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Stay Versus Stay: How Litigation Stays Pending IPRs Impact the 30-Month Regulatory Stay in Hatch-Waxman Litigation

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Upon initiation of a patent infringement action between branded and generic pharmaceutical companies, the Hatch-Waxman Act (21 U.S.C. § 355(j)) provides for an automatic 30-month stay of Food and Drug Administration approval of the Abbreviated New Drug Application (ANDA) for the proposed generic pharmaceutical product. As the legislative history of the Act makes clear, the purpose of the 30-month stay is to permit resolution of the underlying patent dispute before the generic product may enter the market.

The stay serves the interests of both parties: Preventing entry of a generic to the market forestalls significant disruption to the market for the branded pharmaceutical that later removal of an infringing generic product cannot always repair, and precludes the generic from incurring liability that can run into the hundreds of millions of dollars by virtue of launching a product later found to infringe.

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Litigation under the Hatch-Waxman Act has proceeded with the 30-month stay largely serving its intended purpose. However, since enactment of the America Invents Act (AIA) in 2012, parties have sought stays of the district court litigation during the pendency of inter partes review (IPR) proceedings. This has raised questions about the 30-month stay, and whether it should be extended. Although IPRs progress rapidly, with final written decisions for instituted IPRs issuing within 18 months of a petition's filing date,[1] a stay of the district court litigation during some or all of the 18 months significantly shortens the time available for litigation to resolve before the 30-month stay expires.

This article explores two recent cases that have addressed the 30-month regulatory stay in light of litigation stays pending the resolution of IPRs and identifies considerations that can impact extensions of the regulatory stay.

The Regulatory Stay

Under the Hatch-Waxman Act, once a branded pharmaceutical company has received a generic company's Paragraph IV certification[2] asserting that the branded company's Orange Book[3] listed patents covering the Reference Listed Drug (RLD) are invalid or not infringed by the generic drug's commercialization,[4] the branded company has 45 days to file suit in district

[1] *See* 35 U.S.C. § 316(a)(11); 37 C.F.R. § 42.100(b).

[2] *See* 21 U.S.C. § 355(j)(2)(B)(iv).

[3] The "Orange Book" refers to the FDA's Therapeutic Equivalence Determinations publication. Once the FDA approves the branded manufacturer's New Drug Application (NDA), it publishes information about patents identified in the NDA as covering either the drug (including the active ingredient and formulation) or a method of using the drug. *See* 21 U.S.C. § 355(b)(1)(G); 21 C.F.R. § 314.53.

[4] *See* 21 U.S.C. § 355(b)(2)(A)(i)-(iv); *id.* § 355(j)(2)(A)(vii)(I)-(IV).

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court.[5] The filing of the district court litigation initiates a 30-month regulatory stay delaying FDA approval, and hence commercialization, of the generic product while the litigation proceeds.[6]

As noted above, the 30-month stay was intended to bring predictability and unhampered resolution to patent disputes between branded and generic manufacturers.[7] Indeed, it has been recognized that when the 30-month stay does *not* carry the parties to resolution of the patent litigation, an at-risk launch may create market chaos for the branded pharmaceutical company and significant damages for the generic company if its product is later determined to infringe.[8] Thus, in order to encourage the parties to proceed through the litigation purposefully, without intentionally hindering resolution of the patent dispute, the Act gives district courts discretion under 21 U.S.C. § 355(j)(5)(B)(iii) to shorten or extend the regulatory stay where the court finds a party ''failed to reasonably cooperate in expediting the action.''

Stays of Litigation

Federal courts have broad discretionary power to control the disposition of their cases, including the power to grant a temporary stay of the proceedings pending the outcome of administrative actions. District court decisions to grant or deny a stay are based on the consideration of a number of factors, including whether a party will be prejudiced or tactically disadvantaged, whether the co-pending administrative review will simplify issues for the district court, and the present stage and posture of the district court litigation.

As IPR filings have increased, so too have the number of requests for litigation stays. Some courts will grant a stay request based on the filing of an IPR petition,[9] whereas others will order a stay only after the IPR petition has been instituted.[10]

Courts granting stays generally view the IPR process as one that will simplify the litigation by resolving key issues of invalidity. Indeed, if all asserted claims are found unpatentable, the IPR may resolve the litigation entirely. And, even where claims survive, the issues are simplified because the petitioners will be estopped from asserting in the litigation any ground of invalidity it ''raised or reasonably could have raised during that *inter partes* review.''[11] Thus, even when IPR petitions have been filed and instituted late in the litigation, district courts have entertained a request for stay.[12]

IPRs Are Being Filed Increasingly Against Pharmaceutical Patents

In the first couple of years after the AIA was enacted, few IPRs were filed against pharmaceutical patents as compared to patents in other technology areas. In 2013, for example, less than two percent of IPR petitions involved biotechnology and chemistry patents. However, that percentage has increased, reaching about 10 percent in 2015.[13]

Some of these IPRs are filed by generic pharmaceutical manufacturers seeking a rapid and simplified path to invalidating the patents asserted against them in response to their Paragraph IV certifications. The number of litigation stay requests may increase as more IPR petitions are filed.

Pharmaceutical Cases Addressing Requests for Litigation Stays in Light of Pending IPRs and Concurrent Requests to Toll the 30-Month Regulatory Stay

Over the last four months, two courts have considered stays of ANDA litigation pending the outcome of IPRs challenging Orange Book patents, and whether to extend or toll the 30-month stay to maintain the Hatch-Waxman status quo.

Eli Lilly & Co. v. Accord Healthcare Inc.

In *Eli Lilly*,[14] the defendants sought a litigation stay after filing IPR petitions challenging all asserted claims of two of the three patents asserted in the litigation.[15] The court denied the initial stay request, and the defen-

[5] *Id.* § 355(j)(5)(B)(iii).

[6] *Id.*

[7] *See, e.g.*, Cong. Rec. (Aug. 10, 1984), at S10504 (Sen. Hatch) (''The period of time during which an abbreviated new drug application is not to be made effective . . . is extended from 18 to 30 months. . . . This increases the likelihood that the litigation will be concluded within the time period during which ANDA's are not allowed.''); *Ben Venue Labs., Inc. v. Novartis Pharm. Corp.*, 146 F. Supp. 2d 572, 579, 61 U.S.P.Q.2d 1405 (D.D.C. 2001) (recognizing the necessity of the 30-month stay in providing ''an adequate window of time during which to litigate the question of whether a generic will infringe the patented product, without actually having to introduce the generic product to the market.'').

[8] *See, e.g.*, PhRMA, *Implementation of the Hatch-Waxman Act by the U.S. Food and Drug Administration*, at 14 (Jan. 18, 2002) (''The purpose of the [stay] is to allow the orderly and timely resolution of patent infringement conflicts between the pioneer and generic challenger prior to FDA approval of the generic. This avoids the intractable situation that would occur if the generic manufacturer ultimately loses a patent suit after marketing its version of a pioneer drug prior to resolution of the patent conflict. As recognized by Congress when drafting the law, such a situation would destroy market share and pricing structure for the pioneer product and create crippling damage claims for the generic manufacturer.''); *Sanofi-Synthelabo v. Apotex Inc.*, 488 F. Supp. 2d 317, 342-343, 2005 BL 69041 (S.D.N.Y. 2006) (granting preliminary injunction after finding that commercial launch of the generic would cause irreparable harm due to price erosion and loss of good will, as well as corporate and R&D losses).

[9] *See, e.g.*, *Roche Molecular Sys., Inc. v. Cepheid*, No. 14-cv-3228-EDL, Document 63, at 6 (N.D. Cal. Jan. 7, 2015).

[10] *See, e.g.*, *Eli Lilly& Co. v. Accord Healthcare, Inc.*, 2015 BL 407149 (S.D. Ind. Dec. 11, 2015) (granting a post-institution stay noting, ''Last time around, the Court found Defendants' request for stay to be premature in that no *inter partes* review had been instituted and thus there was no parallel proceeding that could address any of the issues in this litigation.'').

[11] 35 U.S.C. § 315(e)(2).

[12] *See, e.g.*, *Ultratec Inc. v. Sorenson Commc'ns, Inc.*, No. 3:13-cv-00346-bbc, Document 876, at 2 (W.D. Wisc. May 13, 2015) (granting post-judgment stay request), *aff'd*, *Ultratec Inc. v. CaptionCall, LLC*, 611 Fed. Appx. 720, 722, 2015 BL 245760 (Fed. Cir. 2015).

[13] Internal statistics compiled by WilmerHale regarding inter partes review and other post-grant proceedings provided by the AIA.

[14] *Eli Lilly & Co. v. Accord Healthcare Inc.*, 2015 BL 407149 (S.D. Ind., Dec. 11, 2015).

[15] Thirty-five defendants were involved in the litigation, accounting for 13 ANDAs. The two patents for which IPRs were

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dants renewed their request after the IPRs were instituted. Eli Lilly opposed both stay requests on the ground that a litigation stay would be prejudicial in light of the limited 30-month regulatory stay period, and argued that if a litigation stay was granted, the court should toll the 30-month regulatory stay until the PTAB issued its final written decision.[16]

While Eli Lilly acknowledged that it could file a preliminary injunction in the event the generic product was commercialized before the litigation concluded, it argued that being forced into an ''unnecessary'' preliminary injunction was highly prejudicial:

> The prospect of otherwise needless preliminary injunction litigation of the sort that the Hatch-Waxman Act regulatory stay should prevent certainly qualifies as a ''prejudice or tactical disadvantage'' to Plaintiffs, and would impose a large and unnecessary burden on the Court.[17]

Indeed, Eli Lilly had argued that the stay would not simplify the litigation because: one of the asserted patents was not subject to the IPRs; not all defendants were parties to the IPRs (and hence would argue that they were not subject to the estoppel effects that apply to unsuccessful petitioners); and the IPRs would not address the defendants' double-patenting, enablement, and written description defenses.[18] Thus, even if Eli Lilly prevailed on the IPRs and the issues of anticipation and obviousness were simplified, a preliminary injunction proceeding would require a substantial amount of effort on likelihood of success on the merits, as well as on the other preliminary injunction factors, by the parties and the court in a compressed timeframe.

In support of its tolling request, Eli Lilly argued that defendants' stay request fell squarely within Section 355(j)(5)(B)(iii) because it was itself a failure to reasonably cooperate in expediting the action: ''Congress plainly did not contemplate that the parties would sit idly and do nothing for months at a time while the regulatory stay time period ran. Basic common sense dictates that the very act of seeking a stay is the opposite of 'expediting the litigation.' ''[19]

After considering the stay factors, the court granted the litigation stay and declined to extend or toll the regulatory stay. In reaching its decision, the court acknowledged the tension between a litigation stay and the 30-month limit on the regulatory stay, and the potential prejudice Eli Lilly could face:

> In previously addressing the issue of prejudice [*i.e.*, pre-institution], the Court observed that the Hatch-Waxman Act provides for a stay of the FDA's approval of Defendants' ANDAs until June 2017; that this regulatory stay period was designed to give the Court an opportunity to address the merits of the patent suit prior to approval of Defendants' ANDA products; and that Defendants' motion to stay creates a very real possibility that this litigation would not be completed before the stay expires. . . . Thus, the Court concluded, Defendants' requested stay unquestionably prejudices Plaintiffs.
>
> Plaintiffs' chief concern [now] on the issue of prejudice is that the case will be delayed such that it will not be resolved before the expiration of the statutory 30-month stay of approval. . . .[20]

The court concluded, however, that any prejudice the plaintiff might face was outweighed by the factors militating in favor of a stay:

> Congress did not tie resolution of the patent litigation to approval of the product . . . . 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.[21]

The court's dismissal of Plaintiff's prejudice concerns was influenced by its view that ''Plaintiff will have ample opportunity to seek an injunction once the IPRs are finally concluded, which eliminates any alleged prejudice to Plaintiffs.''[22] In making this finding, the court did not account for Eli Lilly's arguments noted above regarding the absence of simplification that would be achieved by a stay.

With regard to Eli Lilly's request for an extension of the regulatory stay, the court held that there was ''no law that justifies this request.'' According to the court, ''the only basis that courts have relied on to extend the regulatory stay is the violation of the statutory requirement of 21 U.S.C. § 355(j)(5)(B)(iii) that a party has failed to reasonably cooperate in expediting the litigation,'' and the absence of any specific litigation delays prevented extension of the regulatory stay.[23]

Alcon Labs., Inc. v. Akorn, Inc.

In *Alcon*,[24] the district court raised sua sponte the question of whether the litigation should be stayed after the PTAB instituted Akorn's IPR petition challenging all of Alcon's asserted patent claims. The generic manufacturer opposed a litigation stay, while the branded pharmaceutical company favored a stay provided the 30-month stay would be extended.[25] Although both parties contended that ''some degree of prejudice may befall them if a stay is ordered,'' the court found that, on balance, the stay factors warranted staying the litigation until the PTAB issued final written decisions.

As in *Eli Lilly*, the *Alcon* court refused to extend or toll the regulatory stay, stating that it had no authority to do so: ''A court has discretion to extend the 30-month regulatory stay, but only if a party has 'failed to reasonably cooperate in expediting the action.' Put simply, the Court is not prepared to hold—nor have Plaintiffs argued—that either party has failed to reasonably cooperate in expediting the action.''[26] In this regard, the *Alcon* court noted that it had raised the stay sua sponte.[27]

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instituted were asserted against all defendants; a third patent was asserted against one defendant group.

[16] *Id.*

[17] *See Eli Lilly & Co. v. Accord Healthcare, Inc.*, No. 1:14-cv-00389 SEB-TAB, Document 355, at 8 (S.D. Ind. Oct. 19, 2015) (Plaintiffs' Opposition To Certain Defendants' Joint Motion To Stay Litigation In View of Institution Of *Inter Partes* Review).

[18] *Id.* at 12-15.

[19] *Id.* at 15.

[20] 2015 BL 407149 (emphasis added).

[21] *Id.* (emphasis added) (internal citations omitted).

[22] *Id.* It is interesting to note that the court initially gave credence to Plaintiff's concerns about the running of the clock on the 30-month stay *before* IPR institution, but, in its later opinion, stated that the concerns were ''not a recognized prejudice.''

[23] *Id.*

[24] *Alcon Labs., Inc. v. Akorn, Inc.*, 2016 BL 4735 (D.N.J. Jan. 8, 2016).

[25] *Id.*

[26] *Id.* (internal citations omitted).

[27] *Id.* The *Alcon* court also noted that its view of Section 355(j)(5)(B)(iii) was in accord with a prior District of New Jersey case. *Id.* In that prior case, the court rejected the defendant's argument that the 30-month stay should be shortened or

Thus, notwithstanding the importance of the 30-month regulatory stay to the Hatch-Waxman framework, and the potential for the litigation stay to undermine the 30-month stay by increasing the likelihood that the Plaintiff will need to pursue a preliminary injunction to prevent an at risk launch, both *Eli Lilly* and *Alcon* refused to extend or toll the regulatory stay based on a strict interpretation of 21 U.S.C. § 355(j)(5)(B)(iii). In so doing, both courts rejected the reasoning of two pre-AIA decisions in which courts tolled the 30-month stay pending resolution of administrative proceedings based on both their inherent powers and a broader interpretation of 21 U.S.C. § 355(j)(5)(B)(iii)—*Novartis Corp. v. Dr. Reddy's Labs.* and *Abbott Labs. v. Matrix Labs*.

Novartis Corp. v. Dr. Reddy's Labs., Ltd.

In *Novartis*,[28] Dr. Reddy's requested a stay of the ANDA litigation pending the FDA's safety and efficacy review of its proposed generic product. In analyzing Dr. Reddy's stay request, the court applied the same three factor test later used by the *Eli Lilly* and *Alcon* courts to determine whether a stay pending an IPR was appropriate, i.e., whether (1) a stay would unduly prejudice or present a clear tactical disadvantage to the non-moving party; (2) a stay will simplify the issues in question and trial of the case; and (3) discovery is complete and whether a trial date has been set.[29] Under factor (1), the *Novartis* court found that Novartis would not be unduly prejudiced by the litigation stay *if* it was granted a commensurate extension of the 30-month regulatory stay.[30] The *Novartis* court thus considered—and ultimately granted—an extension of the 30-month stay as part of the three-factor test attendant to its inherent power to control the cases on its docket.

In addition, the *Novartis* court found that it ''further'' had the discretion to extend the regulatory stay under Section 355(j)(5)(B)(iii), because Dr. Reddy's could not ''feasibly argue'' that it was ''reasonably cooperating in expediting the action'' while asking to stay the same.[31]

Abbott Labs. v. Matrix Labs., Inc.

In Abbott,[32] the generic manufacturer, Matrix, requested a five-year stay of litigation because it was unable to commercialize its generic therapy until additional Abbott Orange Book listed patents not involved in the litigation—which Matrix could not argue were invalid or non-infringed—expired. Matrix requested a tolling of the regulatory stay along with its requested litigation stay.[33]

In granting the stay, the court explained that the 30-month period must be tolled to prevent prejudice to Abbott.[34] Like *Novartis*, the *Abbott* court based its decision to extend the regulatory stay on ''the combination of its inherent authority to exercise control over cases pending on its docket and the statutory authority to adjust the thirty-month period [under Section 355(j)(5)(B)(iii)].''[35]

Thus, where the *Eli Lilly* and *Alcon* courts found that they had *no authority* to toll or extend the regulatory stay in granting a litigation stay, the *Novartis* and *Abbott* courts identified *two separate bases* for their authority to extend the regulatory stay. Though the *Novartis* and *Abbott* cases did not involve litigation stays pending IPRs, their reasoning is nevertheless relevant. The issue of whether the court has the authority to extend the regulatory stay to ameliorate any prejudice identified under the undue prejudice/tactical disadvantage prong of the three-pronged test cuts across both sets of cases, as does the issue of whether a request for a litigation stay can justify an extension of the regulatory stay under Section 355(j)(5)(B)(iii).

Extending the 30-Month Stay in Light of Eli Lilly and Alcon's Rejection of Novartis and Abbott

What can parties learn from the rejection of the reasoning in *Novartis* and *Abbott* by the courts in *Eli Lilly* and *Alcon*, and the latter courts' refusal to extend the 30-month stay?

Claimed prejudice or tactical disadvantage.

Although *Eli Lilly* and *Alcon* rejected the parties' claims of prejudice, explaining with specificity all of the issues that will need to be presented in an emergency temporary restraining order (TRO) and/or preliminary injunction proceeding may persuade the court that the plaintiff could be prejudiced or tactically disadvantaged by a litigation stay in the absence of tolled regulatory stay. For example, there may be asserted claims as to which IPRs have not been instituted, or defendants may have asserted defenses that will not be addressed in the IPR(s)—invalidity based on product prior art, enablement, written description, indefiniteness, obviousness-type double patenting, and/or non-infringement.

Under these circumstances, the TRO and/or preliminary injunction proceedings will closely resemble the very proceedings the 30-month stay was designed to avoid, i.e., the collection and presentation of complicated scientific and market evidence and arguments in a very compressed timeframe.

To show that an extension of the regulatory stay is being sought to maintain the status quo rather than to gain a tactical advantage, the party requesting the stay should request the submission of a status report to the court upon issuance of the final written decision in the IPR(s), so the court can lift any regulatory stay the circumstances may then warrant.

Impact on discovery deadlines.

Completion of significant work already done to pursue the case may militate against staying the litigation. In declining to extend the 30-month stay due to alleged discovery abuses, the court in *Bayer Schera Pharma AG v. Sandoz, Inc.* noted that the patent-holder had

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''not toll[ed]'' as a condition of the litigation stay because the Plaintiff had prevented FDA approval of its generic by suing it over patent claims that had been twice rejected in reexamination proceedings and hence lacked merit. *Cima Labs, Inc. v. Actavis Group HF*, No. 2:06-cv-01970-DRD-MAS, Document 40, at 19-20 & n.5 (D.N.J. June 7, 2007) (unpublished).

[28] *Novartis Corp. v. Dr. Reddy's Labs., Ltd.*, No. 1:04-cv-0757-SAS, Document 21 (S.D.N.Y. Oct. 21, 2004).

[29] *See id.*

[30] *Id.*

[31] *Id.*

[32] *Abbott Labs. v. Matrix Labs., Inc.*, No. 09-cv-1586, Document 49 (N.D. Ill. Nov. 5, 2009).

[33] *Id.* at 1.

[34] *Id.* at 4 (''Abbott *could* suffer prejudice if any motion for stay were not accompanied by an order tolling the 30-month limitations period.'' (emphasis in original)).

[35] *Id.* at 4-5.

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never even asked for a Rule 26(f) conference with the ANDA filer.[36] More importantly, the court stated that while it had granted early jurisdictional discovery, the parties never made efforts to take merits discovery concurrently.[37]

Specific delays.

More than any other basis, courts cite a party's failure to meet discovery deadlines in decisions finding a failure to reasonably cooperate under Section 355(j)(5)(B)(iii).[38] It is thus useful to point out any delays or discovery issues coming from the other side. For example, where a party has failed to facilitate relevant discovery, particularly where discovery is located outside of the U.S. (hence necessitating the party's cooperation), it may be possible to argue that the opposing party has not been reasonably cooperative. Notably, some courts have emphasized that parties requesting a regulatory stay extension must have clean hands.[39]

In addition, parties should provide an estimate of the time and expenses associated with any discovery delays. In *Shire LLC v. Watson Pharm., Inc.*, the court denied the request to extend the regulatory stay, but noted that if it had been inclined to grant the extension, it would have opted for a ''specified amount of time proportionate to the length of the delay caused by a party.''[40]

Consistent positions.

One issue that seemed to concern the court in *Eli Lilly* was that Eli Lilly had argued in a different Hatch-Waxman case that a litigation stay pending resolution of an IPR was not prejudicial but rather beneficial to a patent owner.[41] Thus, parties requesting a stay should ensure that they maintain a consistent litigation position regarding litigation stays (and commensurate regulatory stays), or be prepared to clearly explain why the circumstances of a given case are distinguishable from those of a case in which a different position was taken.

Conclusion

The number of requested litigation stays may increase with the expansion of IPR practice against pharmaceutical patents, thus raising concerns about maintaining the benefits of the 30-month regulatory stay. The district courts in *Eli Lilly* and *Alcon* construed their authority to extend the stay narrowly under 21 U.S.C. § 355(j)(5)(B)(iii), requiring a showing of specific instances of failures to reasonably cooperate in expediting the action beyond the stay request itself. Other courts may be more willing to consider arguments to extend the regulatory stay based on the court's inherent authority to prevent prejudice resulting from the effective shortening of the 30-month stay, a broader reading of Section 355(j)(5)(B)(iii), or both, as in *Novartis* and *Abbott*.

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[36] No. 1:08-cv-03710-PGG, Document 160, at 14-15 (S.D.N.Y. Sept. 2, 2010).

[37] *See id.*

[38] *See, e.g., id.*

[39] *Id.* at 8-15.

[40] No. 1:11-cv-2340-JPO, Document 104, at 4 (S.D.N.Y. Sept. 25, 2012).

[41] *See* 2015 BL 407149; *Eli Lilly & Co. v. Accord Healthcare, Inc.*, No. 1:14-cv-00389 SEB-TAB, Document 357, at 2-4 (S.D. Ind. Oct. 26, 2015) (Defendants' Reply Brief in Support of Defendants' Motion for Stay of Litigation).