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

[Granting Plaintiffs' Motion to Exclude Expert Opinions.]

Date: October 2, 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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Jennifer Choe-Groves, Judge: 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 (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 "relate[d] 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."

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[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 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.

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-ribose)Polymerase ("PARP-1") from binding to DNA stand breaks and catalyzing processes that may be linked to genetic instability. Id. at 1:22–45.

Plaintiffs filed a Motion to Exclude Opinions of Dr. Dana Ferraris ("Pls.' Motion") (ECF Nos. 352, 353). Defendants filed a Brief in Opposition to Plaintiffs' Motion to Exclude Opinions of Dr. Dana Ferraris ("Defs.' Br. in Opp.") (ECF No. 368), and Plaintiffs filed a Reply in Support of Their Motion to Exclude Opinions of Dr. Dana Ferraris (ECF No. 385).

For the following reasons, the Court grants Plaintiffs' motion to exclude.

Rule 702 of the Federal Rules of Evidence governs the admissibility of expert testimony, permitting a witness "qualified as an expert by knowledge, skill, experience, training, or education" to testify in the form of an opinion, provided that "the proponent demonstrates to the court that it is more likely than not that:"

> (a) the expert's scientific, technical, or other specialized knowledge will help the trier of fact to understand the evidence or to determine a fact in issue;
> (b) the testimony is based on sufficient facts or data;
> (c) the testimony is the product of reliable principles and methods; and
> (d) the expert's opinion reflects a reliable application of the principles and methods to the facts of the case.

Fed. R. Evid. 702. The party that proffers the expert testimony bears the burden of establishing its admissibility by a preponderance of the evidence. Daubert v. Merrell Dow Pharms., Inc., 509 U.S. 579, 592 n.10 (1993).

The Court must act as a gatekeeper to prevent expert testimony from running afoul of Rule 702, even when the matter will not be tried before a jury. See id., at 596–97; see also Cohen v. Cohen, 125 F.4th 454, 460 (3d Cir. 2025) ("District courts are tasked with a 'rigorous gatekeeping function[.]'") (quoting Elcock v. Kmart Corp., 233 F.3d 734, 741 (3d Cir. 2000)). Although the concerns with allowing broad expert testimony are arguably less relevant when the court is the trier of fact in a bench trial, Rule 702 still applies in the bench trial context. See Magistrini v. One Hour Martinizing Dry Cleaning, 180 F. Supp. 2d 584, 596 n.10 (D.N.J. 2002) ("[W]here the Court itself acts as the ultimate trier of fact . . . , the Court's role as a gatekeeper pursuant to Daubert is arguably less essential"), aff'd, 68 F. App'x 356 (3d Cir. 2003).

The U.S. Court of Appeals for the Third Circuit has described Rule 702 as embodying a "trilogy of restrictions on expert testimony: [1] qualification, [2] reliability[,] and [3] fit." Calhoun v. Yamaha Motor Corp., U.S.A., 350 F.3d 316, 321 (3d Cir. 2003) (quoting Schneider ex rel. Est. of Schneider v. Fried, 320 F.3d 396, 405 (3d Cir. 2003)).

The Parties focus their dispute on this first requirement that a witness must

possess specialized expertise in order to be qualified as an expert. It is black-letter law that for a witness to be qualified to testify as an expert, "the witness [must] possess specialized expertise." Calhoun, 350 F.3d at 321. Plaintiffs note that Dr. Ferraris is a medicinal chemist, which Plaintiffs describe as "someone who studies the chemistry of medicines: 'making molecules, designing them, [and] testing them *in vitro*,' *i.e.*, testing molecules in laboratory vessels rather than in living things (*in vivo*) or in human patients." Pls.' Motion at 1 (citing Transcript of Video-Recorded Deposition of Dana Ferraris, PhD, MBA ("Dep. Tr.") at 22:5–15 (ECF No. 353–3)). Plaintiffs assert that Dr. Ferraris' expert reports "go far beyond the field of medicinal chemistry," and testimony proffered on genetics, cancer biology, clinical trial interpretation, and the treatment of cancer are inadmissible areas outside of Dr. Ferraris' areas of expertise. Id. Plaintiffs argue that Dr. Ferraris' testimony outside his area of expertise should be precluded as inadmissible at trial. Id. at 2, 6–25.

Plaintiff asserts that Dr. Ferraris "***expressly concedes he is not an expert*** in the fields about which Defendants have asked him to opine." Id. at 1 (emphasis in original). Plaintiffs specifically cite passages from Dr. Ferraris' deposition testimony in which he admitted that he is not an expert in genetics, cancer biology, clinical trial interpretation, and the treatment of cancer. Id. at 2 (citing Dep. Tr. at 10:4–7, 10:12–20, 13:13–25, 15:2–16, 16:7–15, 20:15–21:4, 24:3–9, 58:14–24,

159:11–13, 160:8–11, 163:3–8). Dr. Ferraris identified that a person of ordinary skill in the art would include one not only with skills in medicinal chemistry, but also one who works on a team with others with "a medical degree and post-graduate medical education or training (e.g., residency or fellowship) related to oncology, and/or a doctoral degree (Ph.D.) in medicinal chemistry, molecular biology, cancer genetics, and/or related fields, as well as at least several years of experience in these fields and/or the study of cancer and its treatments." Opening Expert Rpt. Dana Ferraris, PhD, MBA ¶ 71 (ECF No. 353–1).

Defendants respond that the challenge to Dr. Ferraris' testimony is an inappropriate attack on his credibility. Defs.' Br. in Opp. at 1. Defendants contend that "[w]hether he modestly agrees he is not formally an expert by training in certain specific subject matter is not dispositive." Id. Defendants describe Dr. Ferraris' experience as broadly related to the entire field of PARP-1 inhibitors and their use in the treatment of cancer, as well as drug development from "soup to nuts" that have gone through clinical trials, including one receiving FDA approval. Id. at 1–2. As Defendants frame the issue, "[t]he question of whether Dr. Ferraris could be 'more qualified' in a particular area goes only to the weight of his testimony, not its admissibility." Id. at 12.

The U.S. Court of Appeals for the Federal Circuit has noted that "[i]n 2023, Rule 702 was amended to clarify that the proponent of expert testimony bears the

burden of establishing its admissibility and to emphasize that an expert's opinion must stay within the bounds of a reliable application of the expert's basis and methodology." EcoFactor, Inc. v. Google LLC ("EcoFactor"), 137 F.4th 1333, 1339 (Fed. Cir. 2025) (en banc), cert. denied, 146 S. Ct. 333 (2025). Although the gatekeeping function is necessarily flexible, the Supreme Court has explained that, "this leeway 'is not discretion to abandon the gatekeeping function' or 'perform the function inadequately.'" Cohen, 125 F.4th at 460 (quoting Kumho Tire Co. v. Carmichael, 526 U.S. 137, 158–59 (1999) (Scalia, J., concurring)).

The Court here focuses on the question of whether Dr. Ferraris is a qualified expert and whether his proposed testimony is within the bounds of a reliable application of his expert basis. Although this case involves a bench trial and this Court is the trier of fact, Rule 702 still applies to the admissibility of an expert.

The Court finds persuasive Dr. Ferraris' own repeated admissions that he is not an expert by training in the fields of genetics, cancer cell biology, clinical trial interpretation, and the treatment of cancer. For example, Dr. Ferraris stated that he is "not an expert in genetics," Dep. Tr. at 10:12–14; he has no "expertise [in] genetics and gene mutations related to cancers," id. at 21:1–4; and he "would not purport to know how to treat a cancer patient," id. at 13:19–21. Plaintiffs note other examples of Dr. Ferraris admitting that he is not qualified in certain matters: Dep. Tr. at 13:13–15 ("not a clinician by training"), 13:16–18 ("never treated a

cancer patient"), 13:22–25 ("not an expert in how to diagnose cancer patients for treatment"), 15:2–5 ("not an expert in choosing a particular course of therapy for a particular cancer patient"), 15:6–9 ("not an expert in determining what genetic screening to give to a cancer patient"), 15:10–12 (never "evaluated the results of a BRCA test for a human patient"), 15:13–16 ("not an expert in the available therapies today for the treatment of any type of cancer"), 16:7–9 (never "conducted a clinical trial"), and 16:10–12 ("not an expert in the design of clinical trials"). Pls.' Motion at 10. The Court agrees with Plaintiffs that, "[s]omeone who admittedly lacks expertise in the interpretation of clinical trials should not be allowed to interpret them at trial." Id. In addition, Plaintiffs described that Dr. Ferraris expressly and repeatedly conceded that he lacks the expertise necessary to offer opinions reliably concerning cancer biology. See Dep. Tr. at 160:8–11 ("not a tissue biologist or a cancer biologist"), 24:7–9 (no "expertise in translational biology"), 58:17–19 ("Not being a cancer biologist…"), 159:11–13 ("I'm not a cancer biologist…"); Pls.' Motion at 13.

The Court is cognizant of the 2023 amendments to Rule 702, which stated in an Advisory Committee note that judges should apply Rule 702 as gatekeepers for admissibility, rather than weighing the evidence. See EcoFactor, 137 F.4th at 1339 ("The Advisory Committee noted that 'many courts have held that the critical questions of the sufficiency of an expert's basis, and the application of the expert's

methodology, are questions of weight and not admissibility. These rulings are an incorrect application of Rules 702 and 104(a).'"). Although EcoFactor did not directly address the qualifications of an expert witness, the Court concludes that the gatekeeping functions of admissibility under amended Rule 702 should not be subsumed by a preference to regard the expert's testimony by credibility or the weight of the evidence, as Defendants argue in their response brief. See, e.g., Defs.' Br. in Opp. at 12.

The Court concludes that it is appropriate to evaluate Dr. Ferraris' qualifications under the admissibility standards of Rule 702, rather than evaluating his testimony as a matter of credibility or weight of the evidence. Dr. Ferraris admitted repeatedly that he is not a trained expert in the fields of genetics, cancer cell biology, clinical trial interpretation, and the treatment of cancer. See, e.g., Dep. Tr. at 10:12–14, 13:13–25, 15:2–16, 16:7–12. Therefore, Dr. Ferraris should be allowed to testify only in areas of his training and expertise, which is medical chemistry. See Toscano v. Case, No. 11-4121, 2013 WL 5333206, at *7 (D.N.J. Sept. 20, 2013) ("Moreover, a proffered expert's field of expertise must encompass the subject matter of the expert's testimony, and not merely be adjacent to it.") (citations omitted); Player v. Motiva Enters. LLC, No. 02-3216, 2006 WL 166452, at *5 (D.N.J. Jan. 20, 2006) ("[W]here a proposed expert's area of experience is adjacent to, but not actually encompassing, the subject matter of his testimony, he

may be deemed unqualified."), aff'd, 240 F. App'x 513 (3d Cir. 2007).

CONCLUSION

For the foregoing reasons, the Court holds that Dr. Ferraris is not a qualified expert under Rule 702 in the fields of genetics, cancer cell biology, clinical trial interpretation, and the treatment of cancer, and he will not be permitted to testify on these issues at trial. Dr. Ferraris is a qualified expert in medicinal chemistry and will be permitted to testify about matters within his field of expertise and training.

IT IS SO ORDERED this 2nd day of October, 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.