MI³ Alert





Medical Innovation Impact Index

6/24/15 - Report #2

General Description of Issue

Inter partes review (IPR) is a post-grant review proceeding authorized by the 2012 AIA (America Invents Act) conducted by the PTAB (Patent Trial and Appeal Board) to review the patentability of one or more claims in an issued patent only on a ground that could be raised under §§ 102 (novelty) or 103 (non-obvious), and only on the basis of prior art consisting of patents or printed publications. The procedure for conducting inter partes review took effect on September 16, 2012, and applies to any patent issued before, on, or after September 16, 2012.

Purports To Do

Known by some as the Patent Death Squad, the PTAB's power under the AIA enables it to invalidate patents that are of little or no merit but can be a significant nuisance to those who are practicing the claimed inventions. Through April 2014, 5,458 claims in 167 patents have been the subject of petitions, 71.2% of which were for electrical/computer (technology) products, and only 5.1% for biopharma products. The PTAB grants—or (continued on pg. 2)...

Success in achieving objective: +0.5

(technology products: +4)

Potential Positive Impact on Innovation

1. Companies faced with (or a party to) infringement suits by patent trolls (non-practicing entities that accumulate patents without practicing them and then file infringement lawsuits) can quickly and inexpensively (relative to litigation) use IPRs to have the claims of the nuisance patents invalidated, thereby enhancing their freedom to operate and eliminating the frivolous suits. While the PTAB is (continued on pg. 2)...

Positive Impact on Innovation: +0.5

(technology products: +4)

Unintended Consequences

1. Hedge fund challenges and shorting: Because anyone can initiate an IPR, investment organizations whose businesses are unrelated to the patents, and, therefore, are not at risk of counter patent infringement suits, can file IPRs against patents owned by companies whose valuations are significantly based on the existence of the patents or on revenues in product lines that are protected by the patents. The investment organizations can (continued on pg. 2)...

Emergence of Unintended Consequences: -4.5

(technology products: -1)

Potential Negative Impact on Innovation

- Hedge fund shorting has the tone of stock manipulation, pure and simple. It hurts investors in the company, as well as the company itself, reducing the value of its stock and jeopardizing its future revenues. This reduces the company's ability to do deals, raise capital, and execute its business, which can severely constrain its development activities;
- 2. Reverse trolling devalues intellectual (continued on pg. 2)...

Negative Impact on Innovation: -4.5

(technology products: -1)

MI³ Score =

-8 (technology products: +6)



IPR is severely negative with respect to medical innovation, but beneficial for technology innovation

Recommendations

The IPR framework has been very effective for clearing out nuisance/junk technology patents, but, has created a series of unintended consequences that severely adversely affect biopharmaceutical innovation. IPR should be amended to address the untoward practices by hedge funds and reverse trolls. We recommend several ways to accomplish this: (a) amend the AIA to bar any entities from filing IPR's "unless the person or the person's real party in interest or privy has been sued for infringement of the patent or has been charged with infringement under that patent," the same way that the AIA restricts (continued on pg. 3)...



Medical Innovation Impact Index

6/24/15 - Report #2 - Page 2

Purports To Do (continued from pg. 1)

"institutes"—IPR petitions for at least one challenged claim 84 percent of the time; among instituted IPRs, all challenged claims are instituted 74 percent of the time; among IPRs that reach a final decision on the merits, all instituted claims are invalidated or disclaimed more than 77 percent of the time;

2. The goal was to offer a much more efficient, less time consuming, and less costly alternative for patent challenges compared to those carried out in the federal courts established under Article III of the Constitution.

Potential Positive Impact on Innovation (continued from pg. 1)

adjudicating the IPR, the courts will often put the litigation on hold;

2. Challenging patents as defendants in the courts is very expensive and time consuming. By decreasing the cost and time, companies engaged in developing and commercializing innovative products can conserve resources, preserve reputation, and can utilize the conserved resources for the development of additional innovative products.

Unintended Consequences (continued from pg. 1)

then short the stocks of the target companies. The IPRs devalue the patents and therefore the valuations of the targets, and the hedge funds reap monetary rewards from the bad news. Several companies, including Acorda, NPS, and Celgene are fighting back: (a) NPS filed a motion for additional discovery to force Hayman Capital Management to disclose all real-parties-in-interest (RPI); (b) Acorda's preliminary response echoed the real-parties-in interest concern and argued that "[u]se of the inter partes review process as a tool to manipulate markets is not what Congress intended"; and (c) the PTAB authorized briefing on Celgene's Motion for Sanctions over whether Hayman and his related companies were, as alleged, "abus[ing] the IPR process for private financial gain." Celgene argued that Hayman intends to use the IPR process for the purpose of affecting the stock price of publicly traded companies, which is "not the purpose for which the IPR process was designed." Celgene also alleged that "one or more of the identified real-parties-in-interest previously threatened to file IPRs against the challenged patents unless Celgene met their demands";

- 2. Reverse (PTAB) trolling: Because anyone can institute an IPR challenge, entities whose businesses are unrelated to the patents, and, therefore, are not at risk of counter patent infringement suits, can use the IPR to devalue patents of companies who stand to advantage themselves using their patents, for example, companies who are poised to receive huge awards following successful patent litigation (but prior to being satisfied). We could call these parties reverse trolls. The reverse trolls can use the same prior art that was used in the litigation, but, because the PTAB's have a lower standard for non-obviousness, the likelihood that claims could be invalidated by the PTAB is higher. So, companies may settle promptly with the reverse trolls in order to avoid a circumstance where the PTAB (aka Patent Death Squads) would invalidate all or several claims;
- 3. Would-be reverse trolls also threaten to file IPR's against products that make-up large percentages of a company's revenues unless the company settles, a practice that is becoming rampant in biopharma.

Potential Negative Impact on Innovation (continued from pg. 1)

property of sound practiced patents, encourages frivolous attacks on legitimate patents, and causes reputational harm, all of which deprive smaller companies developing innovative products of the financial and intellectual resources necessary to carry out their mission:

3. The specter of patent challenge and claim invalidation of biopharma products prior to anticipated marketing exclusivity periods defined in Hatch-Waxman Amendments and other regulations bring great uncertainty into drug development investment.



Medical Innovation Impact Index

6/24/15 - Report #2 - Page 3

Recommendations (continued from pg. 1)

CBM (covered business method post grant reviews) to those entities with standing; (b) limit the right of IPR requesters to trade commercial financial instruments of companies that own the patents subject to the IPR, similar to a pending House Judiciary Committee proposal; (c) exempt biopharma products (those listed in the Orange Book) from IPR since Hatch-Waxman and the new Post Grant Review (available within the first 9 months after issuance) provide effective methods of patent challenge.

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