

IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF NORTH CAROLINA
WESTERN DIVISION
No. 5:15-CV-415-BO

MERCK SHARP & DOHME CORP.,)
)
 Plaintiff,)
)
 v.)
)
 SAVIOR LIFETEC CORP.,)
)
 Defendant.)

ORDER

This cause comes before the Court on plaintiff's motion to stay these proceedings with respect to its claims relating to U.S. Patent No. 6,486,150. The appropriate responses and replies have been filed and a hearing was held on the matter before the undersigned on May 10, 2017, at Raleigh, North Carolina. In this posture, the motion is ripe for adjudication and, for the reasons discussed below, it is granted.

BACKGROUND

This action arose following defendant's filing of an Abbreviated New Drug Application (ANDA) seeking FDA approval to market a generic version of plaintiff's antibiotic drug Invanz® (ertapenem for injection). Plaintiff (Merck) filed this action alleging patent infringement; at this stage, the litigation concerns only plaintiff's U.S. Patent No. 6,486,150 ('150) and No. 5,952,323 ('323). Defendant (Savior) has stipulated that its generic ertapenem product will infringe plaintiff's asserted claims in the '323 patent, but challenges the validity of the '323 patent. Savior challenges both the validity and the alleged infringement of the '150 patent.

Merck filed a separate action in the United States District Court for the District of Delaware against another company seeking to market a generic form of Invanz®. That matter has

proceeded through trial and judgment was entered on October 24, 2016. The Delaware court held that all of the asserted claims related to '323 patent were infringed by the defendant, but that asserted claims related to the '150 patent were invalid for obviousness. *Merck Sharp & Dohme Corp. v. Hospira Inc.*, No. CV 14-915-RGA, 2016 WL 8231143, at *23 (D. Del. Oct. 7, 2016). That decision is currently on appeal in the United States Court of Appeals for the Federal Circuit, with oral argument set for the August 7, 2017, term.

Merck now seeks to stay this action to await a decision by the Federal Circuit on its appeal of the District of Delaware's holding that its '150 patent claims were invalid for obviousness. Savior opposes a stay, and asks this Court to set a schedule in this case which would allow it to render a final decision by October 30, 2017.

DISCUSSION

A district court has inherent authority to manage its docket, which includes the authority to stay litigation pending the outcome of a decision by a court of appeals on an issue which would affect or control the outcome in a case before it. *See, e.g., Xerox Corp. v. 3Com Corp.*, 69 F. Supp. 2d 404, 406 (W.D.N.Y. 1999). When determining whether to stay proceedings, a court considers "(1) whether a stay would unduly prejudice or present a clear tactical disadvantage to the non-moving party; (2) whether a stay will simplify the issues in question and trial of the case; and (3) whether discovery is complete and whether a trial date has been set." *Id.*, *see also Murata Mach. USA v. Daifuku Co.*, 830 F.3d 1357, 1361 (Fed. Cir. 2016).

The second and third factors clearly weigh in favor of entering a stay in this case. A ruling by the Federal Circuit on the validity of the '150 patent claims will plainly simplify the issues in this case, as Merck has asserted that if the Delaware court's decision on invalidity is affirmed there will be no need for a Markman hearing or trial in this case on its claims related to

the '150 patent. Further, as Merck has argued, if the Federal Circuit reverses the District of Delaware's judgment, its opinion could provide valuable guidance for construction of at least one claim that is at issue in this case. The period for discovery in this case has closed, but no trial date has been set.

Savior's primary opposition to a stay is based on perceived prejudice. Specifically, Savior asserts that it will be prejudiced by a stay in any scenario other than one in which the Delaware court's decision is affirmed in full and such opinion is issued prior the FDA's approval of Savior's ANDA. The '150 patent expires on November 15, 2017; Savior hopes with a judgment of invalidity to be able to enter the generic Invanz[®] market prior to the expiration of the patent. Savior's argument related to prejudice might be more compelling if it did not rely on speculative circumstances. First, because the '323 patent expired on May 15, 2017, it appears that Savior may not enter the market with a Invanz[®] generic prior to the expiration of the six month pediatric exclusivity period, which ends on November 15, 2017. Second, Savior has not yet gained tentative approval from the FDA on its ANDA, and thus does not know whether it would be in a position to enter the market on filing of an order in this Court should it find in Savior's favor.

For these reasons, the Court in its discretion holds that the factors to be considered weigh decidedly in favor of a stay of these proceedings as to the '150 patent.

CONCLUSION

Accordingly, Merck's motion to stay [DE 62] is GRANTED. This action is hereby STAYED with respect to all claims concerning plaintiff's '150 patent. The parties are ORDERED to notify the Court within ten days of any substantive rulings by the Federal Circuit in *Merck Sharp & Dohme Corp. v. Hospira Inc.*, No. 2017-1115. Further, in light of

representations made in the papers and during argument as to the effect of the expiration of the '323 patent on May 15, 2017, Savior is DIRECTED to notify the Court within ten (10) days of the date of entry of this order as to whether it intends to proceed on its motion for summary judgment. [DE 67]. In light of the stay, Savior's motion to set a procedural schedule for pretrial proceedings [DE 85] is DENIED without prejudice. The motions to seal [DE 87, 88, 92, 94, and 98] are ALLOWED.

SO ORDERED, this 31 day of May, 2017.


TERRENCE W. BOYLE
UNITED STATES DISTRICT JUDGE