

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

INTERCEPT PHARMACEUTICALS, INC.,  
and INTERCEPT PHARMA EUROPE LTD.,

Plaintiffs,

v.

APOTEX INC., et al.,

Defendants.

C.A. No. 20-1105-MN  
(CONSOLIDATED)

**MEMORANDUM ORDER**

At Wilmington, this 1st day of September, 2022, having reviewed the parties' submissions regarding Defendants' request for leave to amend their answers and counterclaims (D.I. 216, 220, 221, 222, 225, 229) and having held a lengthy hearing on August 31, 2022;

IT IS ORDERED that Defendants' request for leave to amend their answers and counterclaims is GRANTED for the following reasons:

Defendants seek to add affirmative defenses and seek declaratory judgments of unenforceability because of inequitable conduct with respect to six of the seven patents-in-suit. Three of those patents, U.S. Pat. Nos. 9,238,673, 10,173,073, and 10,047,117 (collectively, the "purity patents"), relate to compositions of obeticholic acid ("OCA") containing less than 1% of a particular impurity. The other three, U.S. Pat. Nos. 10,052,337, 10,751,349, and 10,758,549 (collectively, the "particle size patents"), relate to compositions with very small particles of OCA. Defendant's motion was brought almost a year after the deadline to amend and five months after

Plaintiffs produced most of the documents cited by Defendants to support their allegations. (D.I. 26; D.I. 220 at 2, Ex. A-1.)

In accordance with Federal Rules of Civil Procedure 15(a)(2) and 16(b)(4), the Court finds that Defendants have shown good cause to amend their pleadings now and that permitting the amendments would not result in undue prejudice to Plaintiffs. Defendants' theories of inequitable conduct, one of which relates to the purity patents and the other relates to the particle size patents, center on the purity and particle size of batches of OCA that Plaintiffs had a contract manufacturer make in 2004 and 2005. Plaintiffs produced some documents relating to those batches back in March 2022, but Defendants claim that they did not realize that certain batches were manufactured using a process disclosed in the prior art until they received an interrogatory answer on June 13, 2022 that relied on Rule 33(d) and cited documents written in Italian, and they deposed two inventors on July 13 and 27, 2022. Defendants first gave notice that they were pursuing an inequitable conduct theory in their final invalidity contentions on July 7, 2022, then they sought consent to amend their pleadings on August 5, 2022.

Inequitable conduct must be pleaded with particularity in accordance with Rule 9(b), and “the pleading must identify the specific who, what, when, where, and how of the material misrepresentation or omission committed before the PTO.” *Exergen Corp. v. Wal-Mart Stores, Inc.*, 575 F.3d 1312, 1328 (Fed. Cir. 2009). “[A] pleading of inequitable conduct under Rule 9(b) must include sufficient allegations of underlying facts from which a court may reasonably infer that a specific individual (1) knew of the withheld material information or of the falsity of the

material misrepresentation, and (2) withheld or misrepresented this information with a specific intent to deceive the PTO.” *Id.*

For their assertion of inequitable conduct during prosecution of the purity patents, the only “specific individual” named in Defendants’ proposed amended pleadings is Dr. Rewolinski, one of the inventors. (*See* D.I. 220, Ex. A-1 ¶¶ 198–233.) At the hearing, Defendants confirmed that they were only alleging inequitable conduct by Dr. Rewolinski as to those patents. Defendants allege that Dr. Rewolinski knew she made a misleading declaration to the PTO, and Defendants’ proposed pleadings rely on statements made by Dr. Rewolinski at her deposition on July 13, 2022. (*E.g.*, D.I. 220, Ex. A-1 ¶¶ 76–79.)

For their assertion of inequitable conduct during prosecution of the particle size patents, the proposed pleadings allege inequitable conduct on the part of “Intercept, through its prosecution counsel, and the named inventors, including at least Richard Lancaster.” (*Id.* ¶¶ 237, 251, 259.) At the hearing, Defendants confirmed that they did not intend to proceed with inequitable conduct allegations against prosecution counsel; however, Defendants indicated (for the first time) that they sought to accuse not only Mr. Lancaster, but also Dr. Rewolinski. The only “specific individual” identified by Defendants’ proposed allegations regarding the particle size patents is Mr. Lancaster. Dr. Rewolinski is not a named inventor on those patents, nor is there an allegation that she was involved in their prosecution. Accordingly, for the particle size patents, the Court will analyze only whether Defendants can proceed with their allegations that Mr. Lancaster committed inequitable conduct. Defendants’ proposed pleadings rely on the link between evidence of how the batches were made and the particle size data in the possession of Mr. Lancaster to

support an inference that he knew the prior art process made compositions that fall within the particle size patent claims. (*Id.* ¶¶ 87–90.)


Without commenting on the ultimate merits of Defendants’ inequitable conduct allegations, the Court concludes that the proposed pleadings plausibly suggest that Dr. Rewolinski and Mr. Lancaster acted with knowledge and intent, so the amendment is not futile.

It is not possible or feasible for the Court to determine at this juncture, based on the new allegations in Defendants’ proposed pleadings, to make a definitive determination as to whether the evidence Defendants had back in March 2022 would have been enough for Defendants to raise an inequitable conduct claim that could have survived a motion to dismiss. But the Court is persuaded that Defendants cannot be faulted for waiting until they had obtained additional evidence in this case before pleading a defense with such strict requirements for pleading and proof. *See Lipocine Inc. v. Clarus Therapeutics, Inc.*, No. 19-622, 2020 WL 4794576, at \*2–4 (D. Del. Aug. 18, 2020) (Bryson, J.). Connecting how each batch was made with the data of its purity and particle size is an important part of Defendants’ theory. Defendants have persuaded the Court that they did not have a sufficiently complete picture of the evidence until after June 13, 2022, when Plaintiffs’ interrogatory answer linked manufacturing documents written in Italian to the purity and particle size data. The Court further finds that Defendants acted diligently after June 13, 2022, and proposed an amendment in less than two months.

Accordingly, Defendants may proceed with their claims that Dr. Rewolinski committed inequitable conduct during prosecution of the purity patents and that Mr. Lancaster committed inequitable conduct during prosecution of the particle size patents. The Court finds that allowing those claims in the case at this stage will not unduly prejudice Plaintiffs. Defendants say that they will not need any additional fact discovery in support of those claims. Plaintiffs say they will need

some additional fact discovery and also additional time to respond to Defendants' expert reports, which are due soon. The parties should work together to ensure that Plaintiff can accomplish what it needs to do in order to maintain the trial schedule.

Defendants have leave to file the proposed amended pleadings set forth at D.I. 220, Exs. A-1 through A-5.



THE HONORABLE JENNIFER L. HALL  
UNITED STATES MAGISTRATE JUDGE