

**IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY**

**ASTRAZENECA
PHARMACEUTICALS LP,
ASTRAZENECA UK LIMITED,
ASTRAZENECA AB, KUDOS
PHARMACEUTICALS LIMITED,
THE UNIVERSITY OF
SHEFFIELD, AND MSD
INTERNATIONAL BUSINESS
GMBH,**

Plaintiffs,

v.

**NATCO PHARMA LIMITED,
CIPLA LIMITED, CIPLA USA,
INC., ZYDUS
PHARMACEUTICALS (USA) INC.,
AND ZYDUS LIFESCIENCES
LIMITED,**

Defendants.

**Consol. Court No. 3:23-cv-00796-
JCG-TJB**

ANDA CASE

OPINION AND ORDER

[Providing clarification on claim construction for the patents in suit.]

Date: September 21, 2026

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AstraZeneca UK Limited, AstraZeneca AB, KuDOS Pharmaceuticals Limited, The University of Sheffield, and MSD International Business GmbH.

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Theodora McCormick, Lauren B. Cooper, and Alec Wong, Baker, Donelson, Bearman, Caldwell & Berkowitz, PC, of Princeton, N.J.; Michael J. Gaertner, James T. Peterka, Emily L. Savas, David M. Knapp, and Hannah J. Thomas, Buchanan Ingersoll & Rooney P.C., of Chicago, IL. Attorneys for Consolidated Defendants/Counterclaim Plaintiffs Zydus Pharmaceuticals (USA) Inc. and Zydus Lifesciences Ltd.

Choe-Groves, Judge: The Court issues this Opinion and Order to clarify construction of a disputed term, following a claim construction opinion (ECF Nos. 296, 297) that was issued by a prior judge before this matter was reassigned to this Court. The Parties have filed letters indicating that there remains an ongoing dispute regarding the construction of a disputed term following the December 1, 2025, Markman Order, claim construction opinion. See Pls.' Ltr. Req. Clarification (July 10, 2026) (ECF No. 350); Defs.' Resp. Ltr. (July 17, 2026) (ECF No. 354). Upon consideration of the papers and proceedings in this action, the Court issues this Opinion and Order adopting the final constructions of the

prior claim construction opinion (ECF Nos. 296, 297), and providing clarification regarding one of the claim constructions as set forth below.

BACKGROUND

Plaintiffs AstraZeneca Pharmaceuticals, LP, AstraZeneca UK Limited, AstraZeneca AB, KuDOS Pharmaceuticals Limited, The University of Sheffield, and MSD International Business GmbH (collectively, “Plaintiffs”) filed cases against Defendants Natco Pharma Limited (“Natco”), Cipla Limited, Cipla USA, Inc. (collectively, “Cipla”), Zydus Pharmaceuticals (USA) Inc., and Zydus Lifesciences Ltd. (collectively, “Zydus”) (collectively, “Defendants”) arising out of Defendants’ submission of an Abbreviated New Drug Application (“ANDA”) to the United States Food and Drug Administration (“FDA”) seeking approval to commercially manufacture, use, offer for sale, sell, and/or import a generic version of LYNPARZA® (olaparib) tablets, 100 mg and 150 mg, alleging infringement prior to the expiration of certain patents,¹ including U.S. Patent Number 8,859,562

¹ See Compl. (ECF No. 1); Compl. (ECF No. 1), C.A. 3:24-cv-07346-JCG-TJB; Compl. (ECF No. 1), C.A. 3:24-cv-08167-JCG-TJB; Compl. (ECF No. 1), C.A. 3:24-cv-08162-JCG-TJB; Compl. (ECF No. 1), C.A. 3:24-cv-05887-JCG-TJB; Compl. (ECF No. 1), C.A. 3:24-cv-10458-JCG-TJB; Compl. (ECF No. 1), C.A. 3:24-cv-10624-JCG-TJB; Compl. (ECF No. 1), C.A. 3:24-cv-10628-JCG-TJB; Compl. (ECF No. 1), C.A. 3:24-cv-10629-JCG-TJB; Compl. (ECF No. 1), C.A. 3:25-cv-00230-JCG-TJB; Compl. (ECF No. 1), C.A. 3:25-cv-00233-JCG-TJB; Compl. (ECF No. 1), C.A. 3:25-cv-00234-JCG-TJB; see, e.g., Ex. A, U.S. Patent

(the “’562 Patent”). Compl. Patent Infringement (ECF No. 1); see Ex. C, U.S.

Patent Number 8,859,562 (“’562 Patent) (ECF No. 1-3).

The ’562 Patent was issued by the United States Patent and Trademark Office on October 14, 2014, and is titled “Use of RNAI Inhibiting PARP Activity for the Manufacture of a Medicament for the Treatment of Cancer.” ’562 Patent at [45], [54]. The patent is “related to the use of an agent that inhibits the activity of an enzyme which mediates the repair of [deoxyribonucleic acid (DNA)] strand breaks in the treatment of certain forms of cancer[,] in particular breast cancer.” Id. at 1:6–9. “It is believed that genetic instability due to loss of [homologous recombination (“HR”)] repair in human cancers significantly contributes to the development of cancer in [mammalian] cells.” Id. at 1:14–16. The ’562 Patent provides for uses of activities to prevent a nuclear protein called poly(ADP-ribosyl)ationPolymerase (PARP-1) from binding to DNA stand breaks and

Number 7,449,464 (“’464 Patent”) (ECF No. 1-1); Ex. B, U.S. Patent Number 8,475,842 (“’842 Patent) (ECF No. 1-2); Ex. C, U.S. Patent Number 8,859,562 (“’562 Patent) (ECF No. 1-3); Ex. E, U.S. Patent Number 11,970,530 (“’530 Patent”) (ECF No. 1-5), C.A. 3:24-cv-07346-JCG-TJB; Ex. D, U.S. Patent Number 11,975,001 (“’001 Patent”) (ECF No. 1-4), C.A. 3:24-cv-07346-JCG-TJB; Ex. A, U.S. Patent Number 12,048,695 (“’695 Patent”) (ECF No. 1-1), C.A. 3:24-cv-08162-JCG-TJB; Ex. A, U.S. Patent Number 12,144,810 (“’810 Patent”) (ECF No. 1-1), C.A. 3:24-cv-10624-JCG-TJB; Ex. A, U.S. Patent Number 12,178,816 (“’816 Patent”) (ECF No. 1-1), C.A. 3:25-cv-00230-JCG-TJB.

catalyzing processes that may be linked to genetic instability. Id. at 1:22–45.

During claim construction briefing, the Parties filed a prehearing statement, joint claim chart, and briefs. Joint Prehearing Statement and Claim Chart (“Joint Claim Chart”) (ECF No. 192); Pls.’ Opening Claim Construction Br. (“Pls.’ Br.”) (ECF Nos. 199, 211-3)²; Defs.’ Opening Claim Construction Br. (“Defs.’ Br.”) (ECF No. 198); Pls.’ Resp. Claim Construction Br. (“Pls.’ Resp. Br.”) (ECF No. 203); Defs.’ Resp. Claim Construction Br. (“Defs.’ Resp. Br.”) (ECF No. 202). A claim construction hearing pursuant to Markman v. Westview Instruments, Inc. (“Markman I”), 52 F.3d 967 (Fed. Cir. 1995) (en banc), aff’d, 517 U.S. 370 (1996) (“Markman II”), was held on July 16, 2025 (“Hearing Tr.,” ECF No. 230), and an Opinion and Order were issued on December 1, 2025 (collectively, the “Markman Op.”) (ECF Nos. 296, 297) by the prior judge. The matter was subsequently reassigned to this Chambers on April 29, 2026. Assignment Order (Apr. 29, 2026) (ECF No. 326).

² Citations to Plaintiffs’ Opening Claim Construction Brief relate to the redacted public version (ECF No. 211-3). The Court recognizes that a sealed version of Plaintiffs’ Opening Claim Construction Brief was filed. See (ECF No. 199).

LEGAL STANDARDS

I. CLARIFICATION OF PRIOR OPINIONS OR ORDERS

Federal Rule of Civil Procedure 54(b) provides that “any order or other decision, however designated, that adjudicates fewer than all the claims or the rights and liabilities of fewer than all the parties does not end the action as to any of the claims or parties and may be revised at any time before the entry of a judgment adjudicating all the claims and all the parties’ rights and liabilities.” Fed. R. Civ. P. 54(b). The U.S. Court of Appeals for the Federal Circuit (“CAFC”) has recognized that “a district court may (and sometimes must) revisit, alter, or supplement its claim constructions [. . .] to the extent necessary to ensure that final constructions serve their purpose of genuinely clarifying the scope of claims for the finder of fact.” Level Sleep LLC v. Sleep No. Corp., 2020-1718, 2021 WL 2934816, *3 (Fed. Cir. July 13, 2021) (quoting In re Papst Licensing Digit. Camera Pat. Litig., 778 F.3d 1255, 1261 (Fed. Cir. 2015)).

II. CLAIM CONSTRUCTION STANDARD

When the meaning of a patent’s claim language is disputed, the Court must construe the claim as a matter of law. Markman I, 52 F.3d at 979. “[T]he construction of a patent, including terms of art within its claim, is exclusively within the province of the court.” Markman II, 517 U.S. at 372. “The purpose of

claim construction is to ‘determin[e] the meaning and scope of the patent claims asserted to be infringed.’” O2 Micro Int’l Ltd. v. Beyond Innovation Tech. Co., 521 F.3d 1351, 1360 (Fed. Cir. 2008) (quoting Markman I, 52 F.3d at 976).

“The patent is a fully integrated written instrument.” Markman I, 52 F.3d at 978. For the purpose of claim construction, “[a] court should look first to the intrinsic evidence of record, i.e., the patent itself, including the claims, the specification and, if in evidence, the prosecution history.” Vitronics Corp. v. Conceptronic, Inc., 90 F.3d 1576, 1582 (Fed. Cir. 1996) (citing Markman I, 52 F.3d at 979). “In construing terms used in patent claims, it is necessary to consider the specification as a whole, and to read all portions of the written description, if possible, in a manner that renders the patent internally consistent.” Budde v. Harley-Davidson, Inc., 250 F.3d 1369, 1379–80 (Fed. Cir. 2001). “The words of a claim are generally given their ordinary and customary meaning as understood by a person of ordinary skill in the art when read in the context of the specification and prosecution history.” Thorner v. Sony Comput. Ent. Am. LLC, 669 F.3d 1362, 1365 (Fed. Cir. 2012) (citing Phillips v. AWH Corp., 415 F.3d 1303, 1313 (Fed. Cir. 2005) (en banc)).

DISCUSSION

Before the Court are the questions of whether the preamble of Claim 1 of the

'562 Patent is limiting and whether the steps of Claim 1 incorporate a mental intent element for a physician to treat a specific condition. After the issuance of the Markman Opinion, the Parties brought a dispute to the attention of this Court regarding Defendants' prior art disclosures based upon the Parties' interpretation of the December 1, 2025, Opinion. Pls.' Ltr. Req. Clarification; Defs.' Resp. Ltr. For clarity of the record, to address confusion of the Parties, and to promote judicial economy, the Court addresses these issues now.

For the reasons set forth below, the Court holds that the preamble of Claim 1 of the '562 Patent is limiting and that there is a mental intent element in Claim 1 of the '562 Patent.

Claim 1 of the '562 Patent recites:

[a] method of treatment of cancer cells defective in homologous recombination (HR), the method comprising:
 identifying a human patient with a familial predisposition to genelinked hereditary cancer,
 wherein said cancer comprises cancer cells defective in homologous recombination;
 identifying a compound which inhibits PARP-1, and
 administering to said human patient a therapeutically effective amount of said compound.

'562 Patent at 37:26–29, 38:24–28.

During claim construction, the Parties disputed construction of the term “the method comprising” in Claim 1 of the '562 Patent. Joint Claim Chart at 4; Pls.'

Br. at 18–30; Defs.’ Br. at 6–14; Pls.’ Resp. Br. at 20–30; Defs.’ Resp. Br. at 2–13.

Both Parties proposed defining the term by its plain and ordinary meaning but disputed the articulation of what was meant by the plain and ordinary meaning. See Joint Claim Chart at 4. Plaintiffs’ proposed meaning was “the claimed method is not limited to administering a PARP-1 inhibitor in a monotherapy.” Id. Plaintiffs argued that “[t]he claim as a whole requires the two “identifying” steps (i.e., “identifying a human patient with a familial predisposition to gene-linked hereditary cancer” and “identifying a compound which inhibits PARP-1”) to be performed prior to the “administering” step (i.e., “administering to said human patient a therapeutically effective amount of said compound”).” Id. Plaintiffs further asserted that a physician must have a particular intent to practice the claim, and therefore, “[t]he physician [] must understand that the patient has HR-defective cancer and that the compound is a PARP-1 inhibitor in order to possess the requisite intent to practice the claim.” Pls.’ Br. at 21.

Defendants proposed defining the term as “the claimed method is not limited to administering a PARP-1 inhibitor in a monotherapy, and the claimed method steps may be performed in any order.” Joint Claim Chart at 4. Defendants argued that the preamble of Claim 1 provides no antecedent basis for any of the claim terms, and therefore, provided no limitations. Defs.’ Resp. Br. at 4–5. The Parties

thus agreed on the majority of the construction of “the method comprising” as “the claimed method is not limited to administering a PARP-1 inhibitor in a monotherapy,” and disputed whether the three steps provided in Claim 1 of the ’562 Patent must be practiced in a particular order. The December 1, 2025, Opinion held “the method comprising” to require “[t]he two ‘identifying’ steps (i.e., ‘identifying a human patient with a familial predisposition to gene-linked hereditary cancer’ and ‘identifying a compound which inhibits PARP-1’) be performed prior to the ‘administering’ step (i.e., administering to said human patient a therapeutically effective amount of said compound).” Markman Op. at 29, 31.

“[W]hether to treat a preamble as a claim limitation is determined on the facts of each case in light of the claim as a whole and the invention described in the patent.” Eli Lilly & Co. v. Teva Pharma. Int’l GmbH, 8 F.4th 1331, 1343 (Fed. Cir. 2021) (quoting Storage Tech. Corp. v. Cisco Sys., Inc., 329 F.3d 823, 831 (Fed. Cir. 2003)). As a general rule, preambular language is not treated as limiting the scope of a claim. Aspex Eyewear, Inc. v. Marchon Eyewear, Inc., 672 F.3d 1335, 1347 (Fed. Cir. 2012) (citation omitted). When the body of the claim describes a complete invention, including all of its limitations, and the preamble offers no distinct definition of a limitation but states only the intended use or

purpose of the invention, then the preamble is not significant to claim construction.

Pitney Bowes, Inc. v. Hewlett-Packard Co., 182 F.3d 1298, 1305–06 (Fed. Cir.

1999). A claim’s preamble is limiting if it is “necessary to give life, meaning, and vitality to the claim.” Id. The CAFC has “generally construed statements of intended purpose in [] method claims as limiting.” Eli Lilly & Co., 8 F.4th at 1340.

Defendants argue that the language of the preamble is not limiting because the preamble provides no antecedent basis. Defs.’ Resp. Br. at 4–6. In contrast, Plaintiffs contend that the preamble of claim 1 is limiting. Pls.’ Br. at 21.

Plaintiffs rely heavily upon the Eli Lilly & Co. decision. Pls.’ Br. at 21–24. In Eli

Lilly & Co., the CAFC considered claims directed to methods of treating

headaches and certain migraine-related symptoms with administration of an

antibody therapeutic. 8 F.4th at 1334–35. The patent claims at issue recited a

“method for reducing incidence of or treating at least one vasomotor symptom in

an individual” or a “method for treating headache in an individual.” Id. at 1335.

The CAFC considered the purpose of the methods—to treat vasomotor symptoms

such as migraines—as central to the inventions and noted that this purpose was

incorporated “in every section of the patents’ written description.” Id. at 1342.

Despite the prominent nature of the purpose in the written description, the only

mention of the treatment in the claims appeared in the preambles. Id. The CAFC reasoned that:

Under these circumstances, we reject Lilly’s suggestion that the preambles merely state an intended purpose that need not be performed to practice the claims. The preambles limit the scope of the claims because these claims would not read on, for example, the performance of the same method step to treat other conditions.

Id. This interpretation was supported by the claim’s inclusion of a step to administer an “effective amount” of the antibody, because the amount of the antibody needed to treat vasomotor symptoms could differ from the amount needed to treat other conditions. Id. at 1342–43. The CAFC noted additionally that the preambles provided an antecedent basis for at least one claim term. Id. at 1343. The preambles of the claim referred to a method for treating symptoms “in an individual” and a step of the claim provided for administering an “effective amount” of the antibody “to the individual.” Id. “Axiomatically, without an individual experiencing vasomotor symptoms, there would be no effective amount that could be used to treat the nonexistent symptoms.” Id. The “individual” was therefore considered to be “part of the statement of intended purpose.” Id.

The ’562 Patent has only one claim, and the preamble reflects the purpose of the claim to “treat[] cancer cells defective in homologous recombination.” ’562 Patent at 37:26–27; see, e.g., id. at Abstract (“The present invention relates to the

use of an agent that inhibits the activity of an enzyme that mediates repair of a DNA strand break in the manufacture of a medicament for the treatment of diseases caused by a defect in a gene that mediates homologous recombination.”); id. at 1:6–9 (“This invention relates to the use of an agent that inhibits the activity of an enzyme which mediates the repair of DNA strand breaks in the treatment of certain forms of cancer in particular breast cancer.”); id. at 3:18–20 (“A gene involved in HR may be a tumour suppressor gene. The invention thus provides for the treatment of cancer cells defective in the expression of a tumour suppressor.”). Reading the specification as a whole and considering all portions of the written description to be internally consistent requires that a person practicing the claimed method must intend to treat cancer cells defective in homologous recombination. See Budde, 250 F.3d at 1379–80. The purpose of the method here is not confined to the preamble in the same way as in Eli Lilly & Co., because the claim language provides for “identifying a human patient with a familial predisposition to gene-linked hereditary cancer, wherein said cancer comprises *cancer cells defective in homologous recombination.*” ’562 Patent at 37:28–29, 38:24–25 (emphasis added); see Eli Lilly & Co., 8 F.4th at 1342. However, the preamble still limits the scope of the claim because the claim would not read on the performance of the same method steps to treat other conditions, e.g., cancer cells defective in other

ways. See Eli Lilly & Co., 8 F.4th at 1343. This is further supported by the claim language’s incorporation of the phrase “therapeutically effective amount.” ’562 Patent at 38:27–28. “The preamble[] provide[s] the only metric by which one practicing the claim could determine whether the amount administered is a ‘[therapeutically] effective amount.’” Eli Lilly & Co., 8 F.4th at 1342.

“[T]here is no litmus test for determining whether a preamble is limiting.” Id. at 1340 (internal quotation and citation omitted). However, there are established circumstances in which a preamble of a claim directed to methods is limiting. Id. at 1340–41. The Court concludes that the preambular language “a method of treatment of cancer cells defective in homologous recombination (HR)” is more than a mere statement describing the invention’s intended use. ’562 Patent at 37:26–27. Because the preamble is necessary to give meaning and life to Claim 1, the Court holds that the preamble language “a method of treatment of cancer cells defective in homologous recombination (HR)” is limiting. Id.

The Parties also raised arguments regarding whether the language of Claim 1 of the ’562 Patent included an antecedent basis for reading the steps of the method claim in a particular order. Pls.’ Br. at 21; Defs.’ Resp Br. at 4–6. Plaintiffs asserted that a physician must have a particular intent to practice the claim because “[t]he physician [] must understand that the patient has HR-defective cancer and

that the compound is a PARP-1 inhibitor[.]” Pls.’ Br. at 21. Defendants argued that there are no “markers of intent” that would be expected in a claim intending a specific order of steps such as ordinals and conditional language. Defs.’ Br. at 78; Defs.’ Resp. Br. at 6. The Court will not revisit the prior construction that the method steps must be performed in a particular order. Markman Op. at 26–29.

This Court clarifies that the language of the method steps in Claim 1 of the ’562 Patent that a physician “identify[] a human patient with a familial predisposition to gene-linked hereditary cancer, wherein said cancer comprises cancer cells defective in homologous recombination” incorporates an intent to treat a patient with cancer cells defective in homologous recombination. ’562 Patent at 37:28–29, 38:24–25. This would be true regardless of the order that the steps of the claims are to be performed because the intent lies within the claim language. Axiomatically, without knowledge that a patient is suffering from cancer with cancer cells defective in homologous recombination, a physician cannot practice the claimed method as set forth in the ’562 Patent. Therefore, Claim 1 of the ’562 Patent includes a mental intent element for a person to practice the claim.

CONCLUSION

For the foregoing reasons, the Court adopts the final constructions of the Markman Opinion, ECF Nos. 296, 297, and clarifies construction of the language

in Claim 1 of the '562 Patent as follows:

1. the preamble of Claim 1 of the '562 Patent is limiting, as the method requires treatment of cancer cells defective in homologous recombination; and
2. the method steps of Claim 1 of the '562 Patent contain a mental intent element of an intent to treat a human patient with cancer cells defective in homologous recombination to practice the claim.

IT IS SO ORDERED this 21st day of September, 2026.

/s/ Jennifer Choe-Groves

Jennifer Choe-Groves
U.S. District Court Judge*

* Judge Jennifer Choe-Groves, of the United States Court of International Trade, sitting by designation.