

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

CSPC PHARMACEUTICAL GROUP LIMITED,
CSPC OUYI PHARMACEUTICAL CO., LTD.,
CONJUPRO BIOTHERAPEUTICS, INC., and APOTEX INC.,

Petitioners,

v.

IPSEN BIOPHARM LTD.,

Patent Owner.

Case No. IPR2025-00505¹
U.S. Patent No. 11,344,552

**PATENT OWNER'S OPPOSITION TO PETITIONERS'
MOTION TO EXCLUDE EVIDENCE**

¹ Apotex Inc., which filed a petition in IPR2025-01531, has been joined as a petitioner in this proceeding.

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Petitioners’ Motion to Exclude (Paper 43) targets four categories of Patent Owner’s exhibits: (1) Exhibit 2004, on grounds of hearsay, relevance, confusion, and prejudice; (2) Exhibits 2008 and 2009, on grounds of hearsay, relevance, prejudice, and lack of authentication; (3) Exhibit 2010, on grounds of hearsay and relevance; and (4) a broad set of exhibits—Exhibits 2002–2003, 2005–2011, 2013–2015, 2020–2035, 2037, 2039–2042, and 2047–2075—on the grounds that Patent Owner purportedly never cited or relied upon them in its substantive briefing. Each category of objections either mischaracterizes the evidentiary record, misapplies the governing legal standards, or both. The Motion should be denied in its entirety.

I. EXHIBIT 2004 SHOULD NOT BE EXCLUDED

Petitioners move to exclude Exhibit 2004 on grounds of hearsay, as well as alleged irrelevance, confusion, and prejudice. Paper 43 at 2. That is wrong on all counts, and Ex. 2004 should not be excluded.

A. Exhibit 2004 Is Not Hearsay

Petitioner contends that “Patent Owner relies on Exhibit 2004 to claim that only 85 mg/m² of oxaliplatin could be used when treating patients with FOLFIRINOX.” Paper 43 at 2. Not so. Exhibit 2004 is an article published in 2015 in the journal entitled “Cancer Medicine.” Contrary to Petitioner’s contention, Dr. Oberstein references Exhibit 2004 for his opinions that “clinicians

began employing modified dosing strategies for [FOLFIRINOX's] individual components to mitigate the toxicity concerns associated with this combination chemotherapy protocol and that “other references similarly define FOLFIRINOX as including 85 mg/m² oxaliplatin.” Ex. 2076, ¶¶ 58, 240.

Exhibit 2004 is not hearsay. Dr. Oberstein's reliance on this references is to provide an understanding of the state of the art for purposes of the claimed invention. Therefore, it is offered to establish what a POSA would have understood about FOLFIRINOX from the published literature at the time of the invention. Scientific literature offered for that purpose is not hearsay because it is not offered to prove the truth of its contents. *See Joy Techs., Inc. v. Manbeck*, 751 F. Supp. 225, 233 n.2 (D.D.C. 1990) (*aff'd*, 959 F.2d 226 (Fed. Cir. 1992)); *EMC Corp. v. Personal Web Techs., LLC*, IPR2013-00085, Paper 73 at 66 (PTAB May 15, 2014) (“[A] prior art document submitted as a ‘printed publication’ under 35 U.S.C. § 102(b) is offered simply as evidence of what it described, not for proving the truth of the matters addressed in the document.”); *see also Trend Micro Inc. v. Cupp Computing AS*, IPR2019-00764, Paper 34 at 10–11 (PTAB Aug. 25, 2020) (denying motion to exclude technical references offered to show POSA understanding and applying the same principle).

Even if Exhibit 2004 were hearsay—which it is not—Dr. Oberstein's reliance on it independently warrants its consideration. *See* Ex. 2076, ¶¶ 58, 240.

FRE 703 permits an expert to base opinions on otherwise inadmissible material if experts in the field would reasonably rely on that type of material—and published clinical literature on FOLFIRINOX is precisely that. *See* FRE 703; *Brose N. Am., Inc. v. Uusi, LLC*, IPR2014-00417, Paper 49 at 26 (PTAB July 20, 2015) (“Because an expert may rely upon evidence regardless of whether the evidence is admissible . . . we dismiss the Motion as moot.”); *see also* 37 C.F.R. § 42.62(a).

B. Exhibit 2004 Is Not Irrelevant and Will Not Cause Confusion and/or Prejudice

Petitioners’ purported relevance, confusion, and prejudice objections are equally meritless. Petitioners never explain how Ex. 2004—a published clinical article on FOLFIRINOX that is also part of the prosecution history of the patent at issue—is irrelevant to this proceeding. Their substantive dispute about what Exhibit 2004 discloses goes to weight, not admissibility, and is not a proper basis for exclusion. *See Corning Inc. v. DSM IP Assets B.V.*, IPR2013-00043, Paper 96 at 5 (PTAB May 1, 2014) (denying motion to exclude and noting that arguments about the weight of evidence are not grounds for exclusion); *Gnosis S.p.A. v. S. Alabama Med. Sci. Found.*, IPR2013-00118, Paper 64 at 43 (PTAB June 20, 2014). The FRE 403 objection fares no better: Petitioners invoke the labels “confusing” and “unduly prejudicial” but do not identify any prejudice, no specific issue that would be confused, and no attempt to show that any probative value is *substantially outweighed* by those dangers. If Petitioners genuinely believed that

Ex. 2004 was prejudicial or misleading, the remedy was a reply declaration by Dr. Ratain (Petitioners' expert) addressing it directly. They chose not to submit one. A motion to exclude is not a substitute for expert testimony a party chose not to provide.

II. EXHIBITS 2008 AND 2009 SHOULD NOT BE EXCLUDED

Petitioners move to exclude Exhibits 2008 and 2009 “as not being relevant to any issue on which trial has been instituted, for causing confusion and undue prejudice, for containing hearsay, and for lack of authentication.” Paper 43 at 3–5. Petitioner’s arguments fail.

A. Exhibits 2008 and 2009 Are Not Hearsay

Exhibits 2008 and 2009 are not hearsay. Exhibits 2008 is a publication from BIO, a trade association in the biotechnology space, that presents results of “the largest study of clinical drug development success rates to date.” Ex. 2008 at 3. Ex. 2009 is a review article published in the medical journal *Pancreas*. Both exhibits are offered to establish what was publicly understood about clinical development success rates in oncology—thus are being used to establish what a POSA would have understood regarding the state of the art. *See Joy Techs.* 751 F. Supp. at 233 n.2; *EMC Corp.*, IPR2013-00085, Paper 73 at 66; *see also Trend Micro*, IPR2019-00764, Paper 32 at 10–11. And even if Exhibits 2008 and 2009 were hearsay—which they are not—Dr. Oberstein’s reliance on them in forming

his expert opinions (*see, e.g.*, Ex. 2076, ¶ 297) provides an independent basis for their consideration—published clinical development data is precisely the type of literature that oncologists reasonably rely upon and consider. *See* FRE 703; *Brose*, IPR2014-00417, Paper 49 at 26.

B. Exhibits 2008 and 2009 Are Not Irrelevant and Will Not Cause Confusion and/or Prejudice

Petitioners argue that clinical trial success rates are irrelevant to obviousness because they relate to “FDA approval” rather than whether a drug combination is obvious. Paper 43 at 4. This argument misunderstands the legal framework. Reasonable expectation of success is a core element of the obviousness analysis in pharmaceutical cases. *See Pfizer, Inc. v. Apotex, Inc.*, 480 F.3d 1348, 1361 (Fed. Cir. 2007). Dr. Oberstein cited Exhibits 2008 and 2009 for the proposition that the likelihood of success in this field is particularly low, which is directly probative of whether a POSA would have had a reasonable expectation of success in arriving at the claimed invention. Ex. 2076, ¶ 297. Petitioners’ criticisms of these exhibits—that certain data was excluded from the analyses, or that liposomal delivery technologies might affect success rates (*see* Paper 43 at 4)—goes to weight, not admissibility, and the Board is well-equipped to assess those limitations without resorting to exclusion. *See Gnosis*, IPR2013-00118, Paper 64 at 43. If Petitioners believed the exhibits to be misleading or prejudicial, the remedy was responsive expert testimony. They submitted none.

C. Authentication Is Addressed in the Mumford Declaration

Petitioners claim that Patent Owner has not provided evidence that Exhibits 2008 and 2009 are authentic documents published prior to the priority date. Paper 43 at 4–5. Patent Owner has addressed the authenticity and background of these exhibits through the Declaration of June Mumford, which was filed along with Patent Owner’s response and provides the necessary authentication for these exhibits. *See* Ex. 2077 at 8-10; FRE 901(b)(1) (authentication may be accomplished by testimony of a witness with knowledge).

To the extent Petitioners argue that Patent Owner has failed to show that Exhibits 2008 and 2009 are prior art (see Paper 43 at 4 (“... available prior to the priority date.”)), that argument misconstrues the basis on which these exhibits are offered and therefore provides no basis for exclusion. Patent Owner offers these two exhibits as evidence of the state of the art—reflecting what a POSA would have understood about the general landscape of clinical drug development and the likelihood of success in oncology at the time of the invention. These exhibits are probative of what a skilled artisan in the relevant field would have known or expected as of the priority date: Exhibit 2008 documents industrywide clinical development success rates through 2015, and Exhibit 2009 similarly reports on the historical failure rate of phase III trials in metastatic pancreatic cancer specifically

through mid-2015—precisely the context in which the claimed invention was developed.

For the reasons set forth above, Exhibits 2008 and 2009 should not be excluded.

III. EXHIBIT 2010 SHOULD NOT BE EXCLUDED

Petitioners move to exclude Exhibit 2010 on grounds of hearsay, alleged irrelevance, confusion, and prejudice. Paper 43 at 5–6. These objections fail and are particularly untenable given that Exhibit 2010 was authored solely by Dr. Ratain.

A. Exhibit 2010 Is Not Hearsay

For the same reasons described above with respect to Exhibits 2004, 2008, and 2009, Exhibit 2010 is not hearsay. Dr. Oberstein relies on Ex. 2010 for his opinion that a POSA would not have relied on the early phase clinical data in Bayever for a reasonable expectation of success of the claimed invention. Ex. 2076, ¶ 299. Thus, Exhibit 2010 is offered to provide an understanding as to what a POSA would have understood from the art at the time of the invention—specifically, what a POSA would have understood about the predictive relationship between phase II oncology trial success and FDA approval at the time of the invention. *See Joy Techs.* 751 F. Supp. at 233 n.2; *EMC Corp.*, IPR2013-00085, Paper 73 at 66; *see also Trend Micro*, IPR2019-00764, Paper 32 at 10–11. And,

once again, even if it were hearsay, Dr. Oberstein’s reliance on it in forming his expert opinions provides an independent basis for its consideration—published phase II oncology trial literature is precisely the kind of material experts in this field reasonably rely upon, as confirmed by the fact that Dr. Ratain himself considered the subject important enough to research and publish. *See* FRE 703; *Brose*, IPR2014-00417, Paper 49 at 26.

B. Exhibit 2010 Is Not Irrelevant And Will Not Cause Confusion or Prejudice

It is difficult to credit the argument that Dr. Ratain’s own published article regarding clinical trials in oncology is irrelevant to what a POSA would have understood. Dr. Oberstein cited Exhibit 2010 for the proposition that phase II oncology trials have low predictive value for ultimate success—directly probative of whether a POSA would have had a reasonable expectation of success. Ex. 2076, ¶ 299. That is squarely relevant to the obviousness analysis. *See Pfizer, Inc. v. Apotex, Inc.*, 480 F.3d 1348, 1361 (Fed. Cir. 2007). Moreover, Dr. Ratain confirmed in his own deposition that a phase II single-arm trial “would not provide a POSA with an understanding as to whether or not this regimen would succeed in a Phase 3 trial” (Ex. 2073 at 106:6-107:12)—corroborating the core proposition of his own article.

Again, if Petitioners believed Ex. 2010 to be prejudicial or misleading, the remedy was responsive expert testimony. They submitted none.

IV. PETITIONERS' MOTION TO EXCLUDE "EXHIBITS NEVER RELIED UPON" SHOULD BE DENIED

Petitioners' final argument rests on a factually inaccurate premise: that the certain challenged exhibits "are not discussed or cited anywhere in Patent Owner's Response (Paper 21) or Patent Owner's Sur-Reply (Paper 38)," and that Dr. Oberstein's declaration "fails to cite" or "does not substantively discuss" them. Paper 43 at 6-7. Neither assertion withstands scrutiny. Petitioners have mischaracterized the evidentiary record, and their motion should be denied.

For one, many of the challenged exhibits are in fact cited directly and are substantively discussed in Dr. Oberstein's declaration. In turn, Patent Owner's Response and Sur-Rely cite to Dr. Oberstein's discussion and/or reliance on those exhibits. The following table sets forth the exhibits challenged in Petitioners' Section IV and where in the record it was addressed:

Exhibit #	Ex. 2076 (Oberstein Declaration) Citation	Paper 21 (Patent Owner Response) Cite	Paper 38 (Sur-Reply) Cite
2006	¶ 49	p. 34	
2007	¶¶ 240, 299	pp. 27, 29, 40, 48	p. 16
2008	¶ 297	p. 48	
2009	¶ 297	p. 48	
2010	¶ 299	p. 48	
2014	¶ 48	p. 34	
2015	¶ 51	p. 4, 34	
2023	¶ 292	pp. 47-50	pp. 18-19
2026	¶¶ 292-93	pp. 47-50	pp. 18-19
2030	¶¶ 66, 306	pp. 6, 52	pp. 18, 20-21
2033	¶¶ 67, 308-09	pp. 6, 52	pp. 18, 20-21
2034	¶¶ 67, 309	pp. 6, 52	pp. 18, 20-21

2039	¶ 63	pp. 5, 33-34, 40	
2040	¶ 68	p. 6	pp. 10, 20
2041	¶ 200	p. 20	
2042	¶ 200	p. 20	
2047	¶¶ 56-63, 264-266, Appx. B	pp. 4-5, 33-34, 40	pp. 11-12
2048	¶¶ 56-63, 264-266, Appx. B	pp. 4-5, 33-34, 40	pp. 11-12
2049	¶¶ 56-63, 264-266, Appx. B	pp. 4-5, 33-34, 40	pp. 11-12
2050	¶¶ 56-63, 261, 264-266, Appx. B	pp. 4-5, 31-34, 40	pp. 11-12
2051	¶¶ 56-63, 264-266, Appx. B	pp. 4-5, 33-34, 40	pp. 11-12
2052	¶¶ 56-63, 261, 264-266, Appx. B	pp. 4-5, 31-34, 40	pp. 11-12
2053	¶¶ 56-63, 264-266, Appx. B	pp. 4-5, 33-34, 40	pp. 11-12
2054	¶¶ 56-63, 261, 264-266, Appx. B	pp. 4-5, 31-34, 40	pp. 11-12
2055	¶¶ 56-63, 264-266, Appx. B	pp. 4-5, 33-34, 40	pp. 11-12
2056	¶¶ 56-63, 264-266, Appx. B	pp. 4-5, 33-34, 40	pp. 11-12
2057	¶¶ 56-63, 264-266, Appx. B	pp. 4-5, 33-34, 40	pp. 11-12
2058	¶¶ 56-63, 264-266, Appx. B	pp. 4-5, 33-34, 40	pp. 11-12
2059	¶¶ 56-63, 264-266, Appx. B	pp. 4-5, 33-34, 40	pp. 11-12
2060	¶¶ 56-63, 264-266, Appx. B	pp. 4-5, 33-34, 40	pp. 11-12
2061	¶¶ 56-63, 264-266, Appx. B	pp. 4-5, 33-34, 40	pp. 11-12
2062	¶¶ 56-63, 261, 264-266, Appx. B	pp. 4-5, 31-34, 40	pp. 11-12
2063	¶¶ 56-63, 264-266, Appx. B	pp. 4-5, 33-34, 40	pp. 11-12
2064	¶¶ 56-63, 261, 264-266, Appx. B	pp. 4-5, 31-34, 40	pp. 11-12
2065	¶¶ 56-63, 264-266, Appx. B	pp. 4-5, 33-34, 40	pp. 11-12
2066	¶¶ 56-63, 264-266, Appx. B	pp. 4-5, 33-34, 40	pp. 11-12
2067	¶¶ 56-63, 264-266, Appx. B	pp. 4-5, 33-34, 40	pp. 11-12
2068	¶¶ 56-63, 264-266, Appx. B	pp. 4-5, 33-34, 40	pp. 11-12
2069	¶¶ 56-63, 264-266, Appx. B	pp. 4-5, 33-34, 40	pp. 11-12
2070	¶¶ 56-63, 264-266, Appx. B	pp. 4-5, 33-34, 40	pp. 11-12
2071	¶¶ 56-63, 261, 264-266, Appx. B	pp. 4-5, 31-34, 40	pp. 11-12
2072	¶ 53	pp. 4, 33-34	
2074	¶ 278	p. 37	p. 9
2075	¶¶ 64, 67	pp. 5-6	p. 20

As the table above makes clear, Petitioners' characterization of the record is inaccurate.

Petitioners’ argument fares no better with respect to the remaining exhibits. Although certain of the remaining exhibits may not appear in Dr. Oberstein’s declaration or the post-institution briefs, they are part of the official record of this proceeding—having been cited and relied upon by Patent Owner in its Patent Owner Preliminary Response (Paper 9) and/or its motion for discretionary denial of institution (Paper 8), both of which are official papers filed with the USPTO. *See Aylus Networks, Inc. v. Apple Inc.*, 856 F.3d 1353, 1361 (Fed. Cir. 2017) (“[A] patent owner’s optional preliminary response and its post-institution response are both official papers filed with the PTO and made available to the public.”). Pre-institution papers are part of the proceeding record, and Petitioners had full notice of every exhibit cited therein. CSPC cannot credibly claim that exhibits Patent Owner cited in official pre-institution papers were “never relied upon”—that characterization ignores that those exhibits were affirmatively introduced into the record of this very proceeding at the pre-institution stage and were available to Petitioners throughout.

Moreover, the argument that exhibits are “not discussed or cited anywhere in Patent Owner’s Response (Paper 21) or Patent Owner’s Sur-Reply (Paper 38)” is not a ground for exclusion under the Federal Rules of Evidence. A motion to exclude must identify why evidence is not admissible. 37 C.F.R. § 42.64(c). Patent Owner is aware of no PTAB or Federal Circuit decision that has ever

sustained a motion to exclude on the theory that an exhibit was insufficiently cited in post-institution briefing, and Petitioners cite none. For the exhibits not addressed in the table above, the following table sets forth the pre-institution paper(s) in which each exhibit was cited²:

Exhibit Number	Patent Owner Pleading Citation
2001	Paper 10 (Request for Discretionary Denial), pp. 9, 11
2002	Paper 10 (Request for Discretionary Denial), pp. 11, 17, 18
2003	Paper 10 (Request for Discretionary Denial), pp. 11, 18
2005	Paper 10 (Request for Discretionary Denial), p. 27
2011	Paper 10 (Request for Discretionary Denial), p. 35
2012	Paper 10 (Request for Discretionary Denial), p. 35
2013	Paper 10 (Request for Discretionary Denial), p. 35
2016	Paper 9 (Patent Owner Preliminary Response), p. 7
2020	Paper 9 (Patent Owner Preliminary Response), p. 16
2021	Paper 9 (Patent Owner Preliminary Response), p. 16
2022	Paper 9 (Patent Owner Preliminary Response), pp. 19-20
2024	Paper 9 (Patent Owner Preliminary Response), p. 39
2025	Paper 9 (Patent Owner Preliminary Response), p. 39
2027	Paper 9 (Patent Owner Preliminary Response), p. 39
2028	Paper 9 (Patent Owner Preliminary Response), p. 40
2035	Paper 9 (Patent Owner Preliminary Response), p. 51

² Unlike the pre-institution exhibits discussed below, Exhibit 2037 was filed by Patent Owner with its Patent Owner Response and is therefore a post-institution trial exhibit subject to 37 C.F.R. § 42.64(b)(1), which requires a party to file objections to trial evidence within five business days of service. Having failed to timely preserve any objection to Exhibit 2037, Petitioners have waived the right to move for its exclusion. *See* 37 C.F.R. § 42.64(c) (“A motion to exclude evidence must identify the objections in the record and must explain the objections.”).

As stated previously, even setting aside Petitioners' mischaracterization of Patent Owner's reliance on these exhibits, Petitioner has failed to provide any explanation or legal support as to why each of these exhibits is not admissible. Petitioner's grouping of over 61 exhibits does not provide Patent Owner with notice of Petitioner's basis for each exhibit. At most, Petitioner argues without support that "[i]f Patent Owner could not identify a use for these exhibits in their own papers, the exhibits have no tendency to make any fact of consequence more or less probable, and they are therefore irrelevant. Therefore, they are irrelevant to any issues in this proceeding, would cause confusion, and create undue prejudice and should be excluded." Paper 43 at 6. However, as demonstrated by the above tables, that is not true.

Petitioner contends that "[b]ecause Patent Owner never explained the significance of these exhibits, Petitioner was unable to respond to whatever arguments Patent Owner may have intended to advance" and "[a]llowing such evidence to remain in the record would be fundamentally unfair and would undermine the integrity of the adversarial process." Paper 43 at 7. Again, Petitioner has failed to provide any specificity with respect to each exhibit it seeks to exclude. In any event, as indicated above, the vast majority of these exhibits were relied on by Patent Owner and/or Dr. Oberstein. Petitioner had ample

opportunity to review and respond to those reference and have its own expert consider and respond to them. They chose not to do that.

V. CONCLUSION

For the foregoing reasons, Patent Owner respectfully requests that the Board deny Petitioners' Motion to Exclude in its entirety.

Date: May 4, 2026

By: James M. Glass
James M. Glass (Reg. No. 46,729)
QUINN EMANUEL URQUHART &
SULLIVAN LLP
295 5th Ave., 9th Floor
New York, NY 10016
Email: jimglass@quinnemanuel.com
Phone: 212-849-7142
Fax: 212-849-7100

*Counsel for Patent Owner
Ipsen Biopharm Ltd.*

CERTIFICATE OF LENGTH (37 C.F.R. § 42.24(D))

The undersigned hereby certifies that, according to the word-processing system used to prepare the foregoing document, this document is 14 pages and thus complies with the applicable word limit.

Date: May 4, 2026

By: /s/ James Glass

James M. Glass (Reg. No. 46,729)
QUINN EMANUEL URQUHART &
SULLIVAN LLP
295 5th Ave.
New York, New York 10016
Email: jimglass@quinnemanuel.com
Phone: 212-849-7142
Fax: 212-849-7100

Counsel for Patent Owner

CERTIFICATE OF SERVICE (37 C.F.R. §§ 42.6(E), 42.105(A))

The undersigned hereby certifies that on May 4, 2026 copies of the foregoing document were served upon the following parties via electronic mail, with a copy to ipdocket@foxrothschild.com (referencing Attorney Docket No. 340008.00021):

Lead Counsel:

Luke Toft (Reg. No. 75,311)
ltoft@foxrothschild.com
Fox Rothschild LLP
33 South 6th Street, Suite 3600
Minneapolis, MN 55402
Tel: (612) 607-7336
Fax: (612) 607-7100

Backup Counsel:

Joe Chen (Reg. No. 70,066)
joechen@foxrothschild.com
Fox Rothschild LLP
212 Carnegie Center, Suite 400
Princeton, NJ 08540
Tel: (609) 844-3024
Fax: (609) 896-1469

Howard S. Suh (pro hac vice to be filed)
hsuh@foxrothschild.com
Fox Rothschild LLP
101 Park Avenue, 17th Floor
New York, NY 10178
Tel: (212) 878-7914
Fax: (212) 692-0940

Date: May 4, 2026

By: James M. Glass
James M. Glass (Reg. No. 46,729)
QUINN EMANUEL URQUHART &
SULLIVAN LLP
295 5th Ave., 9th Floor
New York, NY 10016
Email: jimglass@quinnemanuel.com
Phone: 212-849-7142
Fax: 212-849-7100

*Counsel for Patent Owner
Ipsen Biopharm Ltd.*