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PTAB's Doors Would Be Closed To Generics Under Hatch Bill

By **Ryan Davis**

Law360 (June 20, 2018, 8:52 PM EDT) -- Proposed legislation by one of the architects of the Hatch-Waxman Act to require generics makers to choose between challenging drug patents under that law or through inter partes reviews would effectively bar generics from using America Invents Act proceedings, attorneys say.

Sen. Orrin Hatch, R-Utah, last week proposed, but has not yet introduced, the Hatch-Waxman Integrity Act, saying that allowing generics makers to challenge patents in inter partes reviews in addition to the traditional framework "threatens to upend the careful Hatch-Waxman balance by enabling two separate paths to attack a brand patent."

The legislation would require those filing abbreviated new drug applications seeking approval of generic drugs, as well as those seeking approval of biosimilars, to certify that that they have not and will not file petitions with the Patent Trial and Appeal Board challenging the patents that cover the branded version of the drug.

Hatch said the bill will give generics makers a choice between using traditional Hatch-Waxman litigation to challenge the patent's validity or an inter partes review, but not both. Attorneys say that isn't much of a choice, since to get a generic drug approved, a company generally must file an ANDA, and to do that, they must pledge not to file an IPR.

"To me, it really seems to wipe out IPRs as tools for generics makers to challenge innovator companies' patents," said Kevin O'Connor of Neal Gerber & Eisenberg LLP. "It seems like it would really be pushing them back into traditional Hatch-Waxman litigation as it has been done for the last few decades."

Since the Hatch-Waxman Act was passed in 1984, the standard practice for generics makers has been to file ANDA certifying that their generic versions won't infringe the patents on the branded drug, or that the patents are invalid, which often spurs district court litigation to resolve those issues before a generic version can be approved by the U.S. Food and Drug Administration.

Since AIA reviews became available in 2012, some generics makers have filed inter partes review petitions to challenge branded-drug patents, in addition to Hatch-Waxman litigation. Hatch said last week that while he supports inter partes review, "I do not support its use in a way that upends or eviscerates Hatch-Waxman."

He said his legislation "would prevent companies from using IPR to put added litigation pressure on innovators above and beyond what Hatch-Waxman already provides. And it would prevent a company that rightfully loses a Hatch-Waxman suit from getting a second bite at the apple."

The use of inter partes reviews to target drug patents apart from the Hatch-Waxman system has long rankled the pharmaceutical industry, which in 2015 made an unsuccessful push for legislation that would exclude drug patents from the AIA review system entirely. Hatch's bill, while not expressly exempting drug patents from review, would have much the same result, attorneys say.

"It's readily apparent where this legislation is coming from. It’s a very pro-brand amendment to Hatch-Waxman," said Kent Walker of Brinks Gilson & Lione.

Since Hatch-Waxman has long been the standard path for drug patent litigation, "I can see why the branded side thinks that generics are circumventing that paradigm" with inter partes review, said Dennies Varughese of Sterne Kessler Goldstein & Fox PLLC.

However, he noted that even when patents are challenged by generics at the PTAB, branded-drug makers still have the advantages conferred by the Hatch-Waxman Act, such as a 30-month stay of approval of the generic version and the right to an injunction.

"The only difference now is that the patent can be put in front of the same agency that issued it and can revoke it if it's found to be of dubious quality," Varughese said. "There is no gamesmanship. That's exactly how the law was intended."

Others said they could see the harm branded-drug makers face in having their patents challenged in both IPRs and Hatch-Waxman litigation.

Michael O'Shaughnessy of Baker Botts LLP said that "in the pharma world, every day counts and every week counts," and if the PTAB can invalidate patents more quickly than would be possible in a Hatch-Waxman case, that could cut into the sales of branded companies and hinder their ability to recoup their investment in a drug.

"Hatch-Waxman never intended for this to be an easy process to strike down patents on drugs," he said. "IPRs make it faster and cheaper, which is giving an advantage to generics makers."

He said Hatch's proposal is a reasonable solution that would restore a system that had been effective for decades.

"This legislation suggests the framework worked well and we need to get back to that," he said. "It would eliminate the loophole created by the AIA to return to a level playing field."

In contrast, "generics would be at a great disadvantage" under the bill, Varughese said. "It removes a tool from their arsenal to challenge patents."

In addition to essentially barring ANDA filers from challenging the patents at the PTAB themselves, the legislation would also require them to certify that no company with which it is "in privity," or has a relationship with, has filed an inter partes review either, which could spur fights in litigation over the relationships between companies.

Moreover, the measure would bar ANDA filers from "relying in whole or in part on any decision issued by the Patent Trial and Appeal Board" to say that the patent is invalid. That means even if someone else successfully got the patent invalidated by the PTAB, the generics company couldn't use that as evidence that the patent is invalid.

That seems intended to cut out the PTAB from being a factor in the Hatch-Waxman process, though it may be possible for filers to get around it.

Walker said filers could just say they aren't relying on the board's decision to argue the patent is invalid, just on the argument that was successful at the board. Nevertheless, the bill as a whole would throw up significant new roadblocks for generics makers, he said.

"It's not a good deal for generics and I don't think it will bring products to the market any faster," he said.

The bill is likely to spur a pitched battle between branded companies and generics if it were introduced and faces uncertain prospects in Congress.

On one hand, the name behind a bill about how the Hatch-Waxman Act should work will likely give it some inherent momentum.

"The fact that it was proposed by Sen. Hatch does carry a little bit more weight," O'Connor said. "The 1984 law did seem to work very well in balancing the incentive to innovate with getting generics to the market more quickly."

At the same time, the AIA was expressly designed to apply to all patents, and a carveout aimed at benefiting one industry is likely to face scrutiny. Moreover, the Trump administration has made lowering drug prices a key agenda item, and legislation that would hamper the entry of low-cost generic drugs runs counter to that goal.

"The overall tenor of Congress and the political landscape in general is focused on concern about drug prices, so may be tough to get support for a bill that would slow down generics," O'Connor said.

The bill is likely to be in the legislative spotlight for the rest of the year, since Hatch, who will retire in January after 42 years in the Senate, said the measure "will be a top priority for me during my remaining months in office."

--Editing by Katherine Rautenberg and Alanna Weissman.
