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A Stay of Litigation Pending IPR Does Not Provide a Basis For Extending 30-Stay of FDA ANDA Approval

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On December 11, 2015, the United States District Court for the Southern District of Indiana granted a motion to stay a Hatch-Waxman litigation pending the outcome of *inter partes* reviews (IPRs) on two of the patents-in-suit in the litigation. *See Eli Lilly and Company, et al. vs. Accord Healthcare Inc., et al.*, No. 1:14-cv-00389, 2015 U.S. Dist. LEXIS 166106 (S.D. Ind. Dec. 11, 2015). The motion to stay in *Eli Lilly* was the second motion to stay filed by the defendants – the first motion was denied as premature because the IPRs had not yet been instituted. *Id.* at *7. Upon the United States Patent and Trademark Office (USPTO) rendering decisions instituting the pending IPRs for two of the patents in suit, the defendants filed a new motion to stay which was granted. *Id.* at *12. Importantly, in granting the motion to stay, the *Eli Lilly* court refused to extend the 30-month stay of FDA approval of defendants' ANDAs.

"In deciding whether to exercise its discretion to stay the litigation once an IPR has been instituted, the Court should consider whether a stay will: (1) simplify the issues and streamline the case for trial; (2) reduce the burden of litigation on the parties and the Court; and (3) unduly prejudice or tactically disadvantage the Plaintiff." *Id.* at *8. The Court went on to state that there was no question that the IPRs would simplify the issues in the litigation and streamline it for trial: "[i]f Defendants are successful in the IPRs, all of the claims of the '703 and '325 patent[s] will cease to exist and 22 parties will be entitled to judgment in their favor and dismissal." *Id.* The Court also noted that the IPRs do not need to eliminate all litigation issues for the stay to be entered – rather, the "potential reduction" of issues is sufficient. *Id.* at *8-*9. Further, the Court was cognizant of the potential waste of time and money in proceeding with the litigation while the IPRs are ongoing. *Id.* at *9. With respect to the second factor, the Court explained that the stay would reduce the burden of proceeding with the litigation on the court and the parties because the litigation was still "in its infancy." *Id.* at *9-*10.

Of particular interest is the court's refusal to give credence to plaintiffs' "chief concern on prejudice … that the case will be delayed such that it will not be resolved before the expiration of the statutory 30-month stay of approval of Defendants' ANDA provided for under the Hatch-Waxman Act." *Id.* at *10-*11. The Court held that the stay would not unduly prejudice Plaintiffs because the "fact that Plaintiffs cannot get final resolution of their case before the expiration of the 30-month stay is not a recognized prejudice that can overcome the strong showing for a stay in this case." *Id.* at *11. Indeed, the Court agreed with defendants' position that "Congress did not tie resolution of the patent litigation to approval of the product" and that Plaintiffs could seek an injunction upon resolution of the IPRs. *Id.*

In further response to plaintiffs argument that, should the court grant defendants' motion to stay, the court should extend the 30-month stay of approval, the court noted that "[t]here is no law that justifies this request." *Id.* at *11. Indeed, the court pointed out that the only basis that courts have relied on for extending the statutory 30-month stay has been when a party failed to cooperate with expediting the litigation – that was not the situation at hand in *Eli Lilly*. *Id.* Accordingly, the court declined to extend the 30-month stay. *Id.*

The recent *Eli Lilly* decision provides guidance for generic pharmaceutical manufacturers contemporaneously engaged in Hatch-Waxman litigations and post-grant proceedings at the USPTO who wish to stay the litigation and focus on the post-grant USPTO proceedings. This case will provide guidance in defeating any attempts that brand pharmaceutical companies may make to extend the 30-month FDA ANDA approval stay because a generic pharmaceutical company sought IPR review of the patents.

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