

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 SUPPLEMENTAL BRIEFING

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

Pursuant to the Board’s May 21, 2026 Order (Paper 49), Patent Owner Ipsen Biopharm Ltd. (“Ipsen”) herein provides supplemental briefing on claim construction of U.S. Patent No. 11,344,552 (“the ’552 patent”).

The phrase “a human patient who has not previously received an antineoplastic agent to treat metastatic adenocarcinoma of the pancreas” refers to a first-line treatment population. As the specification describes, the invention relates to combination therapy “for the (first line) treatment of patients diagnosed with previously untreated pancreatic cancer.” Ex. 1001 at 1:21-25; *see also id.* at 2:17-21. Example 3 describes a study for such first-line treatment methods, the inclusion criteria being “[p]athologically confirmed adenocarcinoma of the pancreas that has not been previously treated in the metastatic setting.” *Id.* at 16:46-67. Exclusion criteria, by contrast, is “[p]rior treatment of pancreatic cancer in the metastatic setting with surgery, radiotherapy, chemotherapy or investigational therapy” and “[p]rior treatment of pancreatic cancer with cytotoxic doses of chemotherapy (patients receiving prior treatment with chemotherapy as a radiation sensitizer are eligible if ≥ 6 months has elapsed from completion of therapy)” *Id.* at 26:46-67.² And as discussed *infra*, the specification indicates that

² During prosecution, applicants likewise described the invention as “first-line treatment pursuant to the claims.” Remarks (Feb. 25, 2022) at 10-11. Applicants also explained the difference between first-line and second-line treatment populations: “[e]xpectations of efficacy and safety of treatments are entirely different at these two separate stages: in second-line therapy, the tumor

the recited doses are “starting” or “initial” doses. Thus, the claimed treatment methods are to a starting dose regimen for first-line treatment, i.e., one in which the patient has metastatic pancreatic cancer that has not previously been treated with an antineoplastic agent for said cancer.

The claimed first-line treatment methods comprise an “antineoplastic therapy” that literally consists of four specific drugs in a specific recited dose:

- 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

Ex. 1001 at claim 1. The specification describes that the recited dose of each drug is a “starting” or “initial” dose. *See, e.g.*, 13:38-45 (referring to the recited doses as “starting (initial) doses”); 30:5-7 (referring to the recited doses as “starting doses”); Tables 1B – 1E (referring to the recited doses as “Initial” doses). The claims additionally recite that the “antineoplastic therapy” is administered “once every two weeks.” *Id.* at claim 1. The specification describes that in the context of this invention, administration of the recited antineoplastic therapy “once every two weeks” includes giving two consecutive administrations two weeks apart. *See*,

may have become more malignant and difficult to treat; patients receiving second-line therapy are also likely significantly more sick and less able to tolerate therapy than those receiving a first-line therapy.” Remarks (Feb. 25, 2022) at 10-11.

e.g., Ex. 1001 at 19:25-36 (referring to “a 2-week cycle”); 24:39-42 (“every two weeks”). One such example of such administration is “on days 1 and 15 of a 28-day cycle.” Ex. 1001 at 18:57-61; 45:21-30 (Table 18) (defining Cycles 1 and 2 each as Days 1 and 15). Thus, claim 1 requires administration of each of the recited drugs in the specifically recited dose for each, once every two weeks.

Under Federal Circuit law, operation of the “comprising” and “consisting of” claim language means that the recited antineoplastic therapy literally consists of administering the four recited drugs in the specific recited doses. “[T]he term ‘comprising’ is well understood to mean ‘including but not limited to.’”³ *CIAS, Inc. v. Alliance Gaming Corp.*, 504 F.3d 1356, 1360 (Fed. Cir. 2007). “It is equally well understood in patent usage that ‘consisting of’ is closed-ended and conveys limitation and exclusion.” *Id.* at 1361. And where claims contain both the terms “comprising” and “consisting of,” the term “consisting of” limits the claim language that follows. *In re Crish*, 393 F.3d 1253, 1257 (Fed. Cir. 2004). As applied here, the “consisting of” language puts each scenario posited by the Board outside the literal scope of claim 1.

³ The “comprising” transitional language of claim 1 provides that the treatment methods may additionally include other drugs. As exemplified by dependent claim 15, the claimed treatment methods may also include administration of other drugs, e.g., a corticosteroid and/or anti-emetic. *See, e.g.*, claim 15. The patent examples also contemplate, for example, pre-medication with dexamethasone and a 5-HT3 antagonist. Ex. 1001 at 24:14-24.

Scenario (1): Claim 1 does not encompass a method in which the patient is first treated with the recited combination of drugs, with at least one at a different dose than recited (e.g., 85 mg/m² versus 60 mg/m² of oxaliplatin), before treatment with the recited antineoplastic therapy. Again, the recited doses in the claims are starting/initial doses. Dr. Oberstein's opinions are as such. Ex. 2076 ¶ 119; Ex. 1210 83:4-25. Dr. Ratain agrees.⁴ See Ex. 2073 126:13-128:4. When asked about the recited doses in the claims, Dr. Ratain testified that they are “the *only* doses of the claimed treatment”:

Q. And is it your understanding that these are the starting doses of the claimed treatment?

A. They're the *only* doses of the claimed treatment.

Ex. 2073 19:13-21:6 (emphasis added). And because the recited antineoplastic therapy “consists of” the recited drugs at the recited starting doses, deviation from that starting dose places a method literally outside the scope of claim 1. Moreover, as it relates to a starting dose of 85 mg/m² oxaliplatin, applicants specifically amended the claims during prosecution not to recite this starting dose. Ex. 1084 at 287. Thus, a first administration of 85 mg/m² oxaliplatin, 60 mg/m² liposomal irinotecan, and the other recited drugs falls literally outside the scope of claim 1.

⁴ Counsel for Petitioner conceded during oral argument that, for example, the recited dose for oxaliplatin in the claims is the starting dose.

Scenario (2): Claim 1 does not encompass a method in which the patient is first treated with the recited drugs at the recited doses, and then two weeks later with the same four drugs but with at least one drug in a dose different from that recited (e.g., 80 mg/m² liposomal irinotecan instead of 60 mg/m² liposomal irinotecan). For the same reasons stated *supra*, the recited doses in the claims are the starting/initial doses. And because the recited antineoplastic therapy must literally “consist of” the four drugs at the specific four recited doses, administered “once every two weeks,” deviation from the recited doses within the claimed administration period falls literally outside the scope of claim 1. Moreover, regarding liposomal irinotecan specifically, if anything, the patent teaches dose **reduction**. Ex. 1001 at 13:20-56, Tables 1B-1E; 30:5-11, Tables 3, 6-9. In fact, the patent teaches that “dose re-escalation to an earlier dose is **not** permitted,” let alone escalating higher than the starting dose. Ex. 1001 at 33:10-12 (emphasis added). Thus, a first administration of the recited drugs in the recited doses, followed two weeks later by a second administration of the same four drugs but a different dose than 60 mg/m² (80 mg/m²) liposomal irinotecan would fall literally outside the scope of claim 1.

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

The undersigned hereby certifies that on May 29, 2026 copies of the foregoing document was served upon the following parties via electronic mail, with a copy to ipdocket@foxrothschild.com (referencing Attorney Docket No. 340008.00021):

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