THE U.S. STILL HAS A DRUG PROBLEM

UPDATE ON PHARMA PATENTS – NOVEMBER 8, 2016

To date, the Patent Trial and Appeal Board has reached a final decision in eight instituted inter partes review (IPR) challenges, including seven IPRs filed by the Coalition for Affordable Drugs and one IPR filed by Erich Spangenberg and me personally on a not-for-profit basis. The outcomes were favorable in seven of the eight IPRs. Our results continue to validate the view that, in many cases, the pharmaceutical industry has abused the U.S. patent system by obtaining and exploiting invalid patents, thereby unjustly benefiting from government-granted monopolies on non-innovative drugs and treatments. Making matters worse, many of the same pharmaceutical companies which have profited through unethical "life cycle management" practices have also avoided paying U.S. taxes by inverting into tax-advantaged foreign companies.

Over the past 15 years, the pharmaceutical industry has been one of, if not, the largest political contributor in the U.S. By making these contributions to both sides of the aisle, Big Pharma has won over the hearts, minds, and wallets of key politicians, influencing policy and protecting its special interests. The system must be fixed, and the IPR process continues to be a critical tool for change by providing a mechanism through which pharmaceutical companies are held accountable and denied unjustified premiums placed on drugs that otherwise would be affordable to Americans. We look forward to continuing our work of challenging dubious patents that enshrine monopolies protecting drugs that lack innovation to the detriment of Americans suffering from illness. Included below are summaries of the IPRs that have reached final decisions to date.

Gattex – Shire PLC

- *Patent: 7056886*
- *PTAB Decision: Patent Claims Invalidated (October 21, 2016)*

The Patent Trial and Appeal Board (PTAB) ruled in favor of the Coalition for Affordable Drugs (CFAD) and invalidated all instituted claims related to the formulation of Gattex. There were certain claims that we strategically did not challenge because they were related to methods of manufacturing which are easier for generics to work around without infringing on the patent. In addition, there were certain "dependent" claims

that were challenged and not instituted. These claims were ultimately "dependent" on claims that were invalidated and as a result, are effectively unenforceable. Furthermore, the Gattex decision will accelerate the entry of generic competition in the treatment of Short Bowel Syndrome (SBS), a treatment for which Shire currently charges $376,000[1] per patient a year (making Gattex one of the most expensive drugs in the world). Gattex generates almost $200 million in annual sales, despite only treating a very small population of patients (<1,000), while Shire also avoids paying its fair share of U.S. taxes on profits through its inversion into a tax-advantaged Irish company.

The patent on the formulation of Gattex never should have been issued as it was obvious, and as a consequence, it was invalid from the beginning. The PTAB's decision will hopefully help expose the broad, troubling practice in the pharma industry of securing invalid patents which are obvious based on existing prior art in order to stifle competition, potentially overcharging state and federal payors, and game the system. In a January 22, 2016 letter to Gilead Chairman, and then CEO, John Martin, the Massachusetts State Attorney General wrote that the high price of Sovaldi (Hepatitis C drug manufactured by Gilead) "may constitute an unfair trade practice in violation of Massachusetts law." The letter went further to say that the AG's office was looking into bringing an unfair commercial conduct complaint against the company. The Sovaldi matter is highly relatable to Gattex and Shire should similarly prepare itself for state attorneys general and federal payors inquiring as to why they are peddling such an expensive drug that should have never received a U.S. patent.

Lialda – Shire PLC

- *Patent: 6773720*
- *PTAB Decision: Patent Claims Not Invalidated (October 5, 2016)*

The PTAB ruled that the claims securing Shire's patent on Lialda were valid. The decision was determined based on an extremely narrow definition of "wax" rather than looking at the obviousness of using a "waxy substance," suggesting that the PTAB was grasping for a reason not to kill the claims. In a telling excerpt from the PTAB's decision, the judges reasoned "[i]n addition, the two U.S. patents listing cetyl alcohol or higher alcohols generally as 'waxes' are outweighed significantly by non-patent extrinsic evidence in the form of relevant treatises, textbooks, and dictionaries that chemically define 'waxes' as being esters."

The arguments around the obviousness of a matrix are almost cruel; the PTAB acknowledged that the types of matrices were well known but that the patent challenge **did not pick the right one**. In doing so, the PTAB has reverted back to virtually requiring **single art anticipation[2].** More concerning, PTAB Judge Jacqueline Bonilla (the author of the final opinion) asked Shire's attorneys, in an oral hearing, whether the patent being challenged **was the only patent listed in the Orange Book**; Shire's attorney confirmed that it was. Clearly, the question was **irrelevant** to the matter before the PTAB. The ONLY question before the PTAB was exclusively whether the patent was valid or not. While the question as to whether Shire's monopoly was protected by a single patent was not applicable to the matters of obviousness, it was evidently a concern of Judge Bonilla. Why would Judge Bonilla ask this question?

If the Lialda patent at issue – which is set to expire in 2020 – were found invalid, there would be no barrier to generic entry, pending Food and Drug Administration (FDA) approval. Currently, there are six known generic

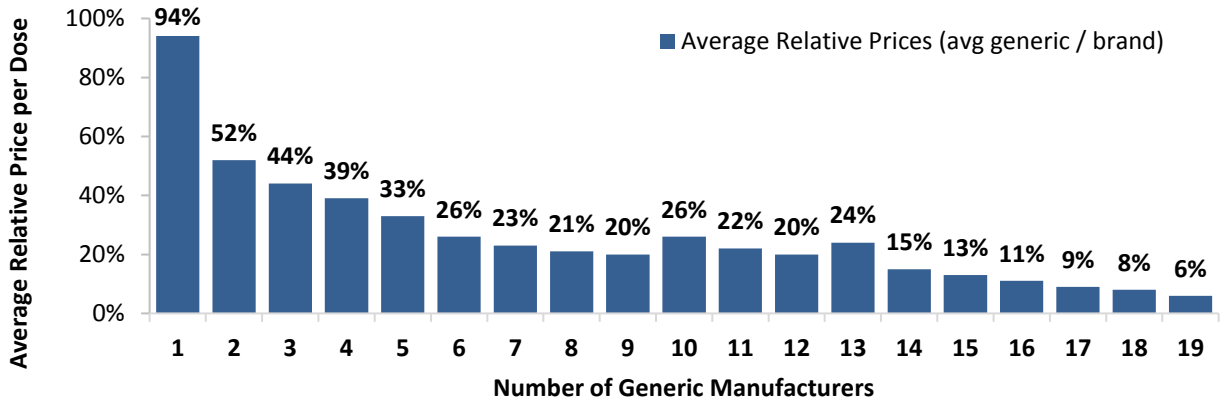
[1] The Wall Street Journal (http://www.wsj.com/articles/shire-to-buy-nps-pharmaceuticals-for-5-2-billion-1420996764).

[2] If a single prior art reference teaches all of the elements of a claim together in the proper context, them the claim would not be patentable.

manufacturers seeking permission to market a generic version of Lialda which have all filed abbreviated new drug applications (ANDA) with the FDA. The unfortunate outcome in this case is that generics stand ready to enter the market and lower drug prices, but instead will likely be embroiled in years of costly legal proceedings over a patent which the PTAB should have invalidated on the grounds that it was obvious.

Generic Competition & Drug Prices[3]

Generic competition is associated with lower drug prices.
The appearance of a second generic reduces the average price to nearly *half* the brand name price.



Suprenza – Alpex Pharma (marketed by Citius Pharmaceuticals)

- *Patent: 8440170*
- *PTAB Decision: Patent Claims Invalidated (October 11, 2016)*

Suprenza was initially approved in 1959[4], yet continued to be secured by multiple patents in the FDA's Orange Book through 2018 and 2029, respectively. In other words, it is an especially egregious example of patent evergreening: a practice of repeatedly extending patents with slight modifications to old drugs. The patent protecting this utterly ridiculous "innovation" claimed that its "speckled appearance" was worthy of a U.S. government-backed monopoly. The pill in question was a diet pill, which was white with blue speckles on it. We used Tutti-Frutti gum as a prior art reference to prove that the appearance of the pill was neither original nor patentable.

The IPR related to Suprenza was instituted by the PTAB on May 20, 2016. Just over a month later, the company that marketed Suprenza (Citius) announced that it was discontinuing the product. In a company press release, CEO Myron Holubiak, said:

> *"Suprenza no longer meets our core strategic objectives. We are dedicating our focus on our Phase 3 asset Mino-Lok and our Phase 2b asset Hydro-Lido for hemorrhoids. We feel that the obesity and weight management market has shifted and therefore we are devoting our efforts on developing our leading two assets. We anticipate a minimal financial impact to Citius from discontinuation since we eliminate our ongoing regulatory expenses […]."* [5]

[3] U.S. Food & Drug Administration.
[4] Citius Pharmaceuticals (http://www.citiuspharma.com/wp-content/uploads/2013/11/Suprenza-Brochure.pdf).
[5] The Pharma Letter (http://www.thepharmaletter.com/article/citius-pharma-discontinues-obesity-drug-suprenza-to-focus-on-core-assets).

The timing, after 57 years of maintaining its branded status, is not lost on us. It is comical that the press release announcing the discontinuance did not mention the impending IPR and certain doom of a drug secured by such an egregious patent. After the patent owner decided not to defend the patent, the PTAB ruled to invalidate and cancel all challenged claims securing the patent. This example highlights the unethical extent of certain evergreening practices, which in this case allowed the owners to benefit from branded status for over half a century. When challenged, it also shows just how indefensible certain patents really are.

Revlimid – Celgene Corporation

- *Patent: 6045501 & 6315720*
- *PTAB Decision: Patent Claims Invalidated (October 26, 2016)*

The PTAB ruled in our favor, invalidating the claims protecting two of Celgene's controlled delivery system patents that are listed in the FDA Orange Book for three of Celgene's cornerstone drugs: Thalomid, Revlimid, and Pomalyst. Celgene effectively patented a process to determine whether or not a woman was pregnant before a prescription would be authorized. Worse yet, Celgene pawned the process from another company; ironically, the company that developed the process did not patent it – likely because it was not patentable – but that didn't stop Celgene.

The obvious and ridiculousness of these patents rival the ridiculousness of Suprenza's "speckled appearance" patentability; sadly and similarly, this also highlights the extent to which pharma companies will go to stifle competition, patenting the absurd in order to add layers of monopolistic red tape.

In a desperate act of cronyism, Celgene even filed a motion with the U.S. Patent and Trademark Office (USPTO) to sanction the Coalition for Affordable Drugs based on a claim of "abuse of process" and to dismiss our challenges. Celgene's motion was littered with references to CFAD's "admitted profit motive," and made the curious argument that filing IPR petitions with a profit motive constitutes an "abuse of process." Yet at the heart of nearly every patent and nearly every IPR, the motivation is clearly profit. We see that the irony of Celgene's claims wasn't lost on anyone. While our profit motives were a truthful irrelevancy – a point we made clear to the PTAB, Celgene's extensive effort to rig the system shines a bright light on just why this is materially relevant and such a large problem. The PTAB agreed with us, rejected Celgene's motion to sanction, and ultimately cancelled every claim of the two patents.

While the invalidated patents were earlier dated and may seem unimportant on the surface, Celgene used these patents to attempt to keep generics from even performing due diligence research for entry into the generic market. In one case, Mylan – a generic drug manufacturer – sued Celgene, alleging that Celgene had implemented distribution restrictions that prevented Mylan from purchasing samples of Celgene's branded products through customary distribution channels, and that Celgene refused to sell Mylan the products directly, thereby precluding Mylan from meeting FDA requirements for developing generic versions of these drugs. Celgene's argument basically followed the logic:

> *Yes, we would love to give you our proprietary drug to do your studies with but, well, there are these other patents for controlling its distribution that you would be infringing if we did that, so we can't give you the drug for research purposes.*

Specifically, among other claims, Mylan asserted that this conduct by Celgene violated federal antitrust laws. As a consequence of our successful IPRs, at least part of the Celgene patent portfolio is now at serious risk. And, while the PTAB did not institute one of our IPRs related to Revlimid, by invalidating the foundational

patents, we think we have made serious inroads into furthering the invalidity of all of Celgene's controlled system-of-distribution patents.

If you have any questions regarding these recent IPR decisions, please reach out to Investor Relations (214-347-8045 or ir@haymancapital.com). If you have concerns regarding questionable drug pricing practices, we strongly encourage you to contact your state's Attorney General's Office or the Division of Consumer Protection.

Best Regards,

J. Kyle Bass

Supplemental Materials - Summary of instituted IPRs that have reached a final written decision:

Reference #	IPR Case No.	Decision Date	Patent Owner	Drug	Patent No.	Claims Invalidated	Outcome
1	IPR2015-00988	10/5/2016	Shire Inc.	Lialda	6,773,720	None	✘
2	IPR2015-00245	10/11/2016	Alpex Pharma SA	Suprenza	8,440,170	1-3, 5, 6, 8, and 9	✓
3	IPR2015-00990	10/21/2016	Shire Inc.	Gattex	7,056,886	46-52 and 61-75	✓
4	IPR2015-01093	10/21/2016	Shire Inc.	Gattex	7,056,886	1-27, 31-40, and 44-45	✓
5	IPR2015-01092	10/26/2016	Celgene Corporation	Pomalyst and Revlimid	6,045,501	1-10 (all)	✓
6	IPR2015-01096	10/26/2016	Celgene Corporation	Pomalyst and Revlimid	6,315,720	1-32 (all)	✓
7	IPR2015-01102	10/26/2016	Celgene Corporation	Pomalyst and Revlimid	6,315,720	1-32 (all)	✓
8	IPR2015-01103	10/26/2016	Celgene Corporation	Pomalyst and Revlimid	6,315,720	1-32 (all)	✓