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Inter Partes Review by Hatch-Waxman Competitors Will Likely Increase Because of the Effect of IPR Decisions on the 30-Month Stay

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A RECENT Goldman Sachs research note revealed that the top four generic biopharmaceutical companies now receive less than a third of the total generic prescriptions. Less than ten years ago, by contrast, those four companies could count on more than half of all prescriptions. This trend confirms that there are more generic competitors challenging patents under Hatch-Waxman and that challenges are being lodged against a wider array of drugs. Now, these companies have a new tool in their arsenal of patent challenges to branded pharma*: inter partes* review (IPR). This approach is faster and less expensive than a typical Hatch-Waxman action, which can cost at least $3–$6 million in legal fees and costs. Thus, IPR may be a sensible alternative to district court litigation for both parties.

Recent case law indicates that IPR may give generic drug companies another advantage. As discussed below, it is possible that an IPR victory adopted by a district court or a decision by the Federal Circuit in a generic's favor could lead to lifting of the mandatory Hatch-Waxman 30-month stay of FDA approval, exactly the same result that would occur with a district court ruling after trial. Thus, IPR could become an even more significant battleground for Hatch-Waxman litigants. Biopharmaceutical companies, brand-name and generic, should consider carefully the implications of IPR—and appeals from IPR decisions—in their larger strategies.

The 30-month stay is a core part of the compromise that led to the creation of the Hatch-Waxman Act. When a patentee (the "brand") files suit under the applicable provision of the Act, 35 USC §271(e)(2)(A), against a generic company (the "generic") that has submitted an ANDA with a paragraph IV certification, the FDA cannot approve the generic's ANDA for 30 months from the date of the patentee's receipt of the notice letter. 21 USC §355(j)(5)(B)(iii). Significantly, the court can lengthen or shorten the stay as a result of the lack of cooperation by the generic or the brand[1] or the entry of a preliminary injunction against the generic. *Id.* Thus, the length of the stay is not absolute, but is subject to equitable considerations, just like any equitable remedy, *e.g.*, an injunction.

A generic will often seek to prevail early in a litigation and thereby end the 30-month stay and obtain marketing approval for its product. The Act explicitly addresses the effect of a generic's win in district court action on the 30-month stay:

> (I) [I]f before the expiration of [the 30-month] period the district court decides that the patent is invalid or not infringed…, the [FDA] approval shall be made effective on –
>
> (aa) the date on which the court enters judgment reflecting that decision. …

21 USC §355(j)(5)(B)(iii)(I).

Accordingly, where the generic prevails, the entry of district court judgment terminates the 30-month stay. Significantly, the pendency of an appeal does not delay FDA approval.[2]

Where the generic loses at trial, but prevails on appeal, the 30-month stay also terminates:

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[1] *See, e.g., Novartis Corp. v. Dr. Reddy's Labs., Ltd.,* No. 04-cv-0757, 2004 WL 236007, at *3 (S.D.N.Y. Oct. 21, 2004).
[2] This, of course, assumes that the generic's ANDA is otherwise approvable.

(II) [I]f before expiration of [the 30-month] period the district court decides that the patent has been infringed –

(aa) if the judgment of the district court is appealed, the approval shall be made effective on

(AA) the date on which the court of appeals decides that the patent is invalid or not infringed. …

21 USC §355(j)(5)(B)(iii)(II).

Thus, the Act requires a decision of a district court or court of appeal to end the 30-month stay.

The question arises as to the effect of a decision of the Patent Trial and Appeal Board (PTAB) in an IPR invalidating the claims of the asserted patent on the 30-month stay.[3] A recent decision of the Federal Circuit is particularly relevant. *See, ePlus, Inc. v. Lawson Software, Inc*., 760 F.3d 1350 (Fed. Cir. 2014). There, e-Plus sued Lawson Software for infringement of two patents, U.S. 6,023,683 and 6,505,172. In its initial decision, the district court held various claims of the two patents valid and infringed, and enjoined Lawson from selling certain products. *Id.* at 1352–53. On appeal, the Federal Circuit affirmed the validity and infringement of only one claim—claim 26—of the '683 patent and remanded the case to the lower court to make any necessary modifications to the injunction. *ePlus, Inc. v. Lawson Software, Inc.,* 700 F.3d 509, 521–23 (Fed. Cir. 2012). On remand, the district court modified the injunction and found Lawson in civil contempt for its violation. Lawson appealed both the injunction and the contempt rulings. During the pendency of that appeal, the PTO completed its reexamination of the '683 patent and cancelled claim 26 as invalid. The PTO's decision was affirmed by the Federal Circuit. *In re ePlus, Inc.,* 540 Fed. App'x 998 (Fed. Cir. 2013)(*per curium*).

In Lawson's latest appeal, the parties agreed, and the Federal Circuit held, that the injunction against Lawson must be vacated because "[i]t is well established that an injunction must be set aside when the legal basis for it has ceased to exist," and any rights "previously conferred" by the patent "ceased to exist" when the PTO's decision was affirmed. 760 F. 3d at 1355–56. The majority also vacated the award of monetary sanctions for violating the injunction. *Id.* at 1357. Thus, after a Federal Circuit affirmance of a PTO decision invalidating a patent, that patent "no longer confers any rights that support an injunction against infringement." *Id.*

A decision by the PTO in a typical reexamination or by the PTAB in an IPR will probably not affect the 30-month stay of FDA approval. In *ePlus*, neither party argued that the PTO's decision by itself terminated the injunction. It would appear that a "court decision" is required, especially when examining the wording of the sections quoted above. Thus, a generic sued under 35 USC §271(e)(2)(A) could file a motion for summary judgment of invalidity after the PTAB's decision invalidating all relevant claims. If the motion is granted,[4] §355 (1)(5)(B)(iii)(I)(aa) dictates that the 30-month stay would terminate when the district court enters judgment for the generic. If the case had been stayed pending the PTAB's decision, the stay would need to be lifted to allow the generic to seek summary judgment. The brand, however, could petition the district court to stay the action or continue the 30-month stay (if one had been entered) while it appeals the PTAB's decision. The stay might not be granted or continued, as it would preclude a ruling on the summary judgment motion, and this would arguably frustrate the intent of the Act to allow generic approval and marketing following a district court judgment of invalidity.

If the generic that prevailed in the PTAB had not yet been sued by the brand, it would not be subject to the 30-month stay. However, FDA approval would be stayed once the generic files its ANDA. The generic would then seek an immediate ruling on the patent's validity. If the brand had already sued other generics, they would undoubtedly rely on the PTAB's decision in seeking summary judgments of invalidity. Once a summary judgment of invalidity was granted, the 30-month stay would terminate for all generics, even those not involved in the IPR.

After an IPR decision invalidating the claims asserted in a Hatch-Waxman action, a motion for summary judgment of invalidity may be the most efficient way for a generic to terminate the 30-month stay. But what if the brand appeals the adverse IPR decision? As noted above, it could be argued that this scenario should not prolong the 30-month stay. But assuming that the 30-month stay was still in place, would a Federal Circuit decision affirming the PTAB's holding of invalidity terminate the stay? Significantly, the Act specifies that a successful appeal by the generic from a district court decision terminates the stay. 21 USC §355 (7)(5)(B)(iii)(II). Under *ePlus*, however, it could

[3]The discussion assumes that the PTAB invalidates all claims asserted in the ANDA litigation.

[4]Even though the standards for invalidation are different between a district court and the PTAB, this does not alter the effect of an adverse PTAB ruling. *See, Fresenius USA, Inc. v. Baxter Int. Inc.,* 733 F.3d 1369 (Fed. Circ. 2013).

be argued that the Federal Circuit's affirmance of a PTAB decision to invalidate the asserted patent claims should have the same effect. In *ePlus,* after affirmance of the PTO's invalidity holding, the court held that the patent-in-suit "no longer confer[red] any rights that support an injunction against infringement." 760 F.3d at 1356–57. If similar reasoning were applied to an appeal of a PTAB ruling, the 30-month stay would terminate once the Federal Circuit affirms the PTAB's finding of invalidity. This outcome remains to be seen. But *ePlus* should be a "heads up" to branded and generic pharma alike that they should carefully consider the implications of IPR when devising their litigation strategies.

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