

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

NOVARTIS AG, NOVARTIS :
PHARMACEUTICALS :
CORPORATION, MITSUBISHI :
TANABLE PHARMA :
CORPORATION, and MITSUI SUGAR :
CO., LTD., :

Plaintiffs, :

v. :

C.A. No. 15-151-LPS

HEC PHARM CO. LTD., HEC PHARM :
GROUP, and HEC PHARM USA INC., :

Defendants. :

REVISED MEMORANDUM ORDER

At Wilmington this **2nd** day of **May, 2016**:

Having heard oral argument and reviewed the parties’ briefing and other materials filed in relation to Plaintiffs’ motion to stay proceedings on U.S. Patent No. 8,324,283 (“the ’283 patent”) pending appeal of an inter partes review (“IPR”) decision on that patent, **IT IS HEREBY ORDERED** that Plaintiffs’ motion (D.I. 72) is **GRANTED IN PART**, for the reasons stated below.

1. Plaintiffs filed a patent infringement action asserting U.S. Patent No. 5,604,229 (“the ’229 patent”) against Defendant HEC in February 2015. HEC included in its May 2015 Answer a counterclaim for declaratory judgment of non-infringement and invalidity of the ’283 patent – a patent which Plaintiffs did not assert. (D.I. 32 at ¶¶ 30-37) In September, the U.S. Patent Trial and Appeal Board (“PTAB”) issued a final decision in an IPR challenge to the ’283

patent. The PTAB found the '283 patent invalid as obvious. (D.I. 74-2 at 51) Subsequently, Plaintiffs filed a Notice of Appeal. *See Novartis AG v. Torrent Pharms.*, App. No. 13-1352 (Fed. Cir.) (filed Dec. 21, 2015). HEC is not involved in the IPR. In light of the appeal, Plaintiffs asked HEC to voluntarily stay proceedings on the '283 patent pending resolution of the IPR appeal. (D.I. 74-2 at 118) HEC refused to do so. (*Id.* at 117) Thus, on November 11, 2015, Plaintiffs filed their motion to stay. (D.I. 72) The Court heard argument on the motion on April 19, 2016. (*See* D.I. 158 (“Tr.”))

2. Whether or not to stay litigation is a matter left to the Court’s discretion. *See Ethicon, Inc. v. Quigg*, 849 F.2d 1422, 1426-27 (Fed. Cir. 1998). 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). The factors courts typically consider in deciding how to exercise this discretion include: (1) whether a stay will simplify the issues and trial of the case, (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, e.g., Enhanced Sec. Research, LLC v. Cisco Sys., Inc.*, 2010 WL 2573925, at *3 (D. Del. June 25, 2010).

3. The Federal Circuit’s decision will likely simplify this case. If the Federal Circuit upholds the PTAB’s conclusion that the '283 patent is invalid, its decision will moot HEC’s counterclaims, thereby allowing the parties to avoid all the costs (including discovery) that would otherwise be incurred in litigation concerning whether the '283 patent is valid and infringed. Alternatively, even if the Federal Circuit modifies the PTAB’s decision, this Court will likely benefit from the Federal Circuit’s guidance relating to that patent, guidance which will almost

certainly include claim construction. Among the issues pending on appeal is whether the PTAB erred in denying Plaintiffs' motion to amend their claims – raising the possibility that the scope of the claims to be litigated in this case may change after conclusion of the appeal. For this and other reasons, it would be complicated and potentially wasteful for the Court to litigate the '283 patent at the same time as the Federal Circuit is reviewing its validity. This factor favors a stay.

4. The stage of the litigation, and the status of the IPR appeal, further support a stay. This litigation is at an early stage: although documents have been produced, fact discovery has not closed and expert reports are not due for another six months. Although a trial date has been set – March 2017 – it is very likely that the pending appeal (which is due to be fully briefed in early June) will be resolved months before that date arrives. This factor favors a stay.

5. The final factor also favors a stay. The stay the Court is entering will not unduly prejudice HEC nor present a clear tactical advantage to Plaintiffs. As noted above, it is likely that the appeal relating to the '283 patent will be resolved before this case goes to trial (on the patent asserted by Plaintiffs). There may be sufficient time after the stay is lifted to complete discovery and other proceedings related to the '283 patent and still include the '283 patent at the March 2017 trial. If not, if a few additional months are necessary to get the '283 patent ready for trial, there will still be sufficient time to do that before the expiration of the statutory stay on FDA approval of Defendants' ANDAs, which runs until March 2018. Moreover, the record suggests that FDA approval of Defendants' ANDAs is unlikely before March 2018 even if all patent-related issues are resolved in Defendants' favor prior to that date. (*See* D.I. 91-3 at 11)

6. Considering all of the factors, and exercising its discretion to formulate the proper case-specific resolution, the Court **HEREBY STAYS PROCEEDINGS RELATING TO THE**

'283 PATENT UNTIL THE EARLIER OF NOVEMBER 1, 2016 OR THE ISSUANCE OF A DECISION FROM THE FEDERAL CIRCUIT ON PLAINTIFFS' APPEAL. The parties **SHALL SUBMIT** a joint status report no later than the earlier of **October 15, 2016 or within seven (7) days of the issuance of a decision** from the Federal Circuit on Plaintiffs' appeal.

When the stay is lifted, the Court will hold Plaintiffs to their representation that they will make every effort to resolve disputes related to the '283 patent efficiently, and, if practicable, within the existing trial schedule. (*See* D.I. 90 at 12)



HON. LEONARD P. STARK
U.S. DISTRICT COURT JUDGE