

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

INTAS PHARMACEUTICALS LTD,
Petitioner

v.

ATOSSA THERAPEUTICS, INC.,
Patent Owner

Case PGR2025-00043
Patent 12,071,391

**PATENT OWNER ATOSSA'S
OBJECTIONS TO EVIDENCE UNDER 37 C.F.R. §42.64**

Pursuant to 37 C.F.R. §42.64(b)(1), Atossa Therapeutics, Inc. (“Atossa”) objects to the admissibility of the following exhibits filed on April 3, 2025, by Petitioner with its Petition for Inter Partes Review. Pap. 1. The Institution Decision issued on November 3, 2025. Pap. 13. Patent Owner’s objections are timely under 37 C.F.R. §42.64(b)(1). Patent Owner serves Petitioner with these objections to provide notice that Patent Owner may move to exclude the exhibits identified below as inadmissible.

I. EX1005-EX1021, EX1024-EX1032, EX1035-1037, And Any Reference To Or Reliance Thereon

Patent Owner objects to the admissibility of EX1005-EX1021, EX1024-1032, EX1035-1037 for at least the following reasons:

Petitioner has failed to authenticate EX1005-EX1021, EX1024-1032, EX1035-1037 under **FRE 901** (authentication) and **FRE 602** (personal knowledge). Specifically, Petitioner has failed to establish that each of these exhibits is what Petitioner claims it to be.

To the extent that Petitioner attempts to rely on any date that may appear in EX1005, EX1007, EX1013-EX1021, EX1024-EX1032, EX1035-EX1037 to establish public accessibility as a printed publication, any such date is hearsay under **FRE 801** (hearsay) and is inadmissible under **FRE 802** (hearsay), and further, any such document in which any such date may appear has not been authenticated and is inadmissible under **FRE 901**.

Including because of these deficiencies, Petitioner has failed to establish that EX1005, EX1007, EX1013-EX1021, EX1024-EX1032, EX1035-EX1037 are prior art printed publications. Therefore, EX1005, EX1007, EX1013-EX1021, EX1024-EX1032, EX1035-EX1037 are not relevant under **FRE 401** (test for relevance) and are inadmissible under **FRE 402** (relevance) and **FRE 403** (probative value outweighed by prejudice, confusing of issues, wasting of time). Petitioner has additionally failed to establish the prior art status of EX1014, EX1019, EX1024, EX1035, and EX1037, each of which significantly post-dates the effective date of the challenged patent (U.S. Patent No. 12,071,391), and thus they are not relevant for this additional reason under **FRE 401**. Further, Petitioner did not cite EX1014-EX1016, EX1018, EX1024-EX1025, EX1027, EX1031, EX1035-1037 in the Petition, and thus they are not relevant for this additional reason under **FRE 401**.

II. Declaration of Jason McConville, Ph.D. (EX1033)

Patent Owner objects to the Declaration of Jason McConville, Ph.D. (EX1033) for at least the following reasons:

Under **FRE 702** (expert testimony), Dr. McConville's opinions are inadmissible because they are conclusory, do not sufficiently disclose underlying facts or data in support, and are unreliable. *See, e.g.*, ¶¶ 49, 51, 59, 75, 79, 84-145. Additionally, under **FRE 401** (test for relevance), **FRE 402** (relevance), and **FRE**

403 (probative value outweighed by prejudice, confusing of issues, wasting of time), his opinions are irrelevant, confusing, and of minimal probative value.

In addition, Dr. McConville's declaration relies on EX1005–EX1014, EX1017–EX1021, EX1028–EX1030, EX1034 for its analysis, and thus, his declaration is also inadmissible to the extent it relies on those exhibits for the reasons discussed above and below.

Further, Paragraphs 16-18, 22, 24, 27-29, 31-38, 40-48, 130, 137, 140, 142, and 146 are not cited in the Petition, and thus they are not relevant for this additional reason under **FRE 401**.

III. Declaration of Ron Bihovsky, Ph.D. (EX1034)

Patent Owner objects to the Declaration of Ron Bihovsky, Ph.D. (EX1033) for at least the following reasons:

Under **FRE 702** (expert testimony), Dr. Bihovsky's opinions are inadmissible because they are conclusory, do not sufficiently disclose underlying facts or data in support, and are unreliable. *See, e.g.*, ¶¶ 42-72, 74-76, 78-85. Additionally, under **FRE 401** (test for relevance), **FRE 402** (relevance), and **FRE 403** (probative value outweighed by prejudice, confusing of issues, wasting of time), his opinions are irrelevant, confusing, and of minimal probative value.

In addition, Dr. Bihovsky's declaration relies on EX1005, EX1013, EX1024–EX1026, EX1031–EX1032, EX1033 for its analysis, and thus, his declaration is also inadmissible to the extent it relies on those exhibits for the reasons discussed above.

Further, Paragraphs 11–13, 18, 20, 23–41, 73, and 86 are not cited in the Petition, and thus they are not relevant for this additional reason under **FRE 401**.

Respectfully submitted,

Dated: November 18, 2025

By: *Megan Raymond*

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CERTIFICATE OF SERVICE

The undersigned hereby certifies that a copy of Patent Owner Atossa's Objections to Evidence Under 37 C.F.R. §42.64 have been served in their entirety on November 18, 2025, by causing the aforementioned documents to be electronically mailed to the following attorneys of record for the Petitioner listed below.

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