites to statements in this exhibit to support the argument that “it was known in the art that drugs linked by cleavable linkers, such as vcMMAE, are more likely to have the bystander effect (see Section VI) and anti-EGFR mAbs conjugated to vcMMAE show potent antitumor activity <i>in vivo</i> and <i>in vitro</i>.” Ex-1002, ¶192. Because the statements were not made by a declarant in this proceeding, the statements are hearsay. Furthermore, reliance on dates stated within the document constitutes hearsay because they are out-of-court statements offered to prove the truth of when the statements in the document were allegedly made.</p> <p><u>Personal Knowledge.</u> F.R.E. 602. This exhibit contains testimony regarding matters for which the declarant does not have personal knowledge.</p> <p><u>Improper Opinion.</u> F.R.E. 701. This exhibit contains impermissible opinion testimony that is based on scientific, technical, or other specialized knowledge and is not rationally based on the declarant's perception. Examples of such impermissible opinion testimony include the hearsay statements described above. Petitioner has not established that the declarant is qualified to provide expert testimony.</p>

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	<p><u>Relevance.</u> F.R.E. 401-403. This exhibit is not relevant to any issue in this IPR proceeding, and any probative value of the exhibit is substantially outweighed by unfair prejudice, confusing the issues, and/or wasting time in that this exhibit is not cited in the Petition and the publication date of this exhibit's content has not been established. Furthermore, the purported publication date does not predate the priority date of the '370 patent.</p> <p><u>Authentication.</u> F.R.E. 901(a). Petitioner has not produced evidence sufficient to support a finding that this exhibit is what Petitioner claims it to be or the date on which it was allegedly published.</p>
1032	<p><u>Hearsay.</u> F.R.E. 801(c) and 802. The declaration of Dr. Bournazos relies on this exhibit to prove the truth of matters described therein. For example, Dr. Bournazos cites to statements in this exhibit to support the argument that "it was known in the art that drugs linked by cleavable linkers, such as vcMMAE, are more likely to have the bystander effect (see Section VI) and anti-EGFR mAbs conjugated to vcMMAE show potent antitumor activity <i>in vivo</i> and <i>in vitro</i>." Ex-1002, ¶192. Because the statements were not made by a declarant in this proceeding, the statements are hearsay. Furthermore, reliance on dates stated within the document constitutes hearsay because they are out-of-court statements offered to prove the truth of when the statements in the document were allegedly made.</p> <p><u>Personal Knowledge.</u> F.R.E. 602. This exhibit contains testimony regarding matters for which the declarant does not have personal knowledge.</p> <p><u>Improper Opinion.</u> F.R.E. 701. This exhibit contains impermissible opinion testimony that is based on scientific, technical, or other specialized knowledge and is not rationally</p>

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	<p>based on the declarant’s perception. Examples of such impermissible opinion testimony include the hearsay statements described above. Petitioner has not established that the declarant is qualified to provide expert testimony.</p> <p><u>Relevance.</u> F.R.E. 401-403. This exhibit is not relevant to any issue in this IPR proceeding, and any probative value of the exhibit is substantially outweighed by unfair prejudice, confusing the issues, and/or wasting time in that this exhibit is not cited in the Petition.</p>
1033	<p><u>Hearsay.</u> F.R.E. 801(c) and 802. The declaration of Dr. Bournazos relies on this exhibit to prove the truth of matters described therein. For example, Dr. Bournazos cites to statements in this exhibit to support the argument that “[t]he HT29 tumor xenograft model and MDA-MB-231M human breast tumor xenograft model are known to have BRAF gene mutation.” Ex-1002, ¶264. Because the statements were not made by a declarant in this proceeding, the statements are hearsay. Furthermore, reliance on dates stated within the document constitutes hearsay because they are out-of-court statements offered to prove the truth of when the statements in the document were allegedly made.</p> <p><u>Personal Knowledge.</u> F.R.E. 602. This exhibit contains testimony regarding matters for which the declarant does not have personal knowledge.</p> <p><u>Improper Opinion.</u> F.R.E. 701. This exhibit contains impermissible opinion testimony that is based on scientific, technical, or other specialized knowledge and is not rationally based on the declarant’s perception. Examples of such impermissible opinion testimony include the hearsay statements described above. Petitioner has not established that the declarant is qualified to provide expert testimony.</p> <p><u>Relevance.</u> F.R.E. 401-403. This exhibit is not relevant to any</p>

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	<p>issue in this IPR proceeding, and any probative value of the exhibit is substantially outweighed by unfair prejudice, confusing the issues, and/or wasting time in that this exhibit is not cited in the Petition and the publication date of this exhibit's content has not been established.</p> <p><u>Authentication.</u> F.R.E. 901(a). Petitioner has not produced evidence sufficient to support a finding that this exhibit is what Petitioner claims it to be or the date on which it was allegedly published.</p>
1034	<p><u>Hearsay.</u> F.R.E. 801(c) and 802. The Petition relies on this exhibit to prove the truth of matters described therein. For example, Petitioner cites to statements in this exhibit to support the argument that “[f]ully human and humanized antibodies have an even lower risk of inducing an immune response in humans than murine or chimeric antibodies.” Pet., 7-8. Because the statements were not made by a declarant in this proceeding, the statements are hearsay. Furthermore, reliance on dates stated within the document constitutes hearsay because they are out-of-court statements offered to prove the truth of when the statements in the document were allegedly made.</p> <p><u>Personal Knowledge.</u> F.R.E. 602. This exhibit contains testimony regarding matters for which the declarant does not have personal knowledge.</p> <p><u>Improper Opinion.</u> F.R.E. 701. This exhibit contains impermissible opinion testimony that is based on scientific, technical, or other specialized knowledge and is not rationally based on the declarant's perception. Examples of such impermissible opinion testimony include the hearsay statements described above. Petitioner has not established that the declarant is qualified to provide expert testimony.</p> <p><u>Relevance.</u> F.R.E. 401-403. This exhibit is not relevant to any issue in this IPR proceeding, and any probative value of the</p>

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	<p>exhibit is substantially outweighed by unfair prejudice, confusing the issues, and/or wasting time in that the publication date of this exhibit's content has not been established.</p> <p><u>Authentication.</u> F.R.E. 901(a). Petitioner has not produced evidence sufficient to support a finding that this exhibit is what Petitioner claims it to be or the date on which it was allegedly published.</p>
1035	<p><u>Interpreter.</u> F.R.E. 604. Petitioner has not produced evidence sufficient to support a finding that the purported interpreter is qualified to perform this translation. For example, the translation certification refers to a "company" but does not include the name of the company.</p> <p><u>Relevance.</u> F.R.E. 401-403. Any probative value of this exhibit is substantially outweighed by unfair prejudice, confusing the issues, and/or wasting time to the extent the translation contained in Exhibit 1035 is inaccurate or unreliable.</p>
1100	<p><u>Relevance.</u> F.R.E. 401-403. This exhibit, as relied upon by Petitioner, lacks relevance, and any probative value of the exhibit is substantially outweighed by unfair prejudice, confusing the issues, and/or wasting time.</p> <p><u>Authentication.</u> F.R.E. 901(a). Petitioner has not produced evidence sufficient to support a finding that this exhibit is what Petitioner claims it to be or the date on which it was allegedly published.</p>
1101	<p><u>Relevance.</u> F.R.E. 401-403. This exhibit, as relied upon by Petitioner, lacks relevance, and any probative value of the exhibit is substantially outweighed by unfair prejudice, confusing the issues, and/or wasting time.</p> <p><u>Authentication.</u> F.R.E. 901(a). Petitioner has not produced evidence sufficient to support a finding that this exhibit is what Petitioner claims it to be or the date on which it was allegedly</p>

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	published.
1102	<p><u>Relevance.</u> F.R.E. 401-403. This exhibit, as relied upon by Petitioner, lacks relevance, and any probative value of the exhibit is substantially outweighed by unfair prejudice, confusing the issues, and/or wasting time.</p> <p><u>Authentication.</u> F.R.E. 901(a). Petitioner has not produced evidence sufficient to support a finding that this exhibit is what Petitioner claims it to be or the date on which it was allegedly published.</p>
1103	<p><u>Relevance.</u> F.R.E. 401-403. This exhibit, as relied upon by Petitioner, lacks relevance, and any probative value of the exhibit is substantially outweighed by unfair prejudice, confusing the issues, and/or wasting time.</p> <p><u>Authentication.</u> F.R.E. 901(a). Petitioner has not produced evidence sufficient to support a finding that this exhibit is what Petitioner claims it to be or the date on which it was allegedly published.</p>

Date: October 28, 2025

Respectfully,

SHEPPARD, MULLIN,  
RICHTER & HAMPTON LLP

/ Christopher Ponder /

Christopher Ponder (Reg. No. 77,167)

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Attorneys for Patent Owner  
Shanghai Miracogen Inc.

**CERTIFICATE OF SERVICE**

The undersigned hereby certifies that, on this date, a copy of the foregoing Patent Owner's Objections to Petitioner's Evidence Pursuant to 37 C.F.R. § 42.64(b)(1) was served via email to all parties to this proceeding at the addresses indicated:

Joe G. Chen, Ph.D. (joechen@foxrothschild.com)

Howard S. Suh (hsuh@foxrothschild.com)

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Date: October 28, 2025

/ Christopher Ponder /

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