



Solving the drug patent problem

Department of Health and Human Services

Office of the Secretary

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Re: HHS Blueprint to Lower Drug Prices and Reduce Out-of-Pocket Costs

Date: 15 July 2018

The Initiative for Medicines, Access & Knowledge (I-MAK) is grateful for the opportunity to respond to the request for comments by the Department of Health and Human Services (HHS) for the Blueprint to Lower Drug Prices and Reduce Out-of-Pocket Costs. 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. Today, people worldwide – including in the United States – are not receiving the lifesaving treatment they need due to skyrocketing prices.

I. Introduction

I-MAK welcomes the Administration's intention to address the epidemic of high drug prices that is keeping affordable health care out of reach of millions of Americans. As an organization working to ensure affordable access to medicines in the United States and around the world, we believe only by taking far-reaching measures that generate sustainable drug development across the biomedical sciences will relief be provided to households and payers in the public and private sector. 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

Today, our policy makers and news outlets focus their attention on the exorbitant prices set by pharmaceutical manufacturers. Yet, insufficient attention is paid to how drug manufacturers are able to set prices at levels that are unaffordable to most, and how they are able to increase the prices of medicines as a means to increase revenues, even after a particular product has been on the market for many years. For example, just this month (July 2018), Pfizer made international headlines when it chose to arbitrarily raise the price of one hundred of its medicines in the United States⁵, after having acted in a similar fashion in 2017⁶. Thus, even with the glare of the media, public and now the Administration, drug manufacturers continue to set high prices with impunity and indifference.

I-MAK's years of research and successful legal challenges show that all too often, drug manufacturers hold unmerited patents on old science. This enables a few manufacturers to corner the market on entire diseases, artificially inflating the price of treatment, and blocking access to affordable generic drugs for decades. We believe America is facing two inter-related challenges: a drug pricing crisis and a patent system that is excessively tilted in favor of pharmaceutical manufacturers over patients. Pharmaceutical manufacturers secure scores of patents to protect and extend their market monopolies, far in excess of what is needed to incentivize drug development. Abuse of the patent system is directly linked to

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>

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

⁵ <https://www.ft.com/content/265c2012-7d9d-11e8-bc55-50daf11b720d>

⁶ <https://www.ft.com/content/b2e0dd80-47ab-11e7-8519-9f94ee97d996>

skyrocketing drug prices: by gaming the patent system with tactics such as ever-greening⁷ and settlement agreements, pharmaceutical manufacturers delay generic competition and keep affordable medicines out of reach for many Americans. We believe that 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 pharmaceutical manufacturers.

Our response is divided into three sections:

- Seek to respond to the framework outlined by HHS in the Blueprint, and to some of the recommendations and questions;
- Provide evidence of how pharmaceutical manufacturers are abusing the patent system; and its impact on drug prices, and recommendations for how the Administration and the federal government can curb such patent abuse;
- Respond in particular to the Administration’s concerns with ‘foreign freeloading’ as both a cause and consequence of high drug prices in the United States.

II. I-MAK analysis of the HHS Blueprint

The Blueprint identifies four overarching goals for lowering drug prices:

1. Increasing Competition
2. Better Negotiation
3. Creating Incentives for Lower List Prices
4. Reducing Patient Out-of-Pocket Spending

I-MAK agrees with these four overarching goals, as collectively and separately these goals would provide relief to American households (and public and private payers) who are struggling with the high prices of medicines, or to end the rationing of new medicines, which neither insurers, households, nor the governments can afford to purchase. As we note in the next section of our response, we believe that addressing the root cause of high prices - patent abuse by pharmaceutical manufacturers - is the critical ingredient to ensure that the United States government meets these four overarching goals. In this section, we specifically respond to the following proposals that HHS has put forward as possible avenues to bring down the price of medicines.

A. *Increasing Competition*

I-MAK would like to comment on two of the proposals included under this pillar: (a) access to reference product samples, and (b) improving the Purple Book.

- Access to reference product samples: Branded pharmaceutical manufacturers employ numerous tactics to extend the monopoly life of branded products far beyond the twenty year monopolies provided under United States patent law. One particular strategy that manufacturers have successfully employed, as identified in the Blueprint, is undermining the ability of follow-on competitors to secure access to reference product samples that are required to secure regulatory approval of a follow-on product. Branded manufacturers have successfully undermined low-cost access by cynically exploiting legitimate measures that seek to ensure drug safety for Americans. We support legislative efforts to prevent pharmaceutical manufacturers from continuing to withhold

⁷ ‘Evergreening’ refers to the strategy of a company obtaining multiple patents covering different features of the same product in order to extend the monopoly period. Patent evergreening is also commonly referred to as “stockpiling”, “thickets”, “layering”, “life-cycle management, or “line extension”.

reference product samples, and thereby close down one avenue that enables pharmaceutical manufacturers to deny Americans access to low-cost generic medicines.

- *Improving the Purple Book*: As biologics increasingly become the standard of treatment for many life-threatening diseases, it is critical that the Purple Book is used to improve transparency around the patent and regulatory status of key biological medicines (and bio-similar products), while avoiding strategies employed by pharmaceutical manufacturers to use the Purple Book to prevent follow-on competition. The “patent dance”⁸ created as part of the Biologics Price Competition and Innovation Act (BCPIA) was intended to provide the needed transparency regarding what patents a reference product holder believes would be infringed by a biosimilar, but the Supreme Court unanimously ruled in 2017 that this was purely optional. I-MAK recommends that the “patent dance” should either be made mandatory, or better yet, that the Purple Book list all such patents for biologic products (just as the Orange Book lists such patents for small molecule products). If neither of these recommendations are implemented, competitors and the public are left without transparency regarding what patents, if any, may be preventing the introduction of a biosimilar. Indeed, based on our conversations with biosimilar actors and their lawyers, the lack of transparency around patents on branded biologics is one of the key reasons competitors are less willing to invest in ‘coming to market’ with more affordable versions of a biologic. If the first option, namely making the “patent dance” mandatory, is adopted, then an additional change should be adopted to require publication of all “patent dance” correspondence between patent holders and proposed biosimilar applicants. Under current law, such correspondence does not have to be published, and thus there is no transparency for the public regarding which patents are believed to be blocking the offering of biosimilars.

III. Stopping pharmaceutical industry abuse of the United States patent system

Only by addressing the underlying abuse and misuse of the patent system by pharmaceutical manufacturers can policy makers curb the epidemic of runaway drug prices in the United States. Generic competition, when two or more manufacturers enter the market, has been proven to be only path that leads to sustainable and durable price reductions for medicines.⁹

Since the introduction of the Hatch-Waxman Act, and especially after the introduction of the TRIPS Agreement, pharmaceutical manufacturers have sought to use both the patent system, and other government-granted exclusivities, to extend monopoly protection for medicines far beyond the twenty years intended under United States law. Manufacturers achieve this expansion through the use of evergreening strategies, a tactic especially used to seek secondary and tertiary patents on existing medicines under the guise of incremental innovation.

Pharmaceutical manufacturers also use other strategies, such as “pay-for-delay”, wherein branded actors pay generics and biosimilars to stay off the market. Although the United States government and Supreme Court have partially addressed ‘pay-for-delay’ strategies, pharmaceutical manufacturers have become astute in developing other ways of making settlements to delay generic and biosimilar entry. Ultimately, the ability of manufacturers to make these types of arrangements that delay competition is primarily based on their evergreening tactics to create a thicket of defensive patents which serve as a business strategy rather than one of seeking genuine inventions and progressing real and meaningful medical developments. To illustrate, Celgene, a pharmaceutical manufacturer, has filed over 100 patents on its blockbuster anti-cancer drug Revlimid, and its patenting strategies are likely to extend its

⁸ The “patent dance”, established under the BCPIA, is an elaborate process of information exchange between a biosimilar applicant and a branded manufacturer which is intended to resolve patent disputes.

⁹ FDA analysis of retail sales data from IMS Health, IMS National Sales Perspective, 1999-2004.

monopoly for approximately two more decades if left unchallenged. In total, Celgene's patenting strategies will provide it with a potential 40 years of market control, and its unmerited patents will cost payers and taxpayers a projected \$45 billion more than if lower-cost generic alternatives were appropriately allowed to enter the market¹⁰. These patenting strategies also impose significant transaction costs on generic and biosimilar manufacturers, which are inevitably passed on to patients.

Patent evergreening is not inevitable. There are a range of measures the United States government can introduce to improve how the patent system functions, and to prevent manufacturers from gaming the patent system. I-MAK recommends seven measures that the United States government could introduce:

1. Stop pharmaceutical manufacturers from over-patenting medicines by ensuring the standard for obtaining a patent is made more rigorous. This can be achieved through federal legislation that raises the bar of what is considered an invention by bringing the obviousness test in line with today's commonly practiced techniques in the pharmaceutical field, while simultaneously strengthening the patent examination process to ensure unmerited patents do not slip through the system.
2. Preserve and expand the role of the public and patients in the patent system. In particular, to increase openness, transparency, and accessibility of the patent system for patients and consumer advocates, the public should be allowed access to the courts in pharmaceutical patent cases. Non-commercial actors - such as public interest groups - should have legal standing in courts to challenge patents, as they are permitted to do so under the current inter partes review (IPR) system. Non-commercial actors should also be able to file appeals. This change can take place via legal action in the courts or through federal legislation.
3. Preserve and strengthen the patent challenge mechanism, namely the IPR and Post-Grant Review (PGR) that is a vital 'check and balance' within the patent system and that is already reducing drug prices. At present, we are concerned with proposed legislation that would undermine the PTAB and which either exempts or places limitations on pharmaceutical patents from being challenged – such legislation should be rejected. Additionally, in order to strengthen the IPR mechanism and increase participation of non-commercial actors who challenge patents, the filing fee should be eliminated for non-commercial actors.
4. Continuation patent applications should be eliminated by federal legislation. This practice allows patent applicants who have had one or more patent applications rejected to overcome the refusal by paying a fee for a new filing. If a patent applicant believes that they deserve a patent on an application that has been finally rejected by an examiner, the applicant has the right to pursue an appeal to the PTAB and thereafter through the federal court system. Therefore, even without continuation patent applications, applicants would still be afforded plenty of opportunities to make their case for a patent. Furthermore, patent applicants who are granted a patent should not be afforded the opportunity to file new continuation applications directly targeted at generic or biosimilar drugs that were designed so as to not infringe the patent holder's original patent.
5. The Hatch-Waxman statute should be updated to include invalidating patents listed in the Orange Book, when such patents are invalidated on the sole basis of a PTAB decision that is subsequently not appealed. This could help accelerate generic entry if all relevant Orange Book

¹⁰ <http://www.i-mak.org/wp-content/uploads/2017/10/Excess-Costs-Briefing-Paper-FINAL-2017-10-24-with-cover-rev.compressed.pdf>

patents on a drug are cancelled under the IPR or PGR process. Such a change to the law could also help accelerate generic entry where it concerns the first ANDA filers' exclusivity by triggering the 180-day exclusivity much sooner, thereby allowing other subsequent generic ANDA filers to enter the market earlier.

6. Congress should harness the power of pre-grant oppositions, which is employed effectively in many parts of the world to improve the performance of the patent system. Pre-grant opposition systems permit knowledgeable experts across all technical fields to weigh in on the merits of a new patent application and submit pertinent information while it is still under review. Allowing third parties to submit evidence improves the quality of patent review, enhances efficiency, and could allow for earlier generic entry in some cases. This also helps patent examiners to more effectively separate merited patent applications from unmerited ones by weighing additional evidence.
7. The Food and Drug Administration (FDA) should be given the authority to implement a more robust process for determining which patents can and should be listed in the Orange Book. This could include a requirement for the NDA holder to file an opinion letter explaining why a patent should be listed on the Orange Book for a particular drug. It could also be made a requirement that the NDA holder identify the specific claims within a listed patent that would be infringed by an ANDA. Such disclosures by the NDA holder should be made public. By insisting on receiving more detailed information from NDA holders as to its patent listings, and making such information public, the FDA will bring more scrutiny and transparency to patent listings.

IV. 'Foreign Freeloading' and high drug prices in the United States

One recommendation included in the Blueprint is an effort to 'fix global freeloading'. The Blueprint rightly points out that other countries pay less than American patients and taxpayers for branded medicines. Yet, we disagree that this is a rationale for critiquing or even seeking to undermine efforts taken by other countries to manage drug prices through pricing measures or via intellectual property safeguards and flexibilities.

Firstly, even if other countries are paying less for medicines, it does not necessarily mean that these countries are 'free-loading' off of American taxpayers and patients. If any free-loading of the United States is occurring, it is by pharmaceutical manufacturers, which acquire federally funded technologies at a low cost and with few reciprocal obligations. These technologies are then commercialized and sold back to American patients and taxpayers at exorbitant prices with no consideration of the value to the patent-holder of inventions developed at taxpayer cost.

Efforts by other countries to control drug prices, whether through direct negotiation, price controls, or intellectual property measures, should be imitated and improved upon, not punished. If the United States government invested in similar measures, and worked more closely with other countries to address unaffordable medicine prices, it is likely that both the United States and other countries could mutually benefit. In addition, the United States government should persuade other countries to spend more on research and development through significant public-sector investments in government-funded research, much of which can then be commercialized (albeit with additional guarantees of affordability and availability).

If instead the United States succeeds in pushing up drug prices (or strengthening intellectual property rules) in other countries, American patients will also be affected. Many lower cost medicines (and most active pharmaceutical ingredients) are manufactured in other countries and exported to the United

States. Stricter standards of intellectual property protection would undermine availability of quality, low-cost generic and biosimilar medicines, whether for patients in other countries or in the United States. Furthermore, as the number of suppliers' decreases globally due to strict rules or other commercial pressures, it could lead to shortages of key medicines, a problem affecting all countries, including the United States.

On the other hand, there are numerous opportunities where the United States government could collaborate with other countries to ensure affordable drug prices. This includes improving transparency of drug pricing and research and development costs, working with other countries at the World Health Organization to set out a 'roadmap' to achieve affordable drug prices, or jointly financing research and development with other countries, while ensuring the American taxpayer recuperates their investment via affordable drug prices.

V. Conclusion

I-MAK welcomes the efforts of the Administration to curb skyrocketing drug prices in the United States. Some of the recommendations that have been already been implemented by the United States government or have been recommended can start to counterbalance the unfettered power of the pharmaceutical industry to charge unaffordable prices for medicines, but we believe most of these actions will not fundamentally transform the pharmaceutical market. Some recommendations have the potential to be gamed by the pharmaceutical industry to continue to charge high prices for medicines.

Ultimately, only by addressing the underlying abuse and misuse of the patent system by pharmaceutical manufacturers can policy makers curb the epidemic of runaway drug prices in the United States. At the same time, we believe that working with other countries to address high drug prices, in lieu of punishing these countries for seeking to protect public health, will ultimately strengthen the American response.