

Federal Trade Commission
Hearings on Competition and Consumer Protection
Topic 8: The role of intellectual property and competition policy in promoting innovation
Date: 20 August 2018

The Initiative for Medicines, Access & Knowledge (I-MAK) is grateful for the opportunity to respond to the request for comments by the Federal Trade Commission (FTC) with respect to the role of intellectual property and competition policy in promoting innovation. I-MAK was established in 2006 with the mission to increase global access to affordable, lifesaving medicines. I-MAK is a team of lawyers, pharmaceutical scientists and health experts who are working to ensure people get the lifesaving medicine they need to survive and lead healthy lives. People worldwide – including in the United States – are not receiving the lifesaving treatment they need due to skyrocketing prices based on the abuse of the patent system.

Our submission responds to Topic 8 of the FTC enquiry, namely the role of intellectual property and competition policy in promoting innovation. In particular, we are focused on the on-going abuse of the patent system, or over-patenting, within the pharmaceutical sector, and the impact this legal and business strategy has upon consumer welfare in the United States.

I. Introduction

High prices of medicines are an on-going crisis across the United States. One in four Americans report difficulty filling a prescription for themselves or family members,¹ and a majority of Americans believe that taking action to lower prescription drug prices should be a top priority for Congress.² Since 2008, the cost index for branded drug prices has nearly tripled,³ and by 2025 prescription drug spending nationally is poised to double again.⁴

Politicians and policy makers at the federal and State level are searching for solutions to provide price relief for government health care programs, companies, and American households. Recently, the White House issued a ‘Blueprint to Lower Drug Prices and Reduce Out-of-Pocket Costs’ to alleviate symptoms of high drug prices and a few of the underlying causes.

Despite these responses, we believe that insufficient attention is focused on the over-patenting problem. I-MAK’s years of research and legal interventions indicate that drugmakers seek and obtain multiple patents as a defensive strategy to delay or block competition for decades. Often, many of these patents are not inventive as they cover science that should be considered common general knowledge and obvious. These patenting strategies enable a few drugmakers to secure the market on entire diseases and artificially inflate the price of treatment.

The United States is facing two inter-related challenges: a drug pricing crisis and a patent system that is out of balance in favor of drugmakers. Drugmakers secure scores of patents to aggressively expand their market and monopoly power far beyond what was intended under United States patent law, and in excess of what is needed to incentivize drug development. Over-patenting can also undermine scientific progress and medical innovation, by locking down science that should otherwise be available in the public domain for research purposes.

¹ Kaiser Health Tracking Poll: September 2016. The Henry J. Kaiser Family Foundation. 2016. Available from: <http://files.kff.org/attachment/Kaiser-Health-Tracking-Poll-September-2016>

² The public’s views of tax reform and other domestic issues. September 2017. POLITICO-Harvard T.H. Chan School of Public Health. Available from: <http://www.politico.com/f/?id=0000015e-a4d7-d873-adfe-bdd740140000>

³ R Kamal and C Cox. What is the recent and forecasted trends in prescription drug spending? Peterson-KaiserHealth System Tracker. 22 May 2017. Available from: <https://www.healthsystemtracker.org/chartcollection/recent-forecasted-trends-prescriptiondrug-spending>

⁴ 2016-2025 Projections of National Health Expenditures. Centers for Medicare and Medicaid Services, Office of the Actuary. 15 Feb 2017

Abuse of the patent system, via strategies such as patent ever-greening, enables drugmakers to exceed twenty years of patent protection intended under United States law. These extended monopolies are directly linked to skyrocketing drug prices that are imposed on consumers over an extended period of time. Policy makers will only be able to curb the epidemic of runaway drug prices in the United States if they address the root cause: the underlying abuse and misuse of the patent system by drugmakers.

While the Federal Trade Commission has tackled other forms of pharmaceutical malfeasance to protect consumer welfare and promote competition, we believe that over-patenting by drug-makers has provided drug companies with market power and monopoly power that greatly exceeds what is acceptable under antitrust laws. This has a direct negative impact upon consumer welfare through medicine prices that grossly exceed the marginal cost for many years beyond the limited duration of patent protection that is intended for drugmakers.

Our response is divided into two sections:

- First, we provide evidence of patent abuse across the pharmaceutical sector, and how such patent abuse dramatically expands the market power and monopoly power of drugmakers.
- Second, we note the consequences of such market power and monopoly power upon consumer welfare, in particular how such power leads to inflated prices of medicines across the United States healthcare sector for a duration that lasts far beyond the limited grant of exclusivity provided under United States patent law.

II. Drugmakers are abusing the patent system to expand their patent monopolies far beyond the twenty years mandated under United States law, providing companies with excessive market power and monopoly power.

Patents are supposed to protect inventions for 20 years beginning from the time the patent was first filed. Currently, drugmakers are filing dozens or even hundreds of patents, resulting in nearly double the length of protection, blocking competition and keeping cheaper versions of medicines off the market.

This month, we published a [study](#) that examined the pharmaceutical patenting practices for the twelve best-selling medicines in the United States, all of which are currently under patent protection.⁵ Our findings demonstrated that the top grossing drugs have on average 125 patent applications, which are filed with a strategic intent to extend commercial monopolies far beyond the intended twenty years of protection. In particular, there are 71 granted patents per drug, and the attempted term of patent protection for each drug is thirty eight (38) years, or nearly double the twenty year monopoly intended under U.S. patent law.

Abbvie, the patent holder for Humira, the world's best-selling drug, has filed 247 patent applications for the product in order to potentially secure at least thirty-nine years of patent protection for the drug.

In some cases, drugmakers file additional patents and then couple the extended monopoly alongside a strategy of 'product hopping' by introducing and aggressively marketing a new patented formulation in order to extend the monopoly. Thus, Pfizer, the patent holder for Lyrica, a drug used to treat neuropathic pain, has employed product hopping with over-patenting to potentially extend its market dominance beyond the mandated term of patent protection.

⁵ <http://www.i-mak.org/overpatented-overpriced-excessive-pharmaceutical-patenting-extending-monopolies-driving-drug-prices/>

With a first patent filed in 1995, and the drug on the market for the past fourteen years, Lyrica has been a major source of revenue for Pfizer. The drug grossed over \$5 billion in global sales last year, \$3 billion from U.S. payers, including insurance companies, Medicare, and Medicaid. The commercial success of the product was driven in large part by the 163% price increases in the last six years, the most severe hike amongst the top twelve drugs. Lyrica was set to go off-patent at the end of 2018 and the entry of generic competition would have quickly and markedly reduced Pfizer's revenue from Lyrica by 70-90% in less than two years. But Pfizer sought and was issued patents for an additional twenty-year period on a controlled-release formulation of the product (Lyrica CR), meaning that patients would take a single pill instead of two or three pills daily. With these patents, Pfizer's hold on the market will remain and, if history is a guide, they will continue major repeated increases in the price of the drug.

Even though some companies engage in 'product hopping', other companies can now create and deploy extensive patent portfolios to extend patent monopolies on an existing product far beyond twenty years without even having to introduce a modified and heavily marketed product to continue dominating a particular therapeutic market.

Revlimid, developed to treat multiple myeloma (and which has also been indicated for treatment of other cancers), has been patented by Celgene, which has sought to expand its control of the market for up to 40 years by filing over 100 patent applications on the drug. In a study we published last year, entitled '[America's Overspend](#)', we assessed that Celgene developed a thicket of patents as a defensive strategy to maximize the monopoly as long as possible and to block generic competition.

Our patent analysis identified a total of 76 granted patents and patent applications for Revlimid® (lenalidomide) as held by Celgene and related companies that have been acquired. In addition, there are 29 abandoned patent applications, making a total of 105. In total, including the pending patent applications, the combined patent protection for these drugs is potentially set to expire at the end of 2036, giving Celgene's Revlimid® patent portfolio a lifespan of at least 40 years.

These 105 patents (including withdrawn patent applications) cover the various hematology cancers and indications for which Revlimid® has been approved. The landscape for Revlimid® comprises the following categories of patents which cover the various indications it has been approved for: methods of use and treatment, including biomarkers, crystalline forms, formulations, devices for assisting patients with filling their prescriptions and controlling distribution of lenalidomide, combination with other inhibitors, and processes for manufacturing lenalidomide. Typically, all these types of patents would be classified as secondary patents. Of the 66 currently granted patents on Revlimid®, 27 are listed on the U.S FDA Orange Book.

Normally, generic versions should be able to enter the market at least in October 2019 when the main patents are to expire. However, generic entry has been delayed following settlement between Celgene and Natco who challenged the very first patents on Revlimid®. Natco has agreed to limited entry into the market from 2022, with full entry into the market in January 2026. Numerous other generic companies are currently in litigation with Celgene over its various patents.

The patent system was designed to provide drugmakers with an exclusive right for twenty years. Yet over-patenting of drugs, including the twelve best-selling products that we recently examined, provides companies with the opportunity to dramatically expand the monopoly term, wherein the thicket of patents delays or prevents competitors from entering the market. This expansion of market power and monopoly

power leads to direct harm to consumer welfare through unaffordable prices for medicines for extended periods of time.

III. Extended patent monopolies enable companies to undermine consumer welfare by charging excessive medicine prices that often continue to increase over the duration of the extended patent term.

Armed with aggressive patenting strategies, drugmakers apply their enhanced market power and monopoly power to charge excessive price for medicines. Our study on over-patenting in the pharmaceutical sector found that for the top twelve selling drugs, forestalling generic competition enabled patent holding drug companies to not only charge high prices, but to continue to increase the price of the drugs over time.

We found that across the top 12 selling drugs in the United States, prices increased on average by 68 percent since 2012, with only one of the top twelve drugs actually decreasing in price. One third of the drugs had price hikes of more than 100 % since just 2012: namely Lyrica (163%), Enbrel (155%), Humira (144%), and Lantus (114%). Not only do prices for these best-selling medicines continue to increase, but the medicines have often been on the market for many years. On average, the twelve best-selling medicines have already been on the market for 15 years, and four of the top twelve drugs have already been on the market for 20 years and have pending patent applications seeking to extend patent life to 2033 (Herceptin, Genentech), 2030 (Rituxan, Biogen/Genentech), 2029 (Enbrel, Amgen), and 2025 (Remicade, Janssen).

Excessive prices for extended periods of time undermine health care spending within various federal and State programs and exert significant financial pressure upon American households. A recent study found that up to 19 million Americans, or 8 percent of the population, travel outside of the United States just to purchase medicines from less expensive sources.⁶

⁶ Kaiser Health Tracking Poll: November, 2016. The Henry J. Kaiser Family Foundation. Available from:<http://files.kff.org/attachment/Kaiser-Health-Tracking-Poll-November2016-Topline>

IV. Conclusion

Patents are granted for a limited duration to drugmakers to recoup investments in research and development and to advance medical science on behalf of patients in the United States (and around the world). The antitrust laws recognize the right of firms to exercise limited market power and monopoly power as a necessary trade-off to encourage medical discovery and development.

Yet today, drugmakers, through aggressive over-patenting strategies, have expanded their market power and monopoly power far beyond what was intended under US patent law, and in excess of the limited monopoly and market power that should be permissible under US antitrust laws. Limited patent monopolies may be acceptable under US antitrust laws, but over-patenting, which leads to excessive market power must be curbed to restore healthy competition and to ensure that medicines ultimately can become affordable for patients across the United States.