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Generics

Generic, Biosimilar Makers' Dual Patent Contests Still Safe

BY GREG LANGLOIS

Generic and biosimilar drug makers such as Teva Pharmaceutical Industries Ltd. and Dr. Reddy's Laboratories Ltd. will continue challenging name-brand drug products both in court and administrative proceedings for the foreseeable future as congressional efforts to eliminate this dual-track option falter.

Hatch-Waxman Act namesake Sen. Orrin Hatch (R-Utah) and others have introduced bills in recent months that would preclude generic and biosimilar drug sponsors from availing themselves of the Patent and Trademark Office's Patent Trial and Appeal Board while also fighting it out in district court. There doesn't seem to be enough support to pass them, even though many observers have criticized the use of PTAB, sometimes seen as too quick to cancel valid patents, McDonnell Boehnen Hulbert & Berghoff LLP partner Kevin Noonan told Bloomberg Law in an interview.

''It just seems to me that Senator Hatch is just voicing this concern,'' said Noonan, who's based in Chicago. ''It's kind of a threat because he's saying Congress could put this provision in and that would stop it right now. I won't say it's a shot across the bow, but I think it is showing some displeasure.''

Critics of PTAB say it too easily invalidates patents. In the pharmaceutical and biotech world, generic and biosimilar makers go there to challenge brand-name drug patents while they're also engaged in district court infringement litigation under procedures set out under two key laws that get low-cost competing products to market. Having a second bite at the apple forces branded drug makers to fight on two fronts and throws a wrench in the generic and biosimilar approval pathways Congress devised, critics say.

''[T]here are many, many instances where a patentee has prevailed in court, and lo and behold, the challenger has had a concurrent IPR filing in the patent office, and the challenger wins,'' Noonan said. ''You win today, and you go through the Federal Circuit appeal and you win—you totally win—and guess what, PTAB says you're invalid.''

Several Proposals Hatch introduced an amendment to the proposed Creating and Restoring Equal Access to Equivalent Samples (CREATES) Act (S. 947) that would have, among other things, amended the Hatch-Waxman Act to require generic drugmakers seeking Food and Drug Administration approval to certify they won't use PTAB inter partes review (IPR) or post-grant review (PGR) proceedings to challenge patents on the name-brand drug. The amendment also would have required biosimilar applicants following Biologics Price Competition and Innovation Act streamlined review procedures to make a similar certification. Biosimilars are highly similar, less expensive copies of complex, name-brand biologic drugs.

Hatch introduced the amendment during a Senate Judiciary Committee hearing but then didn't offer it when the committee marked up the CREATES bill. His goal was to ''discuss it at in the hearing because he believes it is an important issue that needs to be a part of the brand/generic discussion,'' Hatch communications director Matt Whitlock told Bloomberg Law in an email.

His amendment was designed to ''close the loophole'' unintentionally created by the America Invents Act, the 2011 patent reform law that, among other things, created PTAB, Hatch's office said in a summary of the amendment. PTAB was intended to be a way to speed resolution of patent disputes by offering an administrative alternative to lengthy court proceedings.

Rep. Steve Stivers (R-Ohio) also introduced a bill (H.R. 5340) that would alter the standards PTAB uses when evaluating a patent's validity. PTAB applies a different standard than courts do went construing patent claims, and patent challengers enjoy a lower burden of proof. Rep. Thomas Massie (R-Ky.) introduced another bill, the ''Restoring America's Leadership in Innovation Act'' (H.R. 6264), that would do away with PTAB and IPR and PGR procedures altogether.

The Biotechnology Innovation Organization, an industry trade group, said it supports Hatch's and Stivers' proposals. The Association for Accessible Medicines, which represents generic drugmakers, didn't immediately respond to Bloomberg Law's request for comment.

No Traction But don't expect these efforts to get much traction, Noonan said.

''The problem is that this is Congress, and there isn't ever really a groundswell about patenting,'' he said. ''I don't know that there's enough political will or understanding for any of this to happen anytime soon.''

Upcoming midterm elections and confirmation hearings for Supreme Court nominee Brett Kavanaugh will take up Congress's time and energy, Noonan added. And it may be a difficult sell to go after PTAB, especially the proposal to eliminate it, he said. The AIA was billed in part as a patent reform measure needed to confront patentees holding onto invalid patents and stifling competition, keeping drug prices high, Noonan said, ''and all that resonates with people.''

But generic drugmakers' ability to challenge brand-name patents on dual tracks upsets laws designed to get lower-cost drugs on the market, Morrison & Foerster LLP partner and pharmaceutical and biotech patent litigator David A. Manspeizer told Bloomberg Law in an email.

''I don't think the issue is disruption of procedures, as much as it is balance,'' said Manspeizer, who's based in New York City. ''Hatch-Waxman was a carefully crafted balance between the interests and needs of the branded and generic industries, and the public. That balance has shifted over the years since Hatch-Waxman was enacted, as the overall weakening of patent protections in the US has undermined that balance. The availability of IPR and PGR, with their lower burden of proof and different claim construction standard, have further shifted that balance.''

The shift affects how much money gets spent on research and development of new drugs and the drug industry as a whole, Manspeizer said.

''Because pharmaceutical R&D is so incredibly risky, undermining that carefully crafted balance, has, I believe, also resulted in accelerated industry consolidation,'' he said.

PTAB's penchant for invalidating patents at a higher rate than courts, even ones simultaneously upheld in court, has helped weaken the U.S. patent system, Noonan said.

''I think that it's a serious problem because, maybe not today or tomorrow, but if this is the trend, this is the pattern, within a generation, you'll have less incentive for there to be drug patents and drug development,'' he said. ''You are going to get drug development go abroad more if it can't be protected here.''

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