**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 brand1 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. ...


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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2 This, of course, assumes that the generic’s ANDA is otherwise approvable.
3The discussion assumes that the PTAB invalidates all claims asserted in the ANDA litigation.

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. Cir. 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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