Portfolio Media. Inc. | 860 Broadway, 6th Floor | New York, NY 10003 | www.law360.com
Phone: +1 646 783 7100 | Fax: +1 646 783 7161 | customerservice@law360.com

Drugmakers Have Tough Task In Quest For AIA Exemption

By **Ryan Davis**

Law360, New York (September 11, 2015, 4:28 PM ET) -- Pharmaceutical companies may be able to make a case that their patents should not be subject to America Invents Act reviews since they can already be challenged through the Hatch-Waxman process, attorneys say, but the industry's bid to get Congress to exempt drug patents from AIA proceedings could face long odds.

Leaders of branded drug companies on Tuesday reiterated their call for legislation that would prohibit AIA reviews of pharmaceutical patents, in part in response to challenges to numerous drug patents by hedge fund manager Kyle Bass. The companies argue new drug patents are expensive and difficult to obtain and should not be subject to the streamlined AIA process that is now available for all patents.

Since generics makers can seek to invalidate drug patents through the long-established Hatch-Waxman litigation framework, drugmakers have a point that there isn't really a reason for such patents to also be subject to AIA challenges, said Colleen Tracy James of Mayer Brown LLP.

"To me, the most compelling argument is that there already is a procedure, and it doesn't make sense to have another procedure that can usurp Hatch-Waxman," she said.

Nevertheless, Congress has generally been loath to enact laws that impose different rules on patents based on the kind of technology they cover, which could make a blanket AIA exemption for drugs a hard sell for lawmakers.

"Politically, I have a hard time seeing Congress going down this path," said Courtenay Brinckerhoff of Foley & Lardner LLP.

There have long been arguments that patents in certain industries are so valuable that different rules should apply to them, but "for the most part, we've managed to get by for hundreds of years with a system that treats all industries the same," said Thomas Engellenner of Pepper Hamilton LLP.

"I'm not a big fan of different rules for different industries, and I don't think Congress is either," he said.

Calls for an Exemption

The Biotechnology Industry Organization and the Pharmaceutical Research and Manufacturers of America, two major drug industry lobbying groups, sent a letter to Congress in July detailing their request to exempt drug patents from AIA inter partes reviews, known as IPRs.

The groups said that subjecting patents for new drugs, which can cost billions of dollars to develop, to the IPR process as well as Hatch-Waxman challenges could undermine patent protection for medicine. They suggested the exemption be added to legislation aimed at curbing abusive patent litigation, which could be taken up in both houses of Congress later this year.

"The IPR process threatens to disrupt the careful balance that Congress achieved over 30 years ago, by increasing business uncertainty for innovative biopharmaceutical companies having to defend their patents in multiple venues and under differing standards and procedures," the groups said.

An exemption would "preserve the integrity" of the Hatch-Waxman system, where patents for approved drugs are listed in the so-called Orange Book, as well as the Biologics Price Competition and Innovation Act, or BPCIA, the related system for biosimilars, they argued.

"There is no evidence that Congress intended the IPR process to be used by generic and biosimilar companies to challenge biopharmaceutical patents outside of Hatch-Waxman and BPCIA," they said.

The letter argued that an exemption is particularly needed because drug patents have been targeted in AIA reviews by "unscrupulous hedge funds and other questionable entities," a clear reference to Bass, who has filed scores of AIA petitions seeking to invalidate drug patents as part of a short-selling strategy aimed at driving down the price of drug company stocks.

To date, the Patent Trial and Appeal Board has ruled on three of Bass' petitions and denied each one, finding that they did not make a strong enough case that the patents are invalid. The board did not address arguments by the drugmakers that Bass' petitions should be denied on the ground that his investment strategy is an abuse of the AIA process.

Theoretically, generic-drug makers could also use the IPR process as an end-run around traditional Hatch-Waxman litigation in district court, allowing them to invalidate branded drug patents more quickly and potentially enter the market sooner.

While generics makers have filed several IPRs against branded drug patents, it does not appear that any have successfully invalidated patents and allowed earlier market entry so far.

A situation like that would represent a significant change in drug development, however, and the calls for an exemption show that "the pharmaceutical industry wants to solve the problem before it gets to that point," Brinckerhoff said.

A Question of Intent

Drug patents involve a great deal of expensive research and development, and Congress has already set up the Hatch-Waxman framework for challenging them, so it doesn't seem like Congress intended for them to be challenged in the IPR process, said Antoinette Konski of Foley & Lardner.

"While IPRs can be used to challenge drug patents, I don’t believe the intent of the AIA was to have hedge funds use IPRs to challenge patents," she said, adding that "something needs to be done" to keep hedge funds from challenging patents under the AIA.

Congress is going to have to address the fact that the balance of Hatch-Waxman is disrupted by the IPR

process, as well as the issue of hedge funds using the AIA system to manipulate stock prices, James said.

"Certainly, some restrictions and constraints need to be placed on this procedure for the right type of patent," she said, noting that even if Orange Book-listed drug patents were exempt from AIA reviews, they could still be challenged under Hatch-Waxman.

The concern for the pharmaceutical industry is that patents covering drugs are considerably more valuable than patents in an industry like software, where companies may have thousands of patents on various features but each one is of negligible value, said Bernard Knight of McDermott Will & Emery LLP.

"The easier it is to attack drug patents, the less likely it is that there will be incentive to spend money on research and development of new drugs," he said.

However, Knight said that calls for an exemption will likely run up against arguments that the AIA proceedings were designed by Congress to provide a mechanism for cleaning up the many poor-quality patents that some say have been issued by the U.S. Patent and Trademark Office.

"If this is the policy behind the post-grant proceedings, it's a more difficult hurdle to exempt any particular industry from the process," he said.

A Less Drastic Option

One possible alternative to an exemption, Knight said, would be to impose a standing requirement on the IPR process. There is already such a requirement in the AIA's business method patent review program, allowing only companies that have been sued or accused of infringement to challenge patents.

Discarding the rule that anyone at all can file an IPR petition would foreclose generics makers from using them to avoid Hatch-Waxman, and also shut down petitions by hedge funds, he said.

Engellenner said he would be more sympathetic to the pharmaceutical industry's concerns if it were seeking such a standing requirement, but that the requests for a blanket exemption go too far, and would only motivate other industries to push for a bar on AIA reviews of their patents.

"To just seek a total exclusion for the industry of anyone challenging patents goes far beyond what is necessary to remedy the hedge fund problem," he said.

In addition, Engellenner said he doesn't think subjecting drug patents to IPRs is incompatible with the Hatch-Waxman system, since the Congress enacted the AIA to allow review of all patents.

"I'm not at all convinced that there's anything different about generic-drug manufacturers that should prevent them from being able to take advantage of the process," he said.

The high rate at which the PTAB has invalidated patents should be a concern for all patent owners, Engellenner said, and drugmakers should focus on that issue, rather than carving out an exemption for their industry.

"They really should be lobbying for changes to the system to make it fairer for everyone," he said.

--Editing by Mark Lebetkin and Katherine Rautenberg.