
April 14, 2015

Statement of J Kyle Bass
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U.S. House of Representatives
Committee on the Judiciary
Hearing: H.R. 9, The "Innovation Act"

The Honorable Bob Goodlatte
Chairman
House Judiciary Committee
2138 Rayburn Office Building
Washington, DC 20515

The Honorable John Conyers, Jr.
Ranking Member
House Judiciary Committee
B-351 Rayburn Office Building
Washington, DC 20515

Dear Chairman Goodlatte and Ranking Member Conyers:

We applaud your recent efforts to examine ways to strengthen the patent system. As you continue your work in this area, we strongly urge you to preserve important statutory provisions that provide vital patent protections, while promoting industry competition and consumer relief. Specifically, we believe that the United States Patent and Trademark Office's (USPTO) Patent Trial and Appeals Board (PTAB) is effectively serving an important purpose as currently structured under the America Invents Act of 2011 (AIA).

As you know, as part of the AIA, Congress created the administrative trial proceedings to be conducted by the PTAB to improve patent quality and create a more effective and efficient way to challenge patent validity. This is achieved through conducting inter partes reviews (IPR) and other post-grant reviews. The IPR process was designed to overturn a small minority of patents that are particularly vague or lack novelty – regardless of a patent's technology class. Indeed, Mr. Jason Piché, a Medtronic Inc. patent counsel for spinal and biologics



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recently commented that as a result of IPR challenges to pharmaceutical patents, "the drafting of obtuse patents will go away, he said, which is 'a good thing.'"[1] By helping identify the few 'bad apples', IPR helps strengthen the integrity of the vast majority of legitimate and important patents.

The implementation of PTAB IPR proceedings has resulted in significant benefits to both consumers and industry. In particular, IPR proceedings are highly beneficial because they appropriately allow patent validity to be examined by a panel of agency experts rather than a court, and provide a faster, more affordable alternative to the judicial system in challenging patents. The PTAB system as currently structured has thus far been highly effective in eliminating particularly egregious invalid patent claims. We believe the PTAB IPR processes should be left in their current form as the USPTO continues to carry out Congress' directives outlined in the AIA.

The abuse of the patent system by entities acquiring and enforcing weak patents is not limited to one particular industry or type of patent – and for that reason the AIA did not limit its IPR procedures to particular technology classes. And while weak patents in the electrical and computer technology sectors impose costs on large technological companies, weak patents in the pharmaceutical sector impose economic costs that reverberate throughout the U.S. economy in the form of high prices for prescription drugs.

A small number of companies in the pharmaceutical industry have engaged in abusive practices by acquiring and enforcing weak patents. The sheer ridiculousness of simple concepts that are claimed to be "novel" in certain pharmaceutical patents like "siliconized rubber stoppers" (US Pat No. 8,476,010), an "exclusive pharmacy" using "exclusive databases" (US Patent No. 7,895,059), taking an old drug for "at least two weeks" for a chronic condition (8,007,826), taking an old oral contraceptive for "24 days" instead of 21 days (US Patent No. 5,552,394), and certain others, keep these few drug companies' monopolies on old products alive. These abuses of the patent system are taxes on the US economy, public welfare, and every citizen afflicted by diseases that range from Multiple Sclerosis to Narcolepsy and a number of other conditions. If nothing novel is disclosed, a patent owner should not be rewarded with a government grant of a 20-year monopoly.

Hayman Capital Management is a $2 billion investment management firm based in Dallas, Texas. Hayman has been in operation for nine years and has had a

[1] "Pharma Moves From 'Denial' To 'Acceptance' Of Post-Grant Patent Challenges," Brenda Sandburg, *The Pink Sheet*, April 6, 2015.



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successful track record in spotting global imbalances over the past decade. Hayman has been historically successful in identifying, in advance, the subprime mortgage crisis, European sovereign debt crisis, and current stresses in Japan, and counseling politicians and corporate actors about potential consequences. In all cases, we took a simple, common sense approach to each situation, analyzed the specific nuances, and implemented a sound investment policy around our conclusions.

Over the past year, a small number of monopolistic drug franchises that have gone unchecked have become our special focus. We intend to challenge less than 1% of the existing branded drug universe (which includes 3,522 branded prescription drugs, according to IMS data) in order to police the abusive patent tactics used by the worst offending drug companies. Unlike many historical challenges by generic drug companies in the Federal court system and the PTAB, Hayman will **NOT** accept settlement payments in order to drop our challenges. We are filing merit-based IPRs at the USPTO with the full expectation of seeing the challenge through to a final decision by the PTAB. These actions provide one of the few impartial arbiters of abusive patent monopolies in the marketplace.

There are three reasons generic pharmaceutical companies are not effective or reliable policemen of the patent abuses that certain branded manufacturers engage in, which cause harm to the economy, society, and citizens afflicted with disease.

***First***, to avoid the risk of a finding of invalidity in Hatch Waxman litigation and losing a patent, brand manufacturers for years have entered into "pay for delay" arrangements, where brand pharmaceutical companies pay significant sums of money to generic companies to drop lawsuits challenging brand patent validity. In many instances the goal of generic companies is not to *eliminate* the brand's monopoly profits based on weak patents—it is to *share* in those profits with the brand manufacturer. The recent record from IPRs filed by generics challenging brand patents shows this same pattern continuing—a generic filed an IPR on the brand "rubber stopper" patent identified above, and in less than three months the generic dropped the IPR validity challenge and settled with the brand.[2]

***Second***, brand manufacturers' strategies to avoid generic entry have become more sophisticated. In a recent report to Congress[3], the FTC outlined the

[2] *See* Dr. Reddy's Laboratories, Inc. v. Fresenius Kabi USA, LLC, IPR2015-00715, Paper No. 12 (PTAB, April 2, 2015).

[3] Prepared Statement of the Federal Trade Commission, Before the United States House of Representatives Committee on the Judiciary, Subcommittee on Regulatory



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decade-long challenge it has faced in attempting to end “pay for delay” and other antics engaged in by brands and generic “competitors”. These include “no-authorized-generic” commitments (when a brand-name drug firm agrees not to launch its own authorized generic when the first generic company begins to compete), “REMS” strategies (when a brand-name drug firm uses safety protocols to deny generic manufacturers access to samples to prevent the generic from being able to conduct bioequivalence testing—the “exclusive pharmacy” and "exclusive database” patent noted above) and “product hopping” (when brand-name drug firms make minor non-therapeutic changes to their product, obtain patents on these minor changes and shift physician prescribing patters to the newer patent-protected version of the drug, extending the brand monopoly).

***Third***, many times generic companies will forego challenging the validity of a brand patent in favor of attempting to design a drug that does not infringe on the brand patent. When a generic succeeds in avoiding infringement, there will be a period of time where only one generic product is on the market, creating an effective duopoly implicitly designed to keep drug prices and profits sky high. This hurts consumers, who would otherwise benefit from lower prices.

We are not alone in calling attention to the negative impact these tactics have. In 2010, the Federal Trade Commission authored a report titled “Pay for Delay: How Drug Company Pay-Offs Cost Consumers Billions.”[4] The Commission concluded that, “[p]ay-for-delay agreements have significantly postponed substantial consumer savings from lower generic drug prices. The Commission has recommended that Congress should pass legislation to protect consumers from such anticompetitive agreements.”

So far neither the FTC nor generic challenges have stopped “pay for delay”. But the IPR process can. Hayman is not interested in pay for delay or any settlement that does not clear the way for all generic competitors to enter the market and drive down drug prices.

Some have expressed concern that third parties are able to file IPR petitions. Like the procedures for challenging validity that existed at the USPTO prior to the

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Reform, Commercial and Antitrust Law, “Oversight of the Enforcement of the Antitrust Laws,” November 15, 2013. http://judiciary.house.gov/files/hearings/113th/11152013/FTC%20Testimony%20Re%20Antitrust%20Law%20Enforcement%20House%2011%2015%202013.pdf.

[4] https://www.ftc.gov/sites/default/files/documents/reports/pay-delay-how-drug-company-pay-offs-cost-consumers-billions-federal-trade-commission-staff-study/100112payfordelayrpt.pdf.



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AIA (*ex parte* and *inter partes* reexaminations), and like procedures that exist in Europe and the rest of the world (opposition proceedings), Congress specifically provided in the AIA that "any person" may file an IPR proceeding. This is absolutely consistent with US historical practices and sound policy. During his keynote address at the American Conference Institute's recent meeting in New York on post-grant PTO proceedings, PTAB Chief Justice James Donald Smith explained that "[t]he statute divides the world of any patent into two camps, the patent owner and anyone other than the patent owner who, once meeting standing requirements, is permitted to file a petition. It serves everyone's purposes to not be seen to be looking too much at who is bringing the action once they meet those requirements."[5]

The PTAB is operating as Congress intended and has proven to be a powerful and effective tool in ensuring robust oversight of patent validity. Therefore, any changes to the PTAB could reverse tangible positive impacts and interfere with the USPTO's meaningful ongoing efforts to evaluate and improve PTAB processes based on public feedback.

While H.R. 9 has many positive attributes, any change to the PTAB's use of "Broadest Reasonable Interpretation" (BRI) in interpreting patent claims at this juncture would be premature and harmful. If during the patent application process patent owners choose not to narrowly define key patent claim terms—why should they benefit from a narrow construction of claim terms that could salvage validity during an IPR when they chose to leave vague claim terms undefined during prosecution? The "vagueness" of patents is very much a problem created by the patent owner.

Two recent developments further confirm that Congress should wait to act on the BRI issue. In February of this year, the United States Court of Appeals for the Federal Circuit approved of the PTAB's use of BRI, noting that Congress gave this rule-making authority to the Director of the USPTO noting that "the broadest reasonable interpretation standard has been applied by the [USPTO]…for more than 100 years in various types of [USPTO] proceedings."[6] The Federal Circuit further noted its long history of the approval of the use of BRI, explaining that, "[i]ndeed, that [BRI] standard has been applied in every [USPTO] proceeding involving unexpired patents." This includes, of course, pre-AIA proceedings to invalidate patents. On March 27, 2015 USPTO Director Michelle Lee announced a series of rule changes applicable to all IPR proceedings that went into immediate effect and included making motions to amend claims easier during an

[5] "'Reverse Patent Trolls' Allowed To Pursue PTO Patent Challenges," Brenda Sandburg, *The Pink Sheet*, April 6, 2015.
[6] *See In re Cuozzo Speed Techs., LLC*, 778 F.3d 1271 (Fed. Cir. 2015).


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IPR proceeding. If the patent owner is able to amend claims in an IPR, the BRI standard is absolutely the proper standard. Congress should maintain the BRI standard in deference to both the 100 years of USPTO history and to the recent changes announced by Director Lee.

The AIA has been in full effect for only 30 months, and Congress should take a cautious and balanced approach to considering material changes to the PTAB at the request of a single industry. A small minority of drug companies are abusing the patent system to sustain invalid patents that contain no meaningful innovations but serve to maintain their own anti-competitive, high-price monopoly, harming Americans suffering from illnesses.

Our IPR petitions fulfill and define the purpose of the IPR process and address very specific patents that we believe, unlike the vast majority of legitimate patents, do not represent true innovation or invention.

Sincerely,

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