

**IN THE UNITED STATES DISTRICT COURT  
FOR THE DISTRICT OF DELAWARE**

PURDUE PHARMA L.P. and PURDUE  
PHARMACEUTICALS L.P.,

*Plaintiffs,*

v.

ACCORD HEALTHCARE INC.,

*Defendant.*

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Civil Action No. 22-913-WCB

**MEMORANDUM OPINION AND ORDER**

Plaintiffs Purdue Pharma L.P. and Purdue Pharmaceuticals L.P. (collectively, “Purdue”) brought this Hatch-Waxman Act patent case against defendant Accord Healthcare Inc. (“Accord”), alleging infringement of U.S. Patent Nos. 11,304,908 (“the ’908 patent”) and 11,304,909 (“the ’909 patent”). Accord has moved for judgment on the pleadings under Federal Rule of Civil Procedure 12(c). For the reasons set forth below, the motion is DENIED.

**I. Background**

The ’908 and ’909 patents are generally directed to tablet formulations that are “tamper resistant.” ’908 patent, Abstract. As Purdue explains in its brief, the object of the asserted patents is to make tablets that are “hard enough to resist crushing by abusers and viscous enough to deter intravenous abuse by abusers who manage to crush the tablets into particles and mix with water for injection.” Dkt. No. 58 at 2. Claim 1 of the ’908 patent is generally representative of the claimed inventions. It recites as follows:

1. A solid oral extended release pharmaceutical dosage form, comprising a shaped, convection heated, and cooled extended release matrix, said matrix comprising at least one polyethylene oxide (PEO) having, based on rheological measurements, an

approximate molecular weight of at least 800,000, and at least one opioid analgesic, wherein (a) the shaped matrix is convection heated to an elevated temperature that is at least the softening temperature of said PEO for a time period of at least about 1 minute and thereafter cooled; and (b) a plurality of convection heated particles of PEO adhere to or fuse with each other within the matrix.

'908 patent, cl. 1

Purdue owns other patents in the same family as the '908 and '909 patents, including U.S. Patent Nos. 9,763,933 (“the '933 patent”); 9,775,808 (“the '808 patent”); and 9,763,886 (“the '886 patent”). In a prior action brought in this district (“*Accord I*”), Purdue asserted claim 3 of the '933 patent, claim 3 of the '808 patent, and claim 6 of the '886 patent against Accord. In *Accord I*, Judge Andrews held a bench trial and determined that all the asserted claims were invalid for obviousness under 35 U.S.C. § 103. *Purdue Pharma L.P. v. Accord Healthcare Inc.*, No. 20-1362, 2023 WL 2894939, at \*25 (D. Del. Apr. 11, 2023).

## **II. Legal Standard**

Under Federal Rule of Civil Procedure 12(c), “[a]fter the pleadings are closed—but early enough not to delay trial—a party may move for judgment on the pleadings.” A Rule 12(c) motion “will not be granted unless the movant clearly establishes that no material issue of fact remains to be resolved and that [it] is entitled to judgment as a matter of law.” *Jablonski v. Pan Am. World Airways, Inc.*, 863 F.2d 289, 290 (3d Cir. 1988) (internal quotation marks and citation omitted). The standard that applies to a Rule 12(b)(6) motion to dismiss for failure to state a claim also applies to motions brought under Rule 12(c); that is, in the common situation in which the defendant moves to dismiss the complaint, the court “must accept the truth of all factual allegations in the complaint and must draw all reasonable inferences in favor of the non-movant.” *Revell v. Port Auth. of New York, New Jersey*, 598 F.3d 128, 134 (3d Cir. 2010). More generally, “[t]he purpose of judgment on the pleadings is to dispose of claims where the material facts are undisputed and judgment can be entered on the competing pleadings and exhibits thereto, and

documents incorporated by reference.” *Venetec Int’l, Inc. v. Nexus Med., LLC*, 541 F. Supp. 2d 612, 617 (D. Del. 2008).

### **III. Discussion**

Accord argues that Purdue is barred from asserting the claims of the ’908 and ’909 patents because those claims are invalid for obviousness due to collateral estoppel from Judge Andrews’s findings in the *Accord I* action. In response, Purdue argues principally that (1) Accord’s motion impermissibly asks the court to take judicial notice of the *Accord I* trial record; and (2) Accord has failed to demonstrate that collateral estoppel applies to the claims asserted in this case.

#### ***A. Judicial Notice***

The parties dispute whether it is proper to take judicial notice of the *Accord I* record in ruling on the present motion. Requests for judicial notice are governed by Federal Rule of Evidence 201. Under Rule 201, “[t]he court may judicially notice a fact that is not subject to reasonable dispute because it: (1) is generally known throughout the trial court’s territorial jurisdiction; or (2) can be accurately and readily determined from sources whose accuracy cannot reasonably be questioned.” Fed. R. Evid. 201(b). Moreover, if a party requests judicial notice and “the court is supplied with the necessary information,” the court “must take judicial notice.” Fed. R. Evid. 201(c). It is well settled that in ruling on a motion for judgment on the pleadings a court may take judicial notice of “the factual record of a prior proceeding.” *Lundbeck v. Apotex Inc.*, No. 18-cv-88, 2020 WL 3507795, at \*3 (D. Del. June 26, 2020) (citing *Oneida Motor Freight, Inc. v. United Jersey Bank*, 848 F.2d 414, 416 n.3 (3d Cir. 1988)).

Purdue does not dispute that a court may take judicial notice of a prior proceeding, but argues that at the pleading stage the court may take notice of only “the existence of the opinion, not for the truth of the facts asserted in the opinion.” Dkt. No. 58 at 8. That assertion is incorrect.

As the Third Circuit explained in *M & M Stone Co. v. Pennsylvania*, a case cited by Purdue, “[i]n the context of deciding a Rule 12(b)(6) motion that raises issue preclusion concerns . . . it is axiomatic that a court must still consider the prior adjudication in order to determine whether issue preclusion bars that plaintiff’s claims.” 388 F. App’x 156, 162 (3d Cir. 2010). The court added that to “disallow a court from recognizing the existence of other judicial opinions would thwart a defendant’s right to raise issue preclusion in a motion to dismiss, and it would obviate the entire purpose of the doctrine.” *Id.* Other cases are in accord. *See, e.g., Johnson v. City of New York*, 347 F. App’x 850, 851 (3d Cir. 2009) (noting that “a *res judicata* defense may be raised in a motion to dismiss when the defense is apparent on review of court records of which a court can take notice”); *Robinson v. Robinson*, No. 13-5275, 2015 WL 224629, at \*2 (D.N.J. Jan. 15, 2015) (declining to reconsider dismissal of a case due to collateral estoppel because “[r]esolving Plaintiff’s claims only necessitated a review of Plaintiff’s complaint and court records from his prior action in this Court”); *Uniloc 2017 LLC v. Zenpayroll, Inc.*, No. 19-1075, 2021 WL 271800 (D. Del. Jan. 27, 2021) (observing that “[t]he court may decide collateral estoppel on a motion to dismiss under Rule 12(b)(6),” and proceeding to consider the contents of another district court’s claim construction order).

To be sure, for purposes of a Rule 12(c) motion, judicial notice of the prior action extends only to the issues decided and facts found by the court in the prior action. It does not extend, for example, to the evidence presented to the court at trial or transcripts of the proceedings that took place during the action. *See M & M Stone*, 388 F. App’x at 162 (“[A] court that examines a transcript of a prior proceeding to find facts converts a motion to dismiss into a motion for summary judgment.”) (quoting *Lum v. Bank of Am.*, 361 F.3d 217, 221 n.3 (3d Cir. 2004)). But with respect to issues actually decided by the court in *Accord I*, Purdue may be precluded from re-

litigating those issues in this action. Accordingly, for that purpose I may take judicial notice of the trial record in *Accord I*.<sup>1</sup>

### ***B. Collateral Estoppel***

I now turn to whether the requirements for collateral estoppel have been satisfied, such that Purdue would be precluded from asserting the claims of the '908 and '909 patents in this action.

Collateral estoppel applies to an issue when the following four criteria are met: (1) the identical issue was previously adjudicated; (2) the issue was actually litigated in the prior action; (3) the previous determination was necessary to the decision; and (4) the party being precluded must have been fully represented in the prior action. *Jean Alexander Cosms., Inc. v. L'Oreal USA, Inc.*, 458 F.3d 244, 249 (3d Cir. 2006).<sup>2</sup> The parties' dispute focuses on the first criterion: whether the validity issues presented by this case are the same as those decided in *Accord I*.

When determining whether the patent validity issues are the same as those decided in a prior action, courts "do[] not limit collateral estoppel to patent claims that are identical." *Ohio Willow Wood Co. v. Alps S., LLC*, 735 F.3d 1333, 1342 (Fed. Cir. 2013). Instead, courts focus on "the identity of the *issues* that were litigated." *Id.* The question is therefore whether "the differences between the unadjudicated patent claims and adjudicated patent claims . . . materially alter the question of invalidity." *Id.* *Accord* argues that the claims of the '908 and '909 patents are not sufficiently different from the claims asserted in *Accord I* such that the question of validity is materially altered.

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<sup>1</sup> *Accord* also asks that I take judicial notice of the prosecution history of the '908 and '909 patents. Dkt. No. 55 at 6. Because the prosecution histories are not necessary to resolve the present motion, I need not take judicial notice of those items in any event.

<sup>2</sup> In patent cases, regional circuit law applies to general principles of collateral estoppel and Federal Circuit law applies to issues unique to patent cases. *Aspex Eyewear, Inc. v. Zenni Optical Inc.*, 713 F.3d 1377, 1380 (Fed. Cir. 2013).

Claims 1 and 21 are the two independent claims in both the '908 and '909 patents. Each of those claims requires, among other elements, “a plurality of convection heated particles of PEO [polyethylene oxide]” that “adhere to or fuse with each other within the matrix.” As Accord admits in its brief, that limitation was not expressly recited in the claims in *Accord I*. Dkt. No. 55 at 13. And in *Accord I*, Judge Andrews did not discuss or decide whether the prior art asserted in that case disclosed that limitation. *See generally Accord I*, 2023 WL 2894939.

Nonetheless, Accord argues that the presence of the “adhere to or fuse with” limitation does not materially alter the question of invalidity with respect to the asserted claims because “the adherence or fusion of the heated particular of PEO with each other within the matrix is the inherent result of heating the PEO matrix as described in [the prior art asserted in *Accord I*].” Dkt. No. 55 at 13. In support of that assertion, Accord relies on the transcript of the trial in *Accord I*, during which Accord’s expert testified to that general effect. *Id.* (quoting Dkt. No. 55-9 at 212–13, 220–21). As noted, however, testimony offered during a prior proceeding is not subject to judicial notice for purposes of finding facts. *See M & M Stone*, 388 F. App’x at 162.

In addition to its expert’s testimony, Accord points to the disclosures of the '908 patent specification. The specification mentions adherence and fusion only once, in the following passage:

Without wanting to be bound to any theory it is believed that the curing at a temperature that is at least as high as the softening temperature of the high molecular weight polyethylene oxide causes the polyethylene oxide particles to at least adhere to each other or even to fuse.

'908 patent, col. 17, ll. 58–62. In view of that disclosure, Accord asserts that the “adhere to or fuse with” limitation is “an inherent result of curing at the softening temperature of the PEO.” Dkt. No. 60 at 3.

Notably, some of the asserted claims in *Accord I*, such as claim 1 of the '933 patent, required that the dosage form be “air cured by heated air, without compression, for at least about 5 minutes at a temperature above the softening temperature of the high molecular weight PEO.” In *Accord I*, Judge Andrews found that a skilled artisan would “reasonably expect to produce hardened tablets by heating PEO tablets to their melting points in an oven,” and ultimately found the asserted claims to be invalid as obvious. *Accord I*, 2023 WL 2894939, at \*9. Because, in *Accord*'s view, adherence and/or fusion is an inherent result of the curing process claimed in *Accord I*, *Accord* argues that the “adhere to or fuse with” limitation does not materially alter the question of patentability with respect to the '908 and '909 patents.

In response to that argument, *Purdue* contends that (1) inherency doctrine applies only to the disclosures of prior art references, and does not bear on the application of collateral estoppel; and (2) there is a factual dispute as to whether adherence and fusion are inherent results of the curing process claimed in *Accord I*. For purposes of the present motion, I will assume without deciding that the inherency doctrine applies to the present motion.<sup>3</sup> But even assuming that the inherency doctrine applies, I agree with *Purdue* that there is a disputed factual question that precludes a grant of judgment on the pleadings.

As the Federal Circuit has explained, for a particular claim limitation to be inherent in a prior art disclosure, the limitation at issue “necessarily must be present, or the natural result of the combination of elements explicitly disclosed by the prior art.” *PAR Pharm., Inc. v. TWI Pharms., Inc.*, 773 F.3d 1186, 1194 (Fed. Cir. 2014). That standard is a high one; “inherency ‘may not be

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<sup>3</sup> As Judge Fallon explained in *Purdue Pharma L.P. v. Mylan Pharmaceuticals Inc.*, there is competing authority as to whether it is proper to apply the inherency doctrine to previously invalidated claims that are not themselves prior art. *Purdue Pharma L.P. v. Mylan Pharms. Inc.*, No. 15-1155, 2017 WL 784989, at \*8 (D. Del. Mar. 1, 2017), *report and recommendation adopted*, 2017 WL 2569604 (D. Del. June 13, 2017).

established by probabilities or possibilities.” *Endo Pharms. Sols., Inc. v. Custopharm Inc.*, 894 F.3d 1374, 1381 (Fed. Cir. 2018) (quoting *PAR*, 773 F.3d at 1195). In other words, “[t]he mere fact that a certain thing *may* result from a given set of circumstances is not sufficient” to establish inherency. *Id.* (quoting *PAR*, 773 F.3d at 1195).

The disclosure in the ’908 patent specification amounts to no more than an assertion that adherence and/or fusion may result from curing the PEO at a high temperature. The specification qualifies its statement by noting that “it is believed that” curing at a high temperature results in adherence and/or fusion. *See* ’908 patent, col. 17, ll. 58–62. That statement effectively amounts to a suggestion that adherence or fusion may result from curing at high temperatures, which is insufficient to establish inherency. *See Endo*, 894 F.3d at 1381. As the specification demonstrates, a number of variables exist in the manufacturing process, such as the use of direct compression, the order and sequencing of compression and curing, the percentage of PEO that melts, the curing temperature and time, the use of a cooling step, and the equipment used in manufacturing. ’908 patent, col. 17, line 30, through col. 19, line 63. The specification does not state or even imply that adherence and/or fusion is an inherent result of every combination of variables that involve curing PEO at a temperature above its softening temperature. And Judge Andrews did not decide any such questions in his *Accord I* opinion.

More generally, courts have often found that the question of inherency is a factual question that should be reserved for trial. *See, e.g., Purdue*, 2017 WL 784989, at \*8; *Purdue Pharma L.P. v. Collegium Pharm., Inc.*, 335 F. Supp. 3d 149, 166 (D. Mass. 2018) (declining to hold, at the summary judgment stage, that the plaintiff was “estopped from litigating the validity of the [asserted] patent by application of the inherency doctrine”). Even assuming that the inherency doctrine applies to the facts of this case, the question whether adherence and/or fusion is inherent




in curing PEO at a high temperature is a disputed factual question not suitable for resolution at the pleading stage.

Because a factual dispute exists with respect to each independent claim asserted in this action, I need not address the parties' arguments regarding the dependent claims of the '908 and '909 patents. Accord's motion for judgment on the pleadings is DENIED.

IT IS SO ORDERED.

SIGNED this 8th day of September, 2023.

  
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WILLIAM C. BRYSON  
UNITED STATES CIRCUIT JUDGE