

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

UCB, INC., UCB BIOPHARMA SPRL,	:
RESEARCH CORPORATION TECHNOLOGIES,	:
INC. and HARRIS FRC CORPORATION,	:
	:
Plaintiffs,	:
	:
v.	:
	C.A. No. 16-903-LPS
	:
ZYDUS PHARMACEUTICALS (USA) INC.	:
and CADILA HEALTHCARE LTD. d/b/a	:
ZYDUS CADILA	:
	:
Defendants.	:

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**MEMORANDUM ORDER**

At Wilmington this 28<sup>th</sup> day of September, 2017, having considered the parties' submissions related to Defendants Zydus Pharmaceuticals (USA) Inc. and Cadila Healthcare Ltd. d/b/a Cadila's ("Defendants" or "Zydus")<sup>1</sup> motion to stay proceedings pending the conclusion of the appeal ("Accord Appeal") to the Federal Circuit in *UCB, Inc. v. Accord Healthcare, Inc.*, C.A. No. 13-1206-LPS ("UCB v. Accord") and *ex parte* reexamination Control No. 90/013,709 ("reexam"),<sup>2</sup> which both concern the validity of the patent-in-suit, U.S. Reissue Patent No. 38,551 ("the '551 patent"),

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<sup>1</sup>The record indicates that Plaintiffs have yet to serve Cadila Healthcare Limited, which is located in India.

<sup>2</sup>At the time Defendants filed their motion, a final written decision by the PTAB in an IPR challenge to the '551 patent, IPR2016-0024, was still pending, and Defendants sought a stay pending its conclusion as well. (D.I. 7 at 5) On March 22, 2017, the PTAB issued a final written decision finding claims 1-13 of the '551 patent had not been shown to be unpatentable as obvious. (See D.I. 12) The parties have not indicated whether there is a pending appeal of that decision, and thus the Court will not address whether to stay proceedings based on the IPR.

**IT IS HEREBY ORDERED** that Defendants' motion (D.I. 7) is GRANTED IN PART and DENIED IN PART, as explained below.

1. Plaintiffs UCB, Inc., UCB BioPharma SPRL, Research Corporation Technologies, Inc., and Harris FRC Corporation (collectively, "Plaintiffs") filed a patent infringement action asserting the '551 patent against Defendants based on Zydus' filing of ANDA No. 209465 on October 6, 2016. (D.I. 1) By its ANDA submission, Zydus seeks FDA approval to market a generic version of Plaintiffs' antiepileptic drug, Vimpat®, before expiration of the '551 patent. (See D.I. 8 at 1) With its current ANDA (No. 209465), Zydus seeks approval for an intravenous form of Vimpat®. (See *id.*) Zydus has previously submitted an ANDA seeking approval to market a generic tablet form of Vimpat® prior to expiration of the '551 patent. (See *id.*)

2. The '551 patent is the subject of at least two other pending proceedings. First is an appeal from this Court's post-trial judgment in *UCB v. Accord*, which found the asserted claims of the '551 patent not invalid and infringed. (See C.A. No. 13-1206-LPS D.I. 313, 323) The trial in *UCB v. Accord* arose from the submissions by Zydus and other filers of their ANDAs seeking to market a generic tablet form of Vimpat®. Oral argument in the *Accord* Appeal was heard in the Federal Circuit on August 8, 2017. (See *UCB, Inc. v. Accord Healthcare, Inc.*, No. 16-2610 (Fed. Cir.)) Second is the pending reexam of the '551 patent. (See D.I. 9 Ex. 6) In this reexam, the PTO has issued a non-final Office Action rejecting all claims of the '551 patent as obvious. (See D.I. 11 at 1-2) By their motion, Defendants seek to stay the instant lawsuit until the conclusion of both the *Accord* Appeal and the reexam.

3. 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, 255 (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.* at 254-55. 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).

4. 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. 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.<sup>3</sup>

5. 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*, 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.

6. Turning to the third factor, a stay of an appropriate length will not unduly prejudice Plaintiffs. Although Plaintiffs have a valid interest in the prompt resolution of pending litigation, it is likely that the *Accord* Appeal, which was argued nearly two months ago, will be resolved in the near future and sooner than the instant case could be resolved even were Defendants' requested stay to be denied. The automatic 30-month stay on FDA approval of Defendants' ANDA does not expire until February 2019. (See D.I. 3; D.I. 7 at 2) The stay the Court will be entering will preserve the prospect that this litigation could be concluded in advance of that date, and will require Defendants to again seek a stay – and the Court to again evaluate the considerations relating to a stay – before there could be a very substantial threat to completing this particular case before February 2019. The stay will also conserve the parties' and the Court's resources.

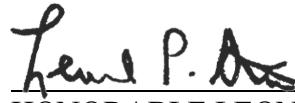
7. The risk of undue prejudice to Plaintiffs would be much greater were the Court to stay this action pending resolution of the reexam. Given the "average length it takes to complete

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<sup>3</sup>As Zydus writes: "Zydus is a party to the Federal Circuit appeal [i.e., the *Accord* Appeal and] of course, Zydus will be bound by the Federal Circuit's decision in [the *Accord* Appeal] consistent with accepted principles of collateral estoppel." (D.I. 11 at 1)

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).<sup>4</sup>

8. Weighing the pertinent factors, and exercising discretion to formulate a proper case-specific resolution, IT IS HEREBY ORDERED that: (i) this case is STAYED until the earlier of: (a) the Federal Circuit’s issuance of a decision in the *Accord* Appeal, or (b) January 31, 2018; and (ii) the parties shall advise the Court no later than the earlier of (a) seven (7) days after the issuance of a decision from the Federal Circuit in the *Accord* Appeal, or (b) January 24, 2018, of their position(s) as to how this case should proceed.



Leonard P. Stark  
HONORABLE LEONARD P. STARK  
UNITED STATES DISTRICT JUDGE

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<sup>4</sup>Under the circumstances, the Court sees no reason to analyze whether Defendants would face hardship or inequity in the absence of a stay.