Big Pharma Seeks Exemption From Patent Law

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Implementation of the America Invents Act ("AIA") has brought substantial changes to the patent law of the United States over the last several years. One of the most significant provisions of the AIA was the creation of *inter partes review* ("IPR"), which provides an alternative mechanism for parties to dispute issued patents based on only on prior art (i.e., issued patents, published patent applications, and published non-patent literature).

The goal of IPR is to provide a faster, less expensive option to traditional litigation for invalidating patents based on a lack of novelty or non-obviousness. IPR may be initiated based on a petition by any person other than the patent owner and may be filed by the later of nine months after the issue date of the patent or after the termination of any post-grant review proceeding.

The IPR process has been the subject of criticism from both sides of the pharmaceutical industry. Large pharmaceutical companies are lobbying for amendments to the patent law that would make pharmaceutical patents exempt from IPR challenges. Big Pharma claims that the process is unfairly set up to favor patent challengers, making it too easy to invalidate pharmaceutical patents. Organizations such as AARP have submitted statements to congress expressing their concern that such an exemption would lead to even higher prescription drug prices.

The fact that any entity can file a petition for IPR does leave Big Pharma open to attack. Of recent note, Kyle Bass and the Coalition for Affordable Drugs have filed multiple petitions for IPR seeking to invalidate a number of patents owned by large pharmaceutical companies. Bass claims these petitions are a way to decrease the cost of prescription costs by invalidating the associated patents. His critics claim the petitions are a devious attempt to profit by devaluing the stock of the pharmaceutical companies that own the patents.

Bass' targets are firing back, with Celgene Corporation recently filing a motion for sanctions in the IPR initiated against its patents. The United States Patent and Trademark Office's Patent Trial Appeal Board ultimately refused to sanction Bass in the Celgene IPRs, claiming Celgene did not show "a non-meritorious patentability challenge." It remains to be seen if other patent owners will make similar attempts.

In addition to potentially leading to higher prescription drug prices, the exemption would leave traditional litigation as the only mechanism to challenge the validity of pharmaceutical patents. With the average cost of patent litigation ranging in the millions of dollars, filing suit would be cost prohibitive for many would be challengers. With the dollars at stake, we can expect the battle over the pharmaceutical patent exemption to continue for some time.

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