Policy Brief: How the Supreme Court Patent Case Could Raise Drug Prices

Executive Summary

The Supreme Court is hearing a case this fall that could get rid of one of our patent system's most important checks and balances: the PTAB, also known as the Patent Trial and Appeals Board. Since the PTAB's job is to review and, in some cases, invalidate unmerited patents that were incorrectly granted in the first place, the case has tremendous impact on some of our top industries, including tech and pharma, and is going to be fiercely debated in the months to come. The stakes are high: the nation is united with over 80 percent[i] of Democrat and Republican voters calling for lower drug prices, and pharma's prolonged monopolies on lifesaving medicines are being revealed as a key driver in skyrocketing medicines prices. The Initiative for Medicines, Access & Knowledge (I-MAK) asserts that the PTAB is a critical agency in the fight for lower drug prices, and that the Supreme Court's decision will have far-reaching implications for the health of Americans for generations to come.

Introduction

This fall, the U.S. Supreme Court is scheduled to hear oral arguments on *Oil Energy States vs. Greene's Energy Group*, which will address the constitutionality of the U.S. Patent and Trademark Office's process to help make sure patents meet the law's requirements. Established by the bipartisan Leahy-Smith America Invents Act (AIA), this process is called the *inter partes review* (IPR) and takes place at the Patent Trial and Appeals Board (PTAB).

The case comes as a majority of Americans say lowering the cost of prescription drugs should be a top priority for Congress and the Trump administration and states including Louisiana, Nevada and Ohio have taken decisive steps to lower medicines prices. While much of the analysis of this case to date has focused on its potential effects on the integrity of patenting in America, there has been limited discussion of its broader implications on drug pricing and access. A ruling in favor of *Oil Energy States* could significantly hamper the United States' ability to assess and remove unmerited patents, and lower the price of lifesaving pharmaceutical drugs.

The Initiative for Medicines, Access & Knowledge (I-MAK) is leading a strategy focused on exposing this root cause of high drug prices: unmerited patents. I-MAK's research has found that one of the big reasons prices are so unaffordable is that pharmaceutical companies are over-patenting lifesaving drugs when there is no new invention that justifies the exclusivity they are granted. For many corporations, over-patenting tactics are simply a way to drag out their monopolies for decades by preventing generic, lower-cost versions from entering the marketplace.

The America Invents Act and patent challenge mechanism were established in part to end the proliferation of unmerited patents that stifle innovation and hurt American business. These bad patents hamper ingenuity, as seen in the case of patent trolls, and contribute to major national challenges, such as unaffordable drug prices. Should the Supreme Court rule in favor of *Oil Energy States,* the United States will be at a deeper disadvantage in its efforts to combat exorbitant drug pricing.

Drawing from I-MAK's experience challenging dozens of pharmaceutical patent cases worldwide and helping improve laws that curb the granting of unmerited patents, this policy brief explains potential effects of the latest Supreme Court case on U.S. drug pricing and access issues, answers some key questions about the patent challenge process and considers case studies that

demonstrate how challenging unmerited patents can dramatically lower the price of prescription drugs.

Four Things to Know About Pharma Patents and the IPR Process

1) State of Pharma Invention: Research & Development vs. Lobbying & Marketing

What happened to U.S. pharmaceutical invention and ingenuity? Over the last decade, the country's biggest pharmaceutical companies have spent more on marketing, lobbyists and share buybacks than they have on new research and development.

According to a recent study by the Institute for New Economic Thinking[ii], between 2006 and 2015, the 18 drug corporations in Standard & Poor's 500 index spent more than $516 billion on buybacks and dividends, compared to $465 billion on research and development. Biogen Idec, for example, spent $14.6 billion on stock buybacks, compared to $13.8 billion on research and development. Gilead spent $27 billion on buybacks, compared to $17 billion on R&D.

Meanwhile, pharmaceutical and health lobbying spending continues to increase – reaching $78 million in the first quarter of 2017.[iii] The Pharmaceutical Researchers and Manufacturers of America, the industry's largest advocate, and the Biotechnology Innovation Organization spent more lobbying Congress and the Trump administration in the first six months of 2017 than they have in that period since 1999.[iv]

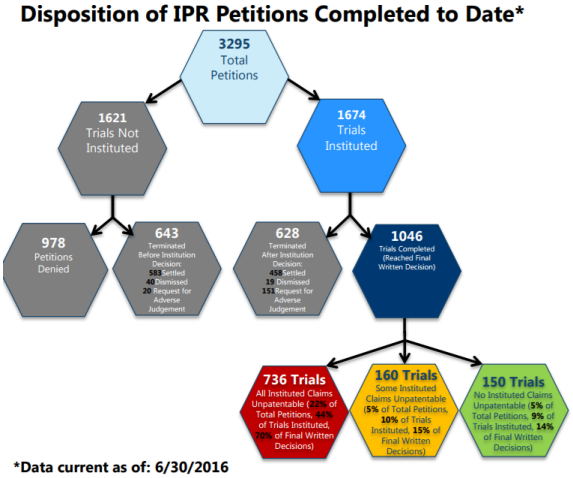
These trends create a vicious cycle: companies have chosen to let the pipeline of novel and non-obvious products take a backseat due in part to Wall Street investors' and shareholders' expectations of ever-higher returns. Faced with this pressure, companies are putting more and more money directly into shareholders' pockets and towards lobbying against measures that would rein in drug prices.

The pursuit of decades of patent exclusivity is no longer fueled by science and technology that pushes the boundaries of existing knowledge. Instead, the patent system has been turned by pharmaceutical companies into a tool for immediate profits that offer maximum returns with the least amount of effort. Each unmerited patent granted allows a pharmaceutical company to artificially inflate the value of a "new" version of the same product—whether it be a different dosage amount or faster dissolving tablet with no real benefits to the consumer—instead of investing in true innovation.

2) IPR Process Advances Innovation and Public Interest

In 2011, Congress passed the Leahy-Smith America Invents Act to curb the spread of unmerited patents, stop abusive litigation and ensure companies and individuals who deserve their patents are working on a fair playing field. In the face of industry's overreliance on over-patenting, the America Invents Act took a major step to restoring the integrity and strength of the U.S. patent system.[v]

Disposition of IPR Petitions Completed to Date*



Narrative:
This graph shows a stepping stone visual depicting the outcomes for all IPR petitions filed to-date that have reached a final disposition.

*Data current as of: 6/30/2016

The legislation established[vi] the Patent Trial and Appeal Board, where each case is heard before a panel of three judges who assess the validity of patents, and its patent challenge process. These measures both allow for public participation and transparency in the U.S. patent system. The PTAB has established itself as an efficient arbitrator. While the U.S.

patent office grants about 5,000 new patents each week, just a handful of those patents are brought before PTAB. Since the PTAB was established five years ago, it has taken up a total of 4,500 cases – a fraction of the millions of active patents. The U.S. Patent and Trademark Office's own analysis finds that pharmaceutical patents are upheld just as often as they are rejected.[vii]

The IPR process has helped bring U.S. patent law more in line with most other high-income countries, including the European Union. Under the America Invents Act (AIA), the U.S. has established more rigorous examination to help improve the quality of U.S. patents. For example, in a recent case, the PTAB ruled a set of Teva's patents for the multiple sclerosis drug Copaxone® did not meet the requirements under U.S. law, enabling generic companies to enter the market with lower priced versions.

While still in its early days, the IPR challenge process has already taken important steps to advance U.S. ingenuity and defend the interests of taxpayers and the public in our patent system.

3) Unmerited Patents Are a Root Cause of High Drug Prices

As the AIA reaffirmed, patents are rights the U.S. government gives to inventions as mandated by our Constitution. Under patent law, patents should only be given to drug products proven to be novel (new), non-obvious (inventive) and useful. Too often, as I-MAK's research has found[viii], drug corporations receive patents that do not hold up under the law's requirements. These drugs fail to meet the law's requirements for a patent because they are developed using previously published information, routine compounds and commonly practiced scientific techniques.

This is not surprising given the realities of the U.S. Patent and Trademark Office. With approximately 9,000 examiners[ix], it now reviews more than 500,000 patent applications each year – up from just 100,000 a couple decades ago.[x] Each week, the office grants about 5,000 new patents. While a proportion of those patents are merited, unjustified patents inevitably slip through the cracks.

In the case of drug corporations that manufacture small molecule drugs such as those used to treat hepatitis C, cancer and other common diseases, there are two main patent types:

- Base compound patents: These patents cover the core substance that make up any medicine and are the foundational patents for every pharmaceutical drug. Base compound patents – like all patents – are awarded 20 years of exclusivity.
- Secondary patents: An ever-thickening web of patents that represent incremental – and increasingly trivial – changes and tweaks on top of the base compound patents. Since every additional patent grants 20 more years of exclusivity, corporations frequently and continuously file applications for secondary patents on the same drugs, opening the door to effectively unlimited years of exclusivity.

With even just one unmerited patent, drug corporations have free license to monopolize the market and charge astronomical prices that prevent people from getting care and place higher burdens on taxpayers. A Harvard study found that government insurance programs could have saved $1 billion from 2000 to 2004 if the patent office had not issued inappropriate extensions for just three drugs. [xi] According to the European Competition Commission, the pharmaceutical industry's tactics to delay generic versions from immediate entry cost the European Union's healthcare system 3 billion Euros.[xii]

As I-MAK's work has revealed, Gilead Sciences has pursued unmerited patents for Sovaldi®, its principal hepatitis C drug. In just the last three and a half years, the company has made more than $33 billion. Meanwhile, there are 3.6 million people with hepatitis C[xiii] in the United States. And **85 percent of people in the U.S. who have been diagnosed with hepatitis C have not received treatment, largely because of the high cost and payers—like insurance companies and Medicaid –denying treatment or rationing it to those who are the sickest.**

A recent study[xiv] found Sovaldi® could be manufactured at $101 per treatment. But Gilead chose to charge up to $1,000 per pill at its launch, and continues to price the drug out of reach of the majority of people who need it. Unmerited patents—granted for science that has been in the public domain for decades—made that possible.

For pharmaceuticals, patents for medicines that are not merited under the law decide if people can get the medicine they need or not.

4) Supreme Court Patent Case Could Reverse Early Progress

While just five years old, the PTAB has begun to inject severely needed checks and balances on the U.S. patent system. It has laid a strong foundation for addressing major national challenges from high drug prices enabled by unmerited patents to frivolous attempts to monopolize things like information sharing over email and through podcasts.[xv]

The PTAB's potential to achieve more on behalf of the American public is only beginning to be realized. As a U.S. Government Accountability Office report found last year, the patent office must continue to improve the quality of the patents it is granting.[xvi]

At the same time, branded drugs, the vast majority of which are protected by clusters of patents, account for more than 70 percent of total U.S. drug spending.[xvii] A recent Kaiser Family Health poll[xviii] found that one in five Americans have chosen not to fill a prescription due to unaffordable prices.

The patent case before the Supreme Court, which could prematurely cripple the United States' efforts to curb unmerited patents, takes on additional weight in light of recent proposals out of the Trump administration and Congress. The administration has not formally announced its drug pricing plan, but draft copies of an expected Executive Order largely favor the pharmaceutical industry, including rolling back regulations that lower the cost of drugs for low-income patients and the hospitals that provide their care. And from Congress, the recently-proposed "Stronger Patents Act" will end the patent challenge process at the PTAB and effectively "undo much of the progress that has been made," as House Judiciary Committee Chairman Bob Goodlatte (R-VA) said at a recent hearing.[xix]

If the Supreme Court rules in favor of *Oil Energy States*, none of the nascent advancements to date will be able to achieve their full potential. The U.S. will lose a major tool for knocking down unmerited patents that are a root driver of high drug pricing and which ensures the integrity of the patent system.

Patent Challenges in Action: Removing Unmerited Patents Lowers Drug Prices

Patent challenges have erupted as a tool used by patient advocates and NGOs to drive down drug prices in nearly 50 countries. This has resulted in significant increases in medicines access and affordability. I-MAK has played a leadership role in this effort: by exposing and challenging unmerited pharmaceutical patents and broken patent laws and systems, I-MAK's team of scientists, lawyers and health experts are helping people needing medicines across 49 countries get expensive drugs faster and cheaper, saving up to 93 percent off the branded drug price.

I-MAK's work globally has shed light on the critical role that patents play in high drug prices and pioneered strategies to challenge patents that are unmerited. The closely watched Supreme Court patent case, should it rule in favor of the IPR process, could cement U.S. consumers' ability to pursue strategies that tackle unjustified patents and exorbitant drug pricing. A negative decision would take the United States backwards, calcifying an archaic patent law that doesn't safeguard patients and consumers from abusive industry practices and patent trolls.

Elected officials, state health programs, patients, healthcare professionals and families across the country are urgently searching for policy, legal and other solutions that will lower the price of

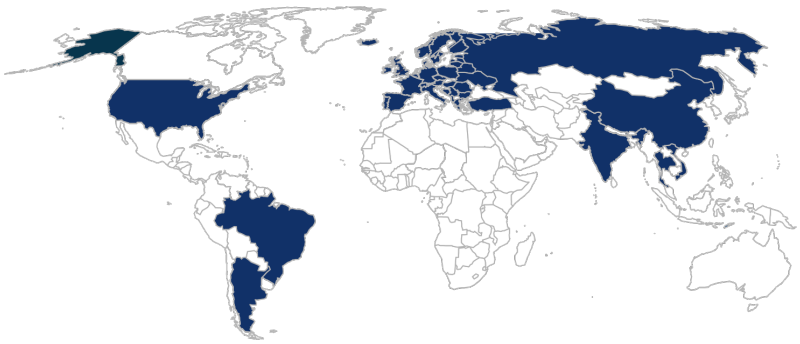
medicine for millions of people. The IPR process is a step in the right direction for creating a stronger patent law. Ultimately, the country needs systemic improvements to patent law so that junk patents are not granted in the first place, enabling decades-long monopolies and exorbitant prices while people go untreated for curable diseases.

Case Studies

Emerging Markets Save Billions on HIV Drugs

I-MAK's successful patent challenges against just three HIV drugs– Ziagen®, Viramune® and Kaletra®– in India helped save global health programs in low and middle-income countries $500 million in five years. Those savings can be reinvested to treat more than one million people.

I-MAK helped the Delhi Network of Positive People win a case on the pediatric drug Viramune® against Boeringer Ingelheim. As a result, this HIV medicine became available in several developing countries. Shortly after I-MAK's case against Ziagen® was filed, Glaxo Smithkline withdrew its patent application. The branded price decreased by 31% and multiple generics began competing in the marketplace.



Countries where I-MAK has filed patent challenges directly and/or supported partners' cases

In the case of Kaletra®, I-MAK's case against Abbott Laboratories resulted in major victories that enabled price reductions for HIV programs in a number of developing countries. In addition, I-MAK's research in collaboration with Harvard University found that Abbott Laboratories had amassed 108 granted patents and pending patent applications in the U.S for the HIV treatment between 1989 and 2012. The majority of those patents do not meet novel and non-obvious requirements, including six patents for a heat-stable formulation technique that has been used in other prescription drugs for decades and eight patents for trivial tweaks to the formulation technique. These 108 patents improperly extended the patent life of this lifesaving medicine by 38 years, keeping generic competition off the market. Patents for this drug have been rejected in multiple countries, helping to lower the price for patients.[xx]

Argentina, Brazil, Thailand and Ukraine Saving $549 Million/Year

I-MAK and five patient advocacy organizations[xxi] are leading a coordinated patent challenge strategy in Argentina, Brazil, Thailand and Ukraine to tackle unmerited patents on lifesaving HIV drugs. The consortium filed patent challenges against Bristol Myers Squibb, Merck, Gilead Sciences, AbbVie and ViiV Healthcare. As a result of I-MAK and its partners' patent challenges and other legal interventions, prices for seven lifesaving HIV medicines have fallen, enabling annualized budget savings of $549 million across these four countries.

European Union Patent Challenges Speed up Generic Competition

In the European Union, which has a robust patent review process, generic companies and patient advocates have filed challenges against unmerited patents. The international medical humanitarian organization Médecins Sans Frontières (MSF), Médecins du Monde (MdM) and 17 other not-for-profit organizations, have challenged patents against Gilead Sciences to speed up access to affordable hepatitis C drugs.

Patent challenges filed by generic companies in the EU have prevented Gilead from abusing the patent system to extend its now-expiring patent protection on Truvada®, an HIV drug, to 2024. Generic companies in Europe are now in a position to enter the market much earlier than would have been possible if Gilead's unmerited secondary patent was not challenged.

First-Ever Civil Society Patent Challenge and Victory in China, World's Largest Active Drug Manufacturer

China serves an essential role in the global pharmaceutical drug supply chain, manufacturing more than 800,000 tons of pharmaceutical ingredients each year. More than 70 percent of all active drug materials consumed in the U.S. and Europe are imported from China and India, including the active drug materials used in hepatitis C treatments.

I-MAK was the first nonprofit to file and win a patent challenge in China. This marked an important step for China in treating its own population of hepatitis C– the largest in the world – and towards opening the supply of raw materials to manufacturers around the world. I-MAK's ongoing work in the country to challenge the remaining unmerited patents on Sovaldi® could save $59 billion, or over a third of the country's annual spending on prescription drugs, and enable immediate generic supply that could benefit patients in China and worldwide.

Conclusion

The Supreme Court's decision on whether the PTAB can continue to review and appropriately invalidate unmerited patents is a critical upcoming decision that will have long-term impact on drug prices. Unmerited patents result in higher drug prices, keeping lifesaving medicines out of reach of people who need them.

Ultimately, the problem of bad patents will need to be addressed at its root. The PTAB reverses bad patents after they are granted - and what our country needs is for bad patents not to be granted in the first place. For this, we will need systemic reform, and for the U.S. Patent and Trademark Office to be strengthened and equipped with appropriate incentives and resources to help increase patent quality, prevent sub-par patent applications from being granted and to allow competition to flourish as a result. American patients and consumers will continue to be harmed until such reform becomes a reality.

References

[i] http://www.politico.com/f/?id=0000015e-7bce-d079-a3fe-7bce31540000

[ii]https://www.ineteconomics.org/research/research-papers/us-pharmas-financialized-business-model

[iii] https://www.nytimes.com/2017/05/29/health/drug-lobbyists-battle-cry-over-prices-blame-the-others.html?mcubz=3

[iv] https://www.opensecrets.org/lobby/indusclient.php?id=H04&year=2017

[v] https://www.uspto.gov/sites/default/files/documents/2016-6-30%20PTAB.pdf

[vi] https://www.ineteconomics.org/research/research-papers/us-pharmas-financialized-business-model

[vii] https://www.uspto.gov/sites/default/files/documents/trial_statistics_2017_08_31.pdf

[viii] http://www.i-mak.org/lopinavirritonavir/

[ix] https://patentlyo.com/patent/2014/11/usptos-swelling-examiner.html

[x] https://www.uspto.gov/web/offices/ac/ido/oeip/taf/us_stat.htm

[xi] Kesselheim AS, Fischer MA, Avorn J. Extensions of intellectual property rights and delayed adoption of generic drugs: effects on Medicaid spending. *Health Aff* (Millwood). 2006;25(6):1637–47.

[xii] European Commission Department of Competition. Pharmaceutical Sector Inquiry Final Report. Adoption Date: 8 July 2009.

[xiii] https://www.cdc.gov/media/releases/2016/p0504-hepc-mortality.html

[xiv] https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4946692/

[xv] https://www.law360.com/articles/891353/fed-circ-affirms-ptab-ax-of-mphj-scann

[xvi] https://www.gao.gov/products/GAO-16-490

[xvii] https://www.nbcnews.com/health/health-news/what-s-blame-high-u-s-drug-costs-n636696

[xviii] https://www.nbcnews.com/health/health-news/what-s-blame-high-u-s-drug-costs-n636696

[xix] https://www.law360.com/ip/articles/944213/patent-system-in-crisis-mode-ex-fed-circ-chief-says?nl_pk=83c09c91-8a96-43b1-a7d3-905347d57d43&utm_source=newsletter&utm_medium=email&utm_campaign=ip

[xx] https://www.msfaccess.org/sites/default/files/MSF_assets/HIV_AIDS/Docs/UTW_Drug_Profiles_LPV_r.pdf

[xxi] International Treatment Preparedness Coalition (ITPC), The All-Ukrainian Network of People Living with HIV, AIDS Access Foundation (AAF), Associação Brasileira Interdisciplinar de AIDS (ABIA), Fundación Grupo Efecto Positivo (FGEP)