

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

APOTEX, INC.,
Petitioner,

v.

IPSEN BIOPHARM LTD.,
Patent Owner.

Case No. IPR2025-01531
U.S. Patent No. 11,344,552

**PATENT OWNER'S REQUEST FOR
DISCRETIONARY DENIAL OF INSTITUTION**

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Ex. 2010	CSPC Pharmaceutical Group Limited, Voluntary Announcement, Exclusive License Agreement with Cipla USA, Inc. for Irinotecan Liposome Injection, May 15, 2025 (“CSPC Press Release”)
Ex. 2011	Robert De W. Marsh et al., Pancreatic cancer and FOLFIRINOX: a new era and new questions, <i>Cancer Med.</i> 2015 Jun;4(6):853-63 (2015) (“Marsh”)
Ex. 2012	Somala Mohammed et al., <i>Pancreatic cancer: Advances in treatment</i> , 20(28) <i>World J. Gastroenterol</i> 9354 (2014) (“Mohammed”)
Ex. 2013	Nebojsa Skorupan et al., First-Line Treatment of Metastatic Pancreatic Ductal Adenocarcinoma: Did 2024 Offer New Insights?, <i>ASCO Daily News</i> , available at

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Ex. 2014	IPR2025-00505, Paper 12, Petitioner’s Updated Mandatory Notices (July 18, 2025)

I. INTRODUCTION

Pursuant to the Director’s March 26, 2025 Memorandum Regarding Interim Processes for PTAB Workload Management (“March 26, 2025 Memorandum”), Patent Owner Ipsen Biopharm Ltd. (“Ipsen”) files this Request for Discretionary Denial of the petition filed by Apotex, Inc. (“Apotex”). A Notice of Filing Date Accorded was entered on September 12, 2025. Paper 4.

The Director should exercise discretion and deny Apotex’s alleged “silent understudy” petition for *inter partes* review (IPR) of U.S. Patent No. 11,344,552 (“the ’552 patent”). Apotex purports to act as a “silent understudy” to an ongoing IPR initiated by CSPC Pharmaceutical Group Limited, CSPC Ouyi Pharmaceutical Co., Ltd., and Conjupro Biotherapeutics, Inc. (collectively, “CSPC”) on the ’552 patent (“the CSPC IPR”), but its actions indicate otherwise. Notably, Apotex has not withdrawn its expert’s declaration, despite Apotex’s stated conditions for withdrawal having been met. At the same time, Apotex’s dilatory tactic—seeking to join the CSPC petition on the last day for Ipsen to have effectively raised schedule modification in the CSPC IPR—deprived Ipsen of any meaningful opportunity to modify deadlines on the basis of Apotex’s late-filed petition. Apotex should not be rewarded for such gamesmanship.

To the extent that Apotex is truly a “silent understudy” and limited to CSPC’s petition, Apotex relies on a petition that suffers from fatal deficiencies and

substantive weaknesses. In particular, CSPC’s petition failed to identify—as required by statute—all real parties in interest. That CSPC’s omission does not implicate a time-bar or estoppel issue here is of no moment under PTAB’s recent de-designation of *SharkNinja v. iRobot Corp.*, IPR2020-00734, Paper 11 at 19-20 (PTAB Oct. 6, 2020) as precedential. Separately, Apotex’s obviousness arguments rely upon an uncertified translation that fails to meet statutory requirements for evidence before the PTAB.

And if Apotex is truly a “silent understudy,” then its substantive arguments are even weaker than those of CSPC. Significantly, the Director has already found that CSPC (and Apotex) present the same or substantially the same arguments and/or art that the Patent Office has considered and decided in Ipsen’s favor. Apotex’s arguments as to why the Patent Office materially erred in this respect are limited to those presented in CSPC’s petition, which are unavailing for reasons discussed herein.

Ipsen respectfully requests denial of Apotex’s petition.

II. PROCEDURAL HISTORY

On January 17, 2025, CSPC filed a petition for *inter partes* review of the ’552 patent. Ex. 2001. CSPC’s petition alleges obviousness of the ’552 patent on the basis of the same lead references, Conroy and Bayever, that were extensively discussed and overcome during prosecution of the ’552 patent. *See* Ex. 2002 at 9-

10. Each of CSPC's asserted grounds of obviousness additionally relied on an uncertified translation of a French-language document, i.e., the Conroy Protocol (Ex. 1004). Ex. 2001 at 39-63.

Pursuant to the March 26, 2025 Memorandum, Ipsen requested discretionary denial of CSPC's petition, in part on the grounds that CSPC's petition presents the same or substantially the same arguments that were overcome during prosecution of the '552 patent, and that CSPC identifies no material error in the Patent Office's determination of patentability. *See* Ex. 2002 at 8-29. The Director denied Ipsen's request for discretionary denial on July 16, 2025. Ex. 2003. In so doing, the Director did not dispute that CSPC's petition presents the same or substantially the same arguments as those overcome during prosecution of the '552 patent. *See id.* at 3. The Director found only that CSPC "provides persuasive evidence that the Office erred in a manner material to the patentability of the challenged claims by not considering or overlooking specific teachings in Conroy's appendix and Conroy's associated protocol, both identified in Conroy itself, that disclose critical limitations in the claims." *Id.*

On August 14, 2025, the Board instituted CSPC's petition. Ex. 2004. The Scheduling Order issued the same day. Ex. 2005. The Scheduling Order provides, in relevant part, that "[t]he parties are directed to contact the Board within a month of this Order if there is a need to discuss proposed changes to this Scheduling

Order or proposed motions that have not been authorized in this Order or other prior Order or Notice.” *Id.* at 1.

On Friday, September 12, 2025, the last business day before the parties’ deadline to request changes to the CSPC IPR’s Scheduling Order, Apotex filed a petition for IPR of the ’552 patent and request for joinder with the CSPC IPR. Papers 1, 3. In its petition, Apotex represents that it “commits to serving as a silent understudy to CSPC [sic] and will abide by all existing deadlines and procedures in IPR2025-00505.” Paper 1 at 68. Along with its petition, Apotex filed an expert declaration from an entirely new expert—Dr. Robert Dreicer. *See* Ex. 1501. Dr. Dreicer’s declaration purports to adopt the opinions of CSPC’s expert, Dr. Mark J. Ratain, but also reserves rights to supplement his own opinion(s). *Id.* at ¶¶ 2, 29, 32-33, 257.

III. BACKGROUND

Pancreatic cancer is one of the leading causes of cancer-related deaths in the U.S. and, due to lack of early clinical symptoms, is usually diagnosed at a late or otherwise advanced stage. Metastatic pancreatic cancer is the most advanced stage of the disease, and it is notoriously difficult to treat, with a grim prognosis and limited therapeutic options. In patients diagnosed with metastatic pancreatic cancer, the median overall survival is less than one year, and the five-year survival rate is approximately 2%.

Ipsen's Onivyde[®] (irinotecan liposome injection) is a treatment for metastatic pancreatic cancer. The FDA recently approved Onivyde[®] as a first-line treatment for adult patients with metastatic pancreatic adenocarcinoma. Onivyde[®]'s first-line treatment regimen, referred to as "NALIRIFOX," is a combination therapy consisting of four different chemotherapy drugs, administered in specific doses and frequency.

The '552 patent recites methods of treatment in accordance with Onivyde[®]'s first-line treatment regimen, NALIRIFOX. Claim 1 is representative:

1. A method of treating metastatic adenocarcinoma of the pancreas in a human patient who has not previously received an antineoplastic agent to treat the metastatic adenocarcinoma of the pancreas, the method comprising administering an antineoplastic therapy to the patient once every two weeks, the antineoplastic therapy consisting of:

- a. 60 mg/m² of liposomal irinotecan,
- b. 60 mg/m² oxaliplatin,
- c. 200 mg/m² of the (l)-form of leucovorin or 400 mg/m² of the (l+d) racemic form of leucovorin, and
- d. 2,400 mg/m² 5-fluorouracil;

to treat the metastatic adenocarcinoma of the pancreas in the human patient.

Ex. 1001 ('552 patent), claim 1. Claim 12, the other independent claim, recites the same combination therapy for a patient "who has not previously received gemcitabine." *Id.* at claim 12. Dependent claims 2-11 and 13-15 recite specific

sequences for administration of the claimed combination therapy and other formulation details. *Id.* at claims 2-11, 13-15.

The '552 patent issued on May 31, 2022, following the Patent Office's determination of patentability over, *inter alia*, Conroy (Ex. 1003) and Bayever (Ex. 1006). Each of these references discloses a different combination therapy for the treatment of metastatic pancreatic cancer, and the therapies disclosed in each differ from that of the '552 patent's claimed methods as summarized below:

Conroy ("FOLFIRINOX")	Bayever	'552 Patent ("NALIRIFOX")
180 mg/m ² non-liposomal irinotecan	60 or 80 mg/m ² liposomal irinotecan	60 mg/m ² liposomal irinotecan
85 mg/m ² oxaliplatin		60 mg/m ² oxaliplatin
400 mg/m ² bolus, followed by 2,400 mg/m ² infusion of 5-fluorouracil	2,400 mg/m ² infusion of 5-fluorouracil	2,400 mg/m ² of 5- fluorouracil
400 mg/m ² leucovorin	200 mg/m ² (<i>l</i> -form) or 400 mg/m ² (<i>l</i> + <i>d</i> racemic form)	200 mg/m ² of <i>l</i> -form of leucovorin or 400 mg/m ² of racemic (<i>l</i> + <i>d</i>) form of leucovorin

See Ex. 1003 (Conroy) at 3; Ex. 1006 (Bayever) at 32-34 (Arm C); Ex. 1001 ('552 patent) at claims 1, 12.

Conroy's FOLFIRINOX regimen differs from the '552 patent's combination therapy in several respects. For example, the FOLFIRINOX regimen includes non-liposomal irinotecan (also referred to as "free irinotecan" or "irinotecan"), in a

different dosage, from the '552 patent regimen's liposomal irinotecan (also referred to as "MM-398," "PEP02," or "nal-IRI"). *See* Ex. 1003 (Conroy) at 3. The FOLFIRINOX regimen also includes a higher dosage of both oxaliplatin and 5-fluorouracil (also referred to as "fluorouracil," "FU," or "5-FU"). *Id.*

Bayever's regimen likewise differs from the '552 patent's combination therapy. Unlike the '552 patent's claimed methods, the Bayever regimen does not include oxaliplatin at all, in any dose. *See* Ex. 1006 (Bayever) at 32-34 (Arm C). In addition, the regimen disclosed in Bayever was administered as second-line therapy, to patients who had progressed on prior gemcitabine therapy, not as a first-line treatment. Ex. 1006 (Bayever) at 26.

The Patent Office found that the '552 patent's NALIRIFOX regimen is non-obvious over the combination of Conroy (Ex. 1003) and Bayever (Ex. 1006). Conroy and Bayever were the basis for a number of obviousness rejections throughout prosecution. Ex. 1084 at 190-201 (Mar. 6, 2018 Rejection); *id.* at 314-327 (Sept. 11, 2018 Rejection); Ex. 1088 at 57-69 (July 8, 2019 Rejection); Ex. 1097 at 188-203 (Feb. 27, 2020 Rejection); Ex. 1119 at 9-22 (Aug. 26, 2021 Rejection). In each rejection, the Patent Office submitted that—notwithstanding the differences between and among them—a POSA would have nonetheless been motivated to combine the disclosures of Conroy and Bayever in order to arrive at the '552 patent's claimed combination therapy with a reasonable expectation of

success. *See, e.g.*, Ex. 1084 (Mar. 6, 2018 Rejection) at 193-94. The '552 patent applicant ultimately overcame these rejections, and the '552 patent issued on May 31, 2022. *See* Ex. 1123 at 401-402 (Notice of Allowability); Ex. 1123 at 461-465 (Corrected Notice of Allowability); Ex. 1001 at 1.

IV. THE DIRECTOR SHOULD EXERCISE DISCRETIONARY DENIAL

A. Apotex's Gamesmanship Prejudices Ipsen and, if Permitted, Incurs a Waste of Party and Board Resources

Apotex filed its petition and motion for joinder to the CSPC IPR on September 12, 2025, which was the last business day prior to the parties' deadline to seek modification of the schedule in the CSPC IPR. *See* Papers 1, 3. Due to Apotex's timing, Ipsen had no meaningful opportunity to request changes to the CSPC IPR's Scheduling Order in view of Apotex's petition and request for joinder. As such, Ipsen is prejudiced under the CSPC schedule insofar as Apotex will rely on testimony of a new expert and/or present new argument(s) and/or evidence.

Apotex claims that its "petition is substantively identical to the petition filed by [CSPC] in IPR2025-00505," and that "Apotex's expert, Dr. Dreicer, has adopted *in toto* the opinions set forth in the declaration submitted by CSPC's expert, Dr. Mark Ratain." Paper 1 at 1. Apotex further purports to "commit[]" to serving as a silent understudy to CSPC and will abide by all existing deadlines and procedures in IPR2025-00505." *Id.* at 68; *see also* Ex. 1501 at 1 ("I have reviewed and considered Dr. Ratain's declaration. I agree with Dr. Ratain's opinions set

forth in his declaration, so I have adopted them.”) (citing Ex. 2006 (IPR2025-00505 Ex. 1002)).

Although Apotex purports to operate as a “silent understudy” to the CSPC IPR, its actions indicate otherwise. Apotex has not withdrawn the declaration of its expert, Dr. Dreicer, despite conditions having been met. Specifically, Apotex has represented that it “will withdraw [Dr. Dreicer’s] declaration if the deposition transcript of CSPC’s expert, Dr. Ratain, becomes available.” Paper 21 at 1. The deposition transcript, filed as Exhibit 2073 to Ipsen’s Patent Owner Response on November 10, 2025, is now available. *See* Ex. 2007. Apotex has yet to withdraw Dr. Dreicer’s declaration. Unless Apotex withdraws its expert’s declaration and commits to relying entirely on the testimony of CSPC’s expert, Dr. Ratain, then requiring Ipsen to depose Apotex’s expert incurs a waste of time and resources.

If Apotex or its expert present new opinion(s), evidence, and/or argument(s), then Ipsen is prejudiced in responding to them under the CSPC IPR deadlines. As discussed, Apotex’s timing effectively precluded Ipsen from seeking modification of the CSPC IPR deadlines. And in the CSPC IPR, Ipsen has already filed its Patent Owner Response. *See* Ex. 2008. If joined to the CSPC IPR, Ipsen will not have had a chance to address new argument(s) and/or evidence presented by Apotex or its expert in its Patent Owner Response.

By seeking to join CSPC's proceeding, Apotex has created a parallel set of deadlines under which it may attempt to introduce new argument(s) and/or evidence. Apotex will be due to respond to Ipsen's request for discretionary denial, and Ipsen will be due to file its Patent Owner Preliminary Response, all before CSPC files its response to Ipsen's Patent Owner Response in the CSPC proceeding. Ex. 2005 at 12 (Petitioner's reply to Patent Owner's response to petition is due February 2, 2026). And Apotex's recent representations suggest that its expert will, in fact, offer new opinions. Paper 8 at 3 (suggesting that Dr. Dreicer "may not agree with" the future opinions of CSPC's expert) and 4 (suggesting that Dr. Dreicer may offer opinions in response to a request for discretionary denial). Apotex's claim to operate as a "silent understudy" is disingenuous, and the Director should reject Apotex's attempted gamesmanship.

B. The Petition on Which Apotex Purports to Rely Is Fatally Deficient

To the extent that Apotex is truly a "silent understudy" of CSPC and relies solely on CSPC's petition, then Apotex is bound by its fatal deficiencies. CSPC's petition and Apotex's "silent understudy" petition fail to comply with express statutory requirements.

1. CSPC's Petition Fails to Identify All Real Parties in Interest

A petition for *inter partes* review may be considered "only if" it "identifies all real parties in interest." 35 U.S.C. § 312(a)(2); *see also* 37 C.F.R. § 42.8(b)(1)

(mandatory notices include identification of “each real party-in-interest for the party”). Determination of “whether a non-party is a ‘real party in interest’ demands a flexible approach that takes into account both equitable and practical considerations, with an eye toward determining whether the non-party is a clear beneficiary that has a pre-existing, established relationship with the petitioner.” *Applications in Internet Time, LLC v. RPX Corp.*, 897 F.3d 1336, 1351 (Fed. Cir. 2018); *see also* PTAB Consolidated Trial Practice Guide, 14 (Nov. 2019) (“[A]t a general level, the ‘real party-in-interest’ is the party that desires review of the patent.”); *id.* at 17-18 (stating that relevant factors include, *inter alia*, a non-party’s relationship with the petitioner and relationship to the petition itself).

CSPC’s petition failed to identify all real parties-in-interest, because it omitted Cipla USA, Inc. (“Cipla”). CSPC’s petition identifies three entities as real parties-in-interest: (1) CSPC Pharmaceutical Group Limited; (2) CSPC Ouyi Pharmaceutical Co., Ltd.; and (3) Conjupro Biotherapeutics, Inc. Ex. 2001 at 4. These three entities cooperated in the preparation and/or submission of NDA No. 218923, which seeks FDA approval to distribute, or have distributed an irinotecan liposome injection product (the “Proposed Conjupro Product”) in the United States. Ex. 2009 at ¶¶ 15, 19, 20. Cipla also has an interest in the commercialization of the Proposed Conjupro Product by virtue of an exclusive

license agreement with CSPC. *See* Ex. 2010 (CSPC Press Release).¹ This relationship renders Cipla a real party-in-interest for purposes of CSPC’s petition, and CSPC’s omission renders its petition fatally deficient.

In its institution decision, the Board declined to address whether Cipla is an unnamed real party in interest, on the basis of *SharkNinja*, Paper 11 at 19-20 and that CSPC’s failure to identify Cipla did not implicate time-bar or estoppel issues. *See* Ex. 2004 at 5. But since that determination, the PTAB has de-designated *SharkNinja* from precedential status, and it is no longer binding.² That CSPC’s petition omits Cipla as a real party in interest is a statutory violation that renders it deficient. Apotex should not be permitted to rely on CSPC’s fatally flawed petition.

2. Apotex’s Petition Relies on an Uncertified Translation of the Conroy Protocol

All of Apotex’s (as “silent understudy” to CSPC) asserted grounds rely on the Conroy Protocol (Ex. 1004), which is written in a language other than English and for which CSPC has provided no certified translation. Apotex’s failure to provide a certified translation of the Conroy Protocol violates 37 C.F.R. § 42.63,

¹ Subsequent to filing its petition, CSPC identified Cipla in an updated mandatory notice pursuant to 37 C.F.R. § 42.8(b). *See* Ex. 2014.

² PTAB de-designates *SharkNinja Operating LLC v. iRobot Corp.*, available at <https://www.uspto.gov/subscription-center/2025/ptab-de-designates-decision> (last visited November 12, 2025).

which governs the form of evidence in *inter partes* review proceedings. As set forth below, denial of Apotex's petition is justified on this ground alone.

Each of Apotex's asserted grounds of obviousness relies on the Conroy Protocol (Ex. 1004). *See* Paper 1 at 39-63. Specifically, Apotex and its expert rely on the Conroy Protocol as disclosing a FOLFIRINOX regimen with a reduced dose of oxaliplatin, specifically at 60 mg/m². *See, e.g.*, Paper 1 at 33; Ex. 1501 at ¶¶ 104-106. The Conroy Protocol is a French language document, but Apotex did not file any certification attesting to the accuracy of the translation. The source document, the untranslated version, cannot be considered because Apotex has not even submitted it, it is in a language other than English, and the purported translation provided by Apotex is unaccompanied by a certificate of translation. *See* 37 C.F.R. § 42.63(b); Ex. 1004.

The Board has denied institution where, as here, each asserted ground of invalidity relies on a reference that fails to comply with 37 C.F.R. § 42.63(b). In *Zhongshan v. Nidec*, the Board denied institution where the petitioner failed to submit the required affidavit under § 42.63(b). *Zhongshan Broad Ocean Motor Co., Ltd. v. Nidec Motor Corp.*, IPR2014-01123, Paper 20 (PTAB Jan. 21, 2015). The Board held that "the filed copies of [foreign references] are defective because Petitioners failed to comply with 37 C.F.R. § 42.63(b) by omitting affidavits attesting to the accuracy of their translations. Accordingly, we do not consider

these references, and as a result, we deny the Petition with respect to all asserted grounds because all such grounds rely on at least one of [the foreign references].” *Id.* at 7-8; *see also Shenzhen Aurora Tech. Co., Ltd. v. Putco, Inc.*, IPR2020-00670, Paper 10 at 5-6 (PTAB Aug. 27, 2020) (denying institution where the petitioner failed to submit the required affidavit under § 42.63(b) for two foreign prior-art references); *Shenzhen Kean Silicone Prod. Co., Ltd. v. PKOH NYC, LLC*, IPR2017-01327, Paper 14 at 42 (PTAB Dec. 6, 2017) (declining to institute on grounds based on foreign prior-art reference where petitioner failed to comply with § 42.63(b)). Apotex should not be permitted the benefit of CSPC’s fatally deficient (or at least statutorily non-compliant) petition.

C. The Director Should Exercise Denial Under 35 U.S.C. § 325(d)

Denial may be appropriate where “the same or substantially the same prior art or arguments previously were presented to the Office.” 35 U.S.C. § 325(d). This entails a two-part analysis that considers: (1) whether the same or substantially the same art or arguments were previously presented to the Patent Office; and (2) if either part of (1) is satisfied, whether petitioner has demonstrated that the Patent Office erred in a manner material to patentability. *Advanced Bionics, LLC v. MED-EL Elektromedizinische Geräte GmbH*, IPR2019-01469, Paper 6 at 7-8 (PTAB Feb. 13, 2020) (precedential).

Whether denial under 35 U.S.C. § 325(d) is warranted entails a fact-specific inquiry that takes into account:

- (a) the similarities and material differences between the asserted art and the prior art involved during examination;
- (b) the cumulative nature of the asserted art and the prior art evaluated during examination;
- (c) the extent to which the asserted art was evaluated during examination, including whether the prior art was the basis for rejection;
- (d) the extent of the overlap between the arguments made during examination and the manner in which Petitioner relies on the prior art or Patent Owner distinguishes the prior art;
- (e) whether Petitioner has pointed out sufficiently how the Examiner erred in its evaluation of the asserted prior art; and
- (f) the extent to which additional evidence and facts presented in the Petition warrant reconsideration of the prior art or arguments.

Becton, Dickinson & Co. v. B. Braun Melsungen AG, IPR2017-01586, Paper 8 at 17-18 (PTAB Dec. 15, 2017) (precedential as to § III.C.5, first paragraph); *see also* Patent Trial and Appeal Board Consolidated Trial Practice Guide, 62-63 (Nov. 2019).

1. Apotex Presents “the Same or Substantially the Same Arguments” Already Considered by the Patent Office

As set forth in Ipsen’s request for discretionary denial of the CSPC petition, CSPC presents the same arguments, based on the same lead references that the Patent Office has already considered and decided in Ipsen’s favor. *See* Ex. 2002 at

8-18. Apotex and its expert purport to rely on the same arguments. Paper 1 at 1; Ex. 1501 at ¶ 2.

The Director has already found by implication that CSPC (and Apotex, as “silent understudy”) presents the “the same or substantially the same art or arguments” that were previously presented to the Patent Office. In declining Ipsen’s request for discretionary denial of CSPC’s petition, the Director did not dispute that CSPC’s petition presents the same or substantially the same arguments that the Patent Office has already considered and decided in Ipsen’s favor. Ex. 2003 at 3. Rather, the Director bypassed the first step of the *Advanced Bionics* analysis, impliedly finding that first step met by resting its decision on the second step, i.e., whether there has been a showing that the Patent Office erred in a manner material to patentability. *See id.*; *Advanced Bionics, LLC*, IPR2019-01469, Paper 6 at 7-8. The Director found that CSPC “provide[d] persuasive evidence that the Office erred in a manner material to the patentability of the challenged claims by not considering or overlooking specific teachings in Conroy’s appendix and Conroy’s associated protocol, both identified in Conroy itself, that disclose critical limitations in the claims.” Ex. 2003 at 3. Thus, there can be no dispute that Apotex (as “silent understudy” to CSPC) relies on the same or substantially the same art or arguments as already presented and overcome before the Patent Office.

2. Apotex Identifies No Material Error in the Patent Office’s Determination of Patentability

The next step is to determine “whether the petitioner has demonstrated that the Office erred in a manner material to the patentability of the challenged claims.” *Advanced Bionics*, IPR2019-01469, Paper 6 at 8. “If reasonable minds can disagree regarding the purported treatment of the art or arguments, it cannot be said that the Office erred in a manner material to patentability.” *Id.* at 9. Moreover, a petitioner “must provide an analysis even when the asserted prior art is on an IDS, but the Examiner did not apply the reference.” *Ecto World, LLC v. RAI Strategic Holdings, Inc.*, IPR2024-01280, Paper 13 at 5 (PTAB May 19, 2025) (precedential). As discussed below, there is no basis to conclude that the Patent Office materially erred in granting the ’552 patent.

(a) Conroy’s Appendix and Protocol Do Not Disclose “Critical Limitations in the Claims”

In declining to grant Ipsen’s request for discretionary denial of CSPC’s petition, the Director cited the Patent Office’s failure to consider or oversight of “specific teachings in Conroy’s appendix and Conroy’s associated protocol, both identified in Conroy itself, that disclose critical limitations in the claims” as “persuasive evidence that the Office erred in a manner material to the patentability of the challenged claims.” Ex. 2003 at 3. As discussed *supra*, the Conroy Protocol

should be discounted for failure to meet statutory requirements. As discussed below, neither reference provides any such disclosure.

Apotex argues that the Patent Office “never recognized that Conroy, the Conroy Protocol, and the Conroy Appendix disclose that FOLFIRINOX patients were administered with 60 mg/m² oxaliplatin.” Paper 1 at 36. Apotex’s characterization of the Conroy references is incorrect. As discussed below, the Conroy references unambiguously disclose that FOLFIRINOX comprises 85 mg/m² oxaliplatin, not 60 mg/m² oxaliplatin.

The Conroy references define FOLFIRINOX as a regimen that comprises 85 mg/m² oxaliplatin. Conroy’s abstract defines FOLFIRINOX as “oxaliplatin, 85 mg per square meter of body-surface area; irinotecan, 180 mg per square meter; leucovorin, 400 mg per square meter; and fluorouracil, 400 mg per square meter given as a bolus followed by 2400 mg per square meter given as a 46-hour continuous infusion, every 2 weeks.” Ex. 1003 at 1. As Conroy reports, patients in the FOLFIRINOX arm of the study received (1) 85 mg/m² oxaliplatin, followed by (2) 400 mg/m² leucovorin, (3) 180 mg/m² irinotecan, and (4) fluorouracil administered as a 400 mg/m² bolus dose followed by a 2400 mg/m² infusion. *Id.* at 3.

The Conroy Protocol and Appendix likewise define FOLFIRINOX by reference to an 85 mg/m² starting dose of oxaliplatin. Conroy Protocol specifies

that FOLFIRINOX treatment “will begin with oxaliplatin 85 mg/m² IV infused over 2 hours.” Ex. 1004 at 15. At his deposition, CSPC’s expert did not dispute that Conroy Protocol teaches 85 mg/m² oxaliplatin as the starting dose. Ex. 2007 at 43:11-14, 83:11-18. A POSA reading Conroy in combination with Conroy Protocol and Conroy Appendix would understand that FOLFIRINOX refers to a treatment regimen defined by, *inter alia*, 85 mg/m² oxaliplatin.

Subsequent references, including those co-authored by Conroy himself, also define FOLFIRINOX as comprising 85 mg/m² oxaliplatin. Referring back to Conroy, Conroy 2013 states that “[t]he FOLFIRINOX regimen included oxaliplatin (85 mg/m²) over 2 h, then irinotecan (180 mg/m²) over 90 min concurrently with leucovorin (400 mg/m²) over 2 h immediately following oxaliplatin, bolus 5-FU (400 mg/m²) and continuous intravenous infusion of 5-FU over 46 h (1,200 mg/m² per day for 2 days).” Ex. 1041 (Conroy 2013) at 2-3. Other references refer to Conroy’s FOLFIRINOX as comprising 85 mg/m² oxaliplatin. *See, e.g.*, Ex. 2011 at 1-2 (“Promising phase II results with FOLFIRINOX (FFX) (oxaliplatin 85 mg/m² . . .) were confirmed in a sentinel phase III study (PRODIGE 4/ACCORD 11”); *see also* Ex. 2007 at 85:8-13, 97:21-98:4 (CSPC’s expert Dr. Ratain agreeing that other papers’ reference to FOLFIRINOX refers to a regimen comprising 85 mg/m² oxaliplatin). The fact that subsequent references that specifically describe the FOLFIRINOX regimen of

Conroy as containing 85 mg/m² oxaliplatin directly contradicts Apotex's urged interpretation otherwise.

To the extent that Conroy refers to a dose of oxaliplatin lower than 85 mg/m², it is in the limited context of dose adjustment for some patients, in some instances of "predefined toxic events." *See, e.g.*, Ex. 1003 at 3. The Conroy Protocol and Conroy Appendix detail the conditions under which dose reduction might be appropriate. *See* Ex. 1004 at 15-20; Ex. 1017 at 3-9. At most, the Conroy references teach that toxicity events may prompt dose reduction *after* treatment comprising oxaliplatin, 85 mg/m², has initiated and only for some patients, under certain circumstances.

Nor does Conroy's reported "median relative dose intensity" suggest or teach preemptive oxaliplatin dose reduction to 60 mg/m². *See* Paper 1 at 46-47. Dr. Ratain, CSPC's expert, agreed that the median relative dose intensity does not even indicate the number of patients who were dose-reduced. Ex. 2007 at 84:9-12. Conroy's reported "median relative dose intensity" would not have motivated pursuit of a first-line treatment regimen comprising 60 mg/m² oxaliplatin, let alone the claimed methods.

(b) The Patent Office Was Not “Misled” by Arguments Regarding the Teachings of First-Line Versus Second-Line Therapy

Apotex argues that Ipsen “led the Office into error by arguing that there was no motivation to combine Conroy’s first-line FOLFIRINOX regimen with the liposomal irinotecan pancreatic treatment methods of Bayever.” Paper 1 at 35. As support, Apotex cites the ’552 patent applicant’s arguments in the subsection titled, “No motivation to combine the references,” in remarks submitted on February 25, 2022. *Id.* (citing Ex. 1119 at 145-148).

Apotex’s citation is misleading insofar as its cited subsection contains several arguments, not limited to those relating to combining the teachings of first- and second-line therapies. *See* Ex. 1119 at 145-48. The argument that Apotex alleges to have “[mis]led” the Patent Office appears in a single paragraph of the cited subsection. *Id.* at 146. In that paragraph, the ’552 patent applicant argues that “there is no basis for combining Conroy and Bayever because there is no basis for combining teachings regarding second-line therapy with teachings regarding first-line therapy.” *Id.* The remainder of that subsection addresses the Patent Office’s argument, based on Melis, that oxaliplatin (and its dosage) is a result-effective variable. *See id.* at 146-48. As discussed *supra*, this is one of the arguments that the ’552 patent applicant overcame (and that Apotex reargues in its

petition), separate from the argument that Apotex argues “[mis]led” the Patent Office.

Apotex’s argument mischaracterizes the ’552 patent applicant’s statements to the Patent Office. The ’552 patent applicant did not argue, as Apotex and Dr. Dreicer state, “that Bayever was limited to treating pancreatic cancer only as a second-line therapy.” Ex. 1501 at ¶ 130; *see also* Paper 1 at 35. Rather, the ’552 patent applicant represented that Bayever covers, but is not limited to, a second-line therapy regimen. Ex. 1098 at 206 (“This liposomal irinotecan, 5-FU, LV regimen is described in Bayever.”); Ex. 1119 at 146 (“Bayever covers the liposomal irinotecan, 5-FU, LV regimen currently approved for ONIVYDE® . . . as a second-line therapy for metastatic pancreatic cancer.”). Thus, Apotex misrepresents the statements alleged to have “led the Office into error.”

Given the extent to which the Patent Office cited and discussed Bayever during prosecution, it strains credulity to argue that the Patent Office was somehow “led” into an erroneous understanding of its contents. Besides Conroy, Bayever was the most frequently cited and extensively discussed reference during prosecution. The Patent Office cited and discussed the disclosure of Bayever in every rejection leading up to resolution of the issue of obviousness in Ipsen’s favor. Under these circumstances, the Patent Office is presumed to have read and understood the contents of Bayever, including the sections that Apotex’s expert,

Dr. Dreicer, cites³ as disclosing first-line treatment. *See Johnson & Johnson Surgical Vision, Inc. v. Alcon Inc.*, IPR2021-00898, Paper 17 at 34-35 (PTAB Nov. 9, 2021) (rejecting an argument that examiners had failed to “fully consider” the disclosure of prior art repeatedly cited and extensively discussed during prosecution); *cf. BlephEx, LLC v. Myco Indus., Inc.*, 24 F.4th 1391, 1402 (Fed. Cir. 2022) (affirming district court determination of likelihood of success in defeating a validity challenge that was based on prior art that was before the Patent Office, on the rationale that “the patent examiner is presumed to have considered it”); *Stone Basket Innovations, LLC v. Cook Med. LLC*, 892 F.3d 1175, 1179–80 (Fed. Cir. 2018) (in affirming denial of a motion under 35 U.S.C. § 285, explaining that “where a party only relies on prior art considered by an examiner in its invalidity contentions, that party has the burden to overcome the deference that is due to a qualified government agency presumed to have properly done its job, which includes one or more examiners who are assumed to have some expertise in interpreting the references and whose duty it is to issue only valid patents.” (internal quotations and alterations omitted)). Similarly here, the examiner should be presumed to have read Bayever in its entirety.

³ See Ex. 1501 at ¶¶ 131-37.

Nevertheless, the prosecution history contradicts Apotex's argument that arguments related to the teachings of first-line versus second-line therapy resulted in any error material to patentability. The '552 patent applicant presented this argument in remarks that did not result in allowance of the claims. In its February 25, 2021 remarks, the '552 patent applicant "provide[d] additional background that may help distinguish the claimed methods from the cited disclosures" of Conroy and Bayever. Ex. 1098 at 206. Specifically, the '552 patent applicant distinguished second-line therapy (as covered by Bayever) from Conroy's disclosure of first-line therapy. *Id.* The Patent Office maintained its obviousness rejection notwithstanding this distinction. *See* Ex. 1119 at 13-15 (finding the '552 patent applicant's arguments "not persuasive"). Thus, even assuming that the '552 patent applicant somehow "[mis]led" the Patent Office regarding the teachings of Bayever (it did not), it was not material to a determination of patentability.

**(c) The '552 Patent Applicant Properly Identified
Unexpected Results of the Claimed Combination
Therapy**

Apotex also argues, in an attempt to evade discretionary denial, that the evidence of unexpected results submitted by the '552 patent applicant was "defective." *See* Paper 1 at 36-38. Apotex's critiques are that the evidence: (1) suffers from "inherent limitations" and improperly invites a cross-trial comparison of efficacy results; and (2) is "refuted" by more recent publications that purport to

show “identical efficacy” between the study of Conroy and the study cited by the ’552 patent applicant. *Id.* Neither argument has merit.

Again, Apotex mischaracterizes the ’552 patent applicant’s statements to the Patent Office. The ’552 patent applicant submitted that the claimed methods—which comprises dose reduction of two drugs and a dose of liposomal irinotecan that is a fraction of the irinotecan contained in FOLFIRINOX—unexpectedly showed “tolerability *and* efficacy.” Ex. 1119 at 149-150 (“Indeed, none of the references teach or suggest tolerability *and* efficacy of 60 mg/m² oxaliplatin in combination with the claimed liposomal irinotecan, oxaliplatin, leucovorin, and 5-FU dosages.” (emphasis in original)). The ’552 patent applicant did not—as Apotex misleadingly suggests—simply cite superior efficacy over FOLFIRINOX as a basis for unexpected results.

The Patent Office is presumably aware of the alleged “inherent limitations” that Apotex cites with respect to the ’552 patent applicant’s submitted references. *See* Paper 1 at 37-38. As Apotex acknowledges, the Wainberg article states the “limitations” upon which Apotex relies and cautions against cross-trial comparisons. Paper 1 at 38 (citing Ex. 1019 at 8). The Wainberg references are moreover listed on the face of the ’552 patent. *See* Ex. 1001 at 16 (identifying Ex. 1018); *id.* at 19 (identifying Ex. 1019). The Patent Office is presumed to have read the Wainberg references and drawn its own conclusions. *See, e.g., Johnson &*

Johnson, IPR2021-00898, Paper 17 at 34-35 (denying institution, in part on the rationale that the examiner is presumed to have read references before the Patent Office during prosecution); *cf. BlephEx*, 24 F.4th at 1402 (“[T]he patent examiner is presumed to have considered” references “cited on the face of the [] patent.”).

Apotex attempts to negate the ’552 patent applicant’s evidence of unexpected results on the same basis that it criticizes that evidence. Namely, Apotex cites references that purport to draw conclusions of comparative efficacy based on cross-trial comparisons. For example, Nichetti (Ex. 1010) purports to “derive survival, response and toxic effects data from [three separate] phase 3 clinical trials.” Ex. 1010 (Nichetti) at 1. Nichetti acknowledges that its meta-analysis is subject to numerous limitations. *See id.* at 10 (section titled, “Limitations”). Nevala-Plagemann (Ex. 1011) is an opinion piece that questions conclusions drawn from clinical trials of NALIRIFOX and FOLFIRINOX. *See* Ex. 1011 (Nevala-Plagemann). To the extent that Apotex critiques Wainberg as impermissibly comparing efficacy outcomes across different clinical trials, Apotex does the same.

The ’552 patent applicant’s evidence of unexpected results shows that NALIRIFOX (the claimed treatment regimen) resulted in improvement in overall survival (OS) and progression-free survival (PFS). *See* Ex. 1018 (Wainberg 2020), Ex. 1019 (Wainberg 2021). Evidence of unexpected results may support a finding

of non-obviousness. *See Millennium Pharm., Inc. v. Sandoz Inc.*, 862 F.3d 1356, 1368 (Fed. Cir. 2017) (unexpected results are among objective indicia that enable “the court to avert the trap of hindsight.” (citation omitted)). The ’552 patent applicant’s evidence of unexpected results submitted by the ’552 patent applicant during prosecution properly supports non-obviousness of the claimed treatment methods.

Apotex cites the Phase III trial of NALIRIFOX as showing no improvement in these outcomes over FOLFIRINOX but ignores the difference in comparator arms between the relevant Phase III studies. *See* Paper 1 at 38-39, 55-56. The comparator arm for the Phase III study of NALIRIFOX (“NAPOLI 3”) was gemcitabine + nab-paclitaxel (“GnP”). *See* Ex. 1010 at 6, Table Summary of Clinical Trial Characteristics. The comparator arm for the Phase III study of FOLFIRINOX (“ACCORD 11,” as reported in Conroy) was gemcitabine. *Id.* GnP had previously been shown to improve survival over gemcitabine. *See* Ex. 2012 at 2 (showing an improvement of 8.5 months, over 6.7 months). The fact that NALIRIFOX demonstrated an improvement over GnP (a comparator arm proven to be superior to the comparator arm referred to in Conroy) supports the clinical superiority of NALIRIFOX over FOLFIRINOX. Indeed, more recent publications indicate that a modified FOLFIRINOX regimen has failed to demonstrate superiority to GnP. *See, e.g.*, Ex. 2013 at 3 (“NALIRIFOX led to better outcomes

than GnP, but [a modified FOLFIRINOX regimen] failed to do so.”). This contradicts Apotex’s assertion that the claimed NALIRIFOX regimen is “identical” to that of FOLFIRINOX.

To the extent that Apotex argues that the Patent Office erred in its consideration of “post-filing” evidence to support patentability, that argument fails as a matter of law. Apotex argues against discretionary denial, in part on the Patent Office’s reliance on “post-filing” evidence of unexpected results. Paper 1 at 36-37. That evidence of unexpected results is “post-filing” does not render it immaterial to patentability. Rather, and as the Federal Circuit has held, “patentability may consider all of the characteristics possessed by the claimed invention, whenever those characteristics become manifest.” *Sanofi-Aventis Deutschland GmbH v. Glenmark Pharms. Inc. USA*, 748 F.3d 1354, 1360 (Fed. Cir. 2014); *see also Knoll Pharmaceutical Co., Inc. v. Teva Pharmaceuticals USA, Inc.*, 367 F.3d 1381, 1385 (Fed. Cir. 2004) (“Evidence developed after the patent grant is not excluded from consideration, for understanding the full range of an invention is not always achieved at the time of filing the patent application.”). The ’552 patent applicant properly relied on post-filing evidence of the claimed methods’ clinical effects to support patentability.

V. CONCLUSION

For the reasons set forth herein, the Director should exercise discretionary denial of Apotex's alleged "silent understudy" petition.

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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 has 6,320 words and thus complies with the applicable word limit.

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

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