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Tips For Protecting Hatch-Waxman Stay After Lilly, Alcon

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One of the most important protections for a brand pharmaceutical company engaging in litigation under the Hatch-Waxman Act is the automatic 30-month stay of U.S. Food and Drug Administration approval of a generic drug under an abbreviated new drug application. This 30-month regulatory stay serves the important policy of minimizing risk of irreparable harm to the brand company by preventing the generic drug from launching until resolution of the underlying patent infringement suit. However, recent district court decisions in Lilly and Alcon show that the increasing tendency of district courts to stay litigation in view of inter partes review proceedings poses a real risk to the protections of the 30-month regulatory stay.


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In particular, if Hatch-Waxman litigation is stayed pending IPR but the 30-month regulatory stay is not extended, there is a significant risk that a generic could launch "at risk" before the merits of the underlying litigation are resolved. Although a brand company can move to extend the 30-month regulatory stay, such motions were denied in both Lilly and Alcon. Accordingly, Lilly and Alcon show that when a brand company is faced with a motion to stay district court litigation in view of an IPR, the most effective strategy for protecting the 30-month regulatory stay is to prevent a litigation stay in the first place. This article provides practical pointers for brand companies opposing motions to stay litigation after Lilly and Alcon.


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Overview of Lilly and Alcon

The Southern District of Indiana recently considered whether a litigation stay was appropriate after claims from some of the asserted patents were instituted for IPR. Eli Lilly v. Accord Healthcare Inc., 2015 WL 8675158 (S.D. Ind. Dec. 11, 2015). After balancing the three stay factors — (1) simplification of the issues and streamlining of the case for trial, (2) reduction of the burden of litigation on the parties and the court, and (3) unduly prejudicial or tactical disadvantage to the nonmoving party — the district court determined that a litigation stay was warranted. The court found that the first two factors heavily favored a stay and rejected Lilly's prejudice arguments, stating "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 *2.

In the end, the court found that any prejudice that exists on the basis of the expiration of the 30-month stay can be "eliminate[d]" because "[p]laintiffs will have ample opportunity to seek an injunction once

the IPRs are finally concluded." Id. In addition, the court refused to extend the 30-month regulatory stay, stating that there was "no basis" to find that the defendants had "failed to reasonably cooperate in expediting the litigation" — the standard for granting such an extension. Id.

The District of New Jersey recently followed suit in Alcon Labs. Inc. v. Akorn Inc., 2016 WL 99201 (D.N.J. Jan. 8, 2016). The court determined that a litigation stay was appropriate under its set of stay factors: (1) unduly prejudicial or tactical disadvantage to the nonmoving party, (2) simplification of the issues in question and trial of the case, and (3) completion of discovery and whether a trial date has been set.

Like in Lilly, the court reasoned that any prejudice to the patent holder that resulted from an expiration of the 30-month regulatory stay could be "prevent[ed]" by the "opportunity to seek an injunction." Id. at *2 (citing Lilly). In addition, as in Lilly, the court also refused to extend the 30-month regulatory stay, again concluding that a court only has the ability to extend the regulatory stay if a party "failed to reasonably cooperate in expediting the action,"[1] which the court did not find the defendants to have done in that case. Id.

Tips for Brand Companies Opposing a Stay of Litigation Pending IPR

In view of Lilly and Alcon, it is clear that brand companies seeking to protect the 30-month stay must do everything they can to prevent a litigation stay in view of IPR proceedings. Indeed, at least for now, it appears district courts are unlikely to tie an extension of the 30-month regulatory stay to a litigation stay.[2] Accordingly, this article provides some practical tips for brand companies to maximize their chances of successfully opposing motions to stay litigation in view of an IPR.

Pick up the pace.

Although district courts articulate the factors they use in determining whether a litigation stay should be granted in different ways, they all generally consider the stage of the litigation when the stay motion was filed. For example, in Alcon, the court examined the deadline for completing discovery, and in Lilly the court weighed the stage of litigation in determining whether a stay would reduce the burden of the parties and the court. See Alcon Labs, 2016 WL 99201 at *1; Lilly, 2015 WL 8675158 at *2. Thus, in order to maximize chances of preventing a litigation stay in view of IPR proceedings, a brand company should seek a case schedule that expedites early fact discovery and claim constructions deadlines as much as possible.

In Lilly, for example, the court found that "[p]laintiffs and all Defendants except Lupin ha[d] engaged in minimal document and written discovery," that "no depositions ha[d] been noticed or taken," and "there [were] no dates for close of fact or expert discovery." Lilly, 2015 WL 8675158 at *2. Likewise, in Alcon, "fact discovery [was] not due to be completed until 45 days after the entry of the Court's Claim Construction Order," and "[o]pening Markman briefs ha[d] not yet been filed." Alcon Labs, 2016 WL 99201 at *2. As the Alcon court recognized, "[m]ost often, cases have been denied a stay due to the late stage of litigation, the fact that discovery was or would be almost completed, or the matter had been marked for trial." Id. Thus, Lilly and Alcon suggest that had discovery been at a more advanced stage, the outcome of the decisions may have been different. Therefore, pushing for a case management schedule that requires early claim construction combined with seeking fact discovery as quickly as possible should reduce the likelihood that a district court will stay the proceedings in view of a future IPR.

Along these lines, a brand company should be upfront with the court about the reasons for seeking such

a schedule, including the fact that it is important to expedite the case in order to protect the 30-month regulatory stay.

Venue and trial dates.

Many courts consider "whether a trial date has been set" as a factor in deciding stay motions. See, e.g., Lilly, 2015 WL 8675158, at *2 (a reason favoring a stay was the lack of a trial date). Thus, it is important to set a trial date and do so as early as possible given the venue in which you file your complaint. To this end, venue considerations are also potentially implicated by Lilly and Alcon — for example, brand companies may find it advantageous to file suit in a venue that is likely to allow for early discovery and trial. In addition, some districts may be more inclined to deny motions to stay than other districts.

Explain why it is unduly prejudicial to the brand company if it is forced to rely on preliminary injunctive relief to prevent an "at risk" launch by a generic.

As discussed above, the district courts in Lilly and Alcon found that the prejudice factor did not weigh against a stay. Their reasoning was that if the 30-month regulatory stay expired while the litigation was stayed pending IPR, then the brand companies could seek an injunction in order to prevent an "at-risk" launch by the generic companies. Brand companies can use this to their advantage as a factor that warrants denying a litigation stay motion, because requiring brand companies to file preliminary injunction motions in the middle of a case weighs against nearly all of the traditional stay factors considered and is contrary to the underlying purpose of the Hatch-Waxman Act.[3]

For example, brand companies should argue that preliminary injunctions expand rather than reduce the "burden of litigation on the parties and the court." Preliminary injunction motions require courts — before the case is fully litigated — to make decisions on the merits both of validity and infringement. To add to that burden, because many Hatch-Waxman cases involve multiple defendants, courts will be forced to make preliminary injunction decisions for many independent defendants. In addition, while it is true that a reduction in the number of asserted claims as a result of an IPR would generally simplify issues, the substantial amount of work required to both bring and decide preliminary injunction motions should balance the scale on this point.

Moreover, brand companies will likely be at "a tactical disadvantage" in the litigation if the court relies on a preliminary injunction motion in order to prevent an "at-risk" launch by generics. In particular, this scenario places a heavy burden on the brand company to win a preliminary injunction motion in order to protect an exclusive right that the Hatch-Waxman Act automatically grants. Moreover, because most Hatch-Waxman cases seek an injunction rather than monetary damages, requiring a brand to rely on a preliminary injunction as a way to preserve the 30-month regulatory stay is effectively requiring a brand company to litigate its entire case in a very compressed time frame — a clear "tactical disadvantage."

Additionally, if a preliminary injunction is denied, the brand company faces a real risk of irreparable harm if the generic drug is launched before a finding of liability on the merits. In particular, if the generic launches "at risk" but is later found to infringe, the brand company will have already suffered the damages that the 30-month regulatory stay was intended to prevent — namely, launch of a generic drug before a determination of liability. Accordingly, although Lilly and Alcon did not find prejudice to weigh against a stay of litigation, brand companies should continue to argue unfair prejudice, including why it is unfair to force a brand company to rely on speculative preliminary injunctive relief as the only means for preventing an "at risk" launch of the generic.

Conclusion

Lilly and Alcon make clear that may be challenging for brand companies to prevent a litigation stay in view of pending IPR proceedings. However, as this area of law develops, implementing some of the suggestions in this article may help increase a brand company's chances of overcoming a motion to stay litigation in view of an IPR.

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[1] Both the Lilly and Alcon courts felt bound by the language of 21 U.S.C. § 355(j)(5)(b)(iii), which requires failure to "reasonably cooperate" in expediting the lawsuit in order to extend the regulatory stay.

[2] But note that other district courts have applied a seemingly less stringent standard than Lilly and Alcon for extending the 30-month regulatory stay. See, e.g., Novartis Corp. v. Dr. Reddy's Labs Ltd., 2004 WL 2368007 (S.D.N.Y. Oct. 21, 2004) (extending 30-month regulatory stay in view of generic's motion to stay litigation pending "the FDA's reevaluation of the safety and efficacy of [the generic's] product").

[3] The grant of a litigation stay in cases involving Orange Book patents contradicts the purpose of the Hatch-Waxman Act. While this precise point has been thoroughly covered by others (see What the Court Got Wrong About Hatch-Waxman in Alcon, Brian D. Coggio, IP Law360 (Feb. 1, 2016)), the authors agree that brand companies should continue to stress prejudice on this basis, even though the reasoning was rejected in Lilly and Alcon.
