

IT IS HEREBY ORDERED that: (i) Plaintiffs' motion for judgment on the pleadings (D.I. 11) is DENIED WITHOUT PREJUDICE; and (ii) Defendants' motion for a stay (D.I. 14) is GRANTED IN PART and DENIED IN PART, as explained further below.

1. Plaintiffs first filed a patent infringement action asserting the '551 patent against Defendants based on Defendants' filing of ANDA No. 204787 in July 2013. (D.I. 1 ¶ 34) Hetero, a defendant in the consolidated action *UCB v. Accord* in this Court, served discovery requests, helped develop invalidity contentions, participated in claim construction, and conducted fact and expert discovery as part of a defense team. (D.I. 12 at 4) Six weeks before trial, Hetero amended its ANDA application to convert its certification from Paragraph IV to Paragraph III (meaning it was no longer seeking FDA approval to market its generic drug product before expiration of the '551 patent), and was dismissed from the suit upon stipulation of the parties. (D.I. 12 at 4)

2. The remaining parties to *UCB v. Accord* proceeded to trial without Hetero. After post-trial briefing had concluded, Hetero notified Plaintiffs that it had once again amended its certification – this time, back to Paragraph IV – and once again was asserting that the '551 patent is invalid. (D.I. 18 at 1) It was also, once again, seeking to market its ANDA product before expiration of the '551 patent. (See D.I. 18 at 1) On June 17, 2016, Plaintiffs filed the instant patent infringement action against Defendants, asserting again that Defendants' ANDA infringed the '551 patent. (D.I. 1) The parties stipulated to a stay of all proceedings pending this Court's decision in *UCB v. Accord*. (D.I. 7)

3. On September 2, 2016, this Court issued a final opinion in *UCB v. Accord*,

decision, the Court will not address whether to stay proceedings on the basis of the IPR.

finding the asserted claims of the '551 patent infringed and not invalid. (See C.A. No. 13-1206-LPS D.I. 313, 323) The judgment entered in that case is currently on appeal to the Federal Circuit, which heard oral argument on August 8, 2017. (See *UCB, Inc. v. Accord Healthcare, Inc.*, No. 16-2610 (Fed. Cir.)) Also pending is the reexam of the '551 patent, which was accepted for filing on April 29, 2016. (D.I. 18 at 14)²

4. Once this Court's opinion issued in *UCB v. Accord*, the parties' stipulated stay lifted and Defendants filed their Answer, admitting infringement but asserting counterclaims for a judgment of invalidity based on the same anticipation, obviousness, and obviousness-type double patenting theories that had been litigated in *UCB v. Accord*. (See D.I. 8) On September 13, 2016, Plaintiffs filed their motion for judgment on the pleadings. (D.I. 11) In their motion, Plaintiffs contend that Defendants have admitted their proposed generic product infringes claims 9, 10, and 13 of the '551 patent, and further that they "had a full and fair opportunity to litigate the validity of the '551 patent in [*UCB v. Accord*], which was decided in Plaintiffs' favor. [Defendants] should not be allowed to try again." (D.I. 12 at 2)

5. On October 5, 2016, Defendants responded to Plaintiffs' motion by opposing judgment on the pleadings and cross-moving for a stay. (See D.I. 14, 15) Defendants seek a stay of proceedings in this case pending a decision by the Federal Circuit in the *Accord* Appeal or completion of the reexam, whichever, if either, is first to find the asserted claims invalid. (See D.I. 14)

²According to briefing submitted in a related action, *UCB, Inc. v. Zydus Pharmaceuticals (USA) Inc.*, C.A. 16-903 (D. Del.) (D.I. 11 at 1-2), the PTO has issued a non-final office action rejecting all claims as invalid. In the instant action, the parties have not advised the Court as to the status of the reexam.

6. Whether or not to stay litigation is a matter left to the Court's discretion. *See Dentsply Int'l Inc. v. Kerr Mfg. Co.*, 734 F. Supp. 656, 658 (D. Del. 1990). In exercising this discretion, the Court must weigh the competing interests of the parties and attempt to maintain an even balance. *See Landis v. N. Am. Co.*, 299 U.S. 248, 254-55 (1936). Courts typically rely on three factors in determining whether a stay is appropriate: (1) whether a stay will simplify the issues for trial, (2) whether discovery is complete and a trial date has been set, and (3) whether a stay would unduly prejudice or present a clear tactical disadvantage to the non-moving party. *See id.* Sometimes courts also consider whether the moving party would face hardship or inequity in going forward with the litigation. *See Enhanced Sec. Research, LLC v. Cisco Sys., Inc.*, 2010 WL 2573925, at *3 (D. Del. June 25, 2010).

7. The potential for simplification of the issues in this case is significant. If the Federal Circuit finds some or all of the asserted claims of the '551 patent invalid, its decision would moot some or all of Plaintiffs' claims. The same is true of the PTO's decision in the reexam. If the reexam results in any claim being invalidated, and that decision is upheld on appeal (or is not appealed), the consequence would be the elimination from the instant lawsuit of all infringement and invalidity issues based on that claim. Thus, it would be potentially wasteful to litigate the '551 patent at the same time that the Federal Circuit and the PTO are reviewing its validity. Alternatively, if the *Accord* Appeal results in a finding that any claim of the '551 patent has not been proven invalid, it is quite likely that the validity of such a claim would not have to be relitigated in the instant action – or, if it should need to be evaluated again, the litigation of

that issue is certain to be far narrower, and less complex, than otherwise.³ Additionally, if the asserted claims were to be amended during the reexam, the scope of the claims to be litigated may change. The simplification factor, then, supports a stay.

8. The second factor, whether discovery is complete and a trial date has been set, further supports a stay. While this case is likely to be able to be completed expeditiously and with relatively little (if any) discovery, given the parties' experience litigating similar, if not identical, issues in *UCB v. Accord* (a case in which Defendants remained parties until almost literally the "eve of trial"), it is nonetheless true that this particular case is in its infancy. Discovery is not necessarily "complete" and no trial date has been set – indeed, a scheduling order has not yet been entered.

9. The Court is not persuaded that a stay of an appropriate length will unduly prejudice or present a clear tactical disadvantage to Plaintiffs. Though Plaintiffs have a valid interest in the prompt resolution of pending litigation, it is almost certain that the *Accord* Appeal will be resolved well before this case goes to trial, and thus a stay until a decision is issued in that appeal has the potential to conserve the time and resources of the Court and the parties – including Plaintiffs. Additionally, the 30-month stay of FDA approval does not expire until (at the earliest) November 5, 2018 (*see* D.I. 3; *see also* D.I. 20 at 2 n.2)⁴, meaning – given the

³As Defendants write: "Even assuming that the Federal Circuit were to affirm the district court's judgment in the related case [i.e., *UCB v. Accord*], there may be no open issues, in which case Defendants could drop their challenge to the Patent-In-Suit. And, in the unlikely event that an issue or two remained following a judgment of validity in the other proceedings, any follow-on proceeding would be narrow in scope." (D.I. 20 at 2)

⁴Defendants state that the stay does not expire until December 17, 2018. (*See* D.I. 20 at 2 n.2)

unusual circumstances here – that expedited resolution of this case on the merits may be possible before expiration of the stay, once the *Accord* Appeal is completed.

10. The timing for the completion of the reexam is less predictable, although it is nearly certain to take longer to conclude than will the *Accord* Appeal (especially if an appeal is taken from the reexam). Given the “average length it takes to complete a reexamination (including appeals), it follows that the stay, if granted, would almost certainly last many years.” *Cooper Notification, Inc. v. Twitter, Inc.*, 2010 WL 5149351, at *4 (D. Del. Dec. 13, 2010). Such a delay “may result in some inherent prejudice to the plaintiff.” *Nestle Oil OYJ v. Dynamic Fuels, LLC*, 2013 WL 3353984, at *2 (D. Del. July 2, 2013).

11. Weighing the pertinent factors, and exercising discretion to formulate a proper case-specific resolution, the Court concludes that it is appropriate to stay this action until the earlier of (i) the issuance of a decision by the Federal Circuit in the *Accord* Appeal, or (ii) January 31, 2018. In this way, the Court maximizes the likelihood that it will have the benefit of any holding or views the Federal Circuit issues with respect to issues that are overlapping with the issues presented in the instant litigation. However, as the stay will expire in approximately four months – at which point more than nine months will be left on the automatic 30-month stay – there may still be time remaining (under the unusual circumstances presented here) to complete this litigation on the merits before that stay expires.⁵

12. The Court may award judgment on the pleadings “where the moving party clearly establishes there are no material issues of fact, and that he or she is entitled to judgment as a

⁵Under the circumstances, the Court sees no reason to analyze whether Defendants would face hardship or inequity in the absence of a stay.

matter of law.” *DiCarlo v. St. Mary Hosp.*, 530 F.3d 255, 259 (3d Cir. 2008). Plaintiffs seek such a judgment based on application of the doctrines of collateral estoppel, equitable estoppel, and *stare decisis*. (See D.I. 12 at 8-20) Given the Court’s decision to exercise its discretion to stay this matter, the Court will not at this time determine if Plaintiffs can meet their burden to obtain the relief they have requested.

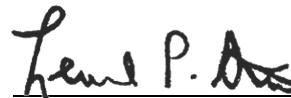
Accordingly, IT IS HEREBY ORDERED that:

A. Plaintiffs’ motion for judgment on the pleadings (D.I. 11) is DENIED WITHOUT PREJUDICE to renew upon the lifting of the stay of this action.

B. Hetero’s motion to stay (D.I. 14) is GRANTED IN PART and DENIED IN PART, to the extent explained in this Order.

C. This case is STAYED until the earlier of: (i) the Federal Circuit’s issuance of a decision in the *Accord* Appeal, or (ii) January 31, 2018.

D. The parties shall advise the Court no later than the earlier of (i) seven (7) days after the issuance of a decision from the Federal Circuit in the *Accord* Appeal, or (ii) January 24, 2018, of their position(s) as to how this case should proceed.



HONORABLE LEONARD P. STARK
UNITED STATES DISTRICT JUDGE