Tahir Amin and Priti Krishtel
Initiative for Medicines, Access & Knowledge (I-MAK)
601 West 26th Street
Suite 325-32
New York, NY 10001

September 17, 2017

Dockets Management Staff (HFA-305)
Food and Drug Administration
5630 Fishers Lane
Rm. 1061
Rockville, MD 20852

RE: Docket No. FDA-2017-N-3615 for "Administering the Hatch-Waxman Amendments: Ensuring a Balance Between Innovation and Access; Public Meeting; Request for Comments

Dear Commissioner Gottlieb:

Thank you for convening the recent meeting entitled "Administering the Hatch-Waxman Amendments: Ensuring a Balance Between Innovation and Access." As an organization that has worked around the globe for the past decade to increase generic competition through patent reform, we are eager to provide comments to help facilitate the availability of lower-cost generic drugs for patients in the United States.

The Initiative for Medicines, Access & Knowledge (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. With two decades of experience in intellectual property, patent and health care law, we founded I-MAK in 2006 to prevent unmerited pharmaceutical patents from blocking affordable access to lifesaving medicines. We believe that unmerited patents should not be permitted to prevent legitimate competition.

Over the past decade, we have won more than 80% of our challenges against unmerited patents. Patent challenges and other interventions on seven antiretroviral drugs in four countries has so far enabled price reductions that have resulted in actual savings of US$695 million per year.

While The Drug Price Competition and Patent Term Restoration Act (Hatch-Waxman) has brought more generic drugs to the U.S. market, it is clear that brand-name pharmaceutical companies have developed a toolbox of tactics to subvert the good intentions of Hatch-Waxman and block generic competition, referred to by the industry as lifecycle management. Gaming strategies such as "pay for delay" and "evergreening" that form part of this product life cycle management strategy were both noted as troubling and commonplace during testimony at the public meeting on July 19, 2017.

I-MAK initiative for medicines access & knowledge

I-MAK's work and policy solutions are applicable to the patent tactics industry uses to block generic competition. The issue of secondary patenting is particularly worrisome as companies reconfigure existing products rather than invent anything new. These types of patents, coupled with marketing strategies, allow companies to maintain legal monopolies that prevent generic competition and maintain high drug prices. This practice allows companies to leverage unmerited secondary patents to make billions of dollars at the expense of taxpayers, businesses, and consumers. Below, we discuss how secondary patenting and innovation are playing out in America's pharmaceutical industry today.

Secondary Patenting

The proliferation of low-quality, secondary patents following the passage of Hatch-Waxman has been well-documented. Hemphill and Sampat showed that the number of patents granted on medicines approved between 2000 and 2002 "roughly doubled" when compared with medicines approved between 1985 and 1987.[1] A separate review of patents granted in the U.S. on new medicines registered by the FDA between 1988 and 2005 revealed that companies more consistently and aggressively pursue secondary patents on their "best-selling" products "*suggesting [secondary patents] reflect deliberate attempts by branded firms to lengthen their monopoly for more lucrative drugs"*.[2]

Secondary patents are hotly contested: The pharmaceutical industry calls this incremental innovation. Critics refer to this practice as evergreening, and more and more evidence is showing that such patents when challenged are not found valid. By developing a strategic series of patents, many of which are purely defensive, pharmaceutical companies create a thicket of secondary patents around the original compound patent in order to deter or delay generic competition. At the same time, the patent holder adds several years of extra patent life. Essentially, this tactic is what drives "pay for delay settlements" where branded companies halt competition by paying generic companies to stay off the market. This practice of evergreening has been discussed in numerous academic studies[3] and must be addressed if public and private payers hope to address skyrocketing drug prices and healthcare costs.

Innovation

As we consider recommendations for the panel, it is important to discuss the realities of innovation in the U.S. pharmaceutical industry today. A common claim of industry is that the adoption of more stringent approval or patentability criteria would prohibit the industry from recouping research and development costs and investing in future innovation. Given the proliferation of secondary patents since the passage of Hatch-Waxman, evidence suggests that companies are more intent on preserving existing products than in inventing new ones. Indeed, the U.S. Federal Trade Commission itself noted in 2012 that companies use secondary patenting as part of its marketing and advertising strategy in order to enable "product switching" or "product hopping" – whereby the branded drug company will, prior to

[1] Hemphill S and Sampat B. "Drug Patents at the Supreme Court." *Science* 22 Mar. 2013: 1386-387.
[2] Kapczynski A, Park C, Sampat B. "Polymorphs and Prodrugs and Salts (Oh My!): An Empirical Analysis of "Secondary" Pharmaceutical Patents. PLOS ONE **7**(12): e49470. doi: 10.1371/journal.pone.0049470.
[3] Amin T and Kesselheim A. 2012. Secondary patenting of branded pharmaceuticals: A case study of how patents on two HIV drugs could be extended for decades. Health Affairs, 31, no.10 (2012):2286-2294

patent expiration, withdraw the original marketed product forcing consumers to switch to a reformulated version.[4]

If companies were not granted many of the secondary patents they seek, they would be less likely to spend significant amounts on advertising and marketing seeking to switch health care providers and patients to a new version of a product, which offers little or no additional benefit. As a result, health care systems and patients would save significant resources.

Recommendations

We understand that the Food and Drug Administration (FDA), as a regulatory body, cannot single-handedly fix a complex and compromised patent system. We commend you and the panel for recognizing your role in the eventual cost of prescription drugs and for your desire to repair the unintended consequences of Hatch-Waxman that allow pharmaceutical companies to game the system. We urge you to work with congressional leaders, health advocates, and your colleagues in the U.S. Patent and Trade Office and the Federal Trade Commission to restore integrity and effectiveness.

In order to do so, we will respond to your specific request for suggestions on actions that the FDA itself can take to create meaningful change within its purview. Next, we will offer solutions to get more Americans the medicine they need to get well, to ensure treatments are priced fairly and are cost-effective, and to improve our medicine innovation pipeline.

Steps the FDA Can Take Today

Improving the process for allowing patents to be listed on the Orange Book:

Efforts have been made recently by the FDA through its new Rules in October 2016 to improve how an NDA holder's method of use patents and the relevant claims are listed on the Orange Book. However, given that NDA holder's are known to use strategic patent listings on the Orange Book to string out litigation and delay generic entry, we recommend that the FDA implement a more robust process that requires the following:

- An opinion letter from a patent attorney for the NDA holder explaining why a patent should be listed on the Orange Book for a particular drug, and
- 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.

Under the current law, the FDA has correctly stated that its role in listing patents in the Orange Book is ministerial and that patent law issues are beyond its expertise and authority. While that is the case, we

[4] Federal Trade Commission. *FTC Files Amicus Brief Explaining That Pharmaceutical "Product Hopping" Can Be the Basis for an Antitrust Lawsuit*. Web. 27 Nov. 2012. Available: https://www.ftc.gov/news-events/press-releases/2012/11/ftc-files-amicus-brief-explaining-pharmaceutical-product-hopping.

believe that the agency has an important role to play in enabling generic entry of drugs as early as is legally possible. As such, the FDA should insist on receiving more detailed information from NDA holders as to its patent listings as outlined above. By doing so and making such information public, it will help to bring more scrutiny and transparency to patent listings and potentially deter any gaming of the system as such information could be used later in legal proceedings.

A New Vision for More Competition and More Integrity

1. Bringing Hatch-Waxman into the 21st Century to speed up generic entry

Integrating Inter Partes and Post Grant Review into Hatch Waxman

The America Invents Act of 2011 (AIA) created new proceedings at the U.S Patent and Trademark Office that are administered by the Patent Trial and Appeal Board (PTAB). These proceedings, known as Inter Partes Review (IPR) and Post Grant Review (PGR), allow for any person to petition to cancel one or more claims of an issued patent.

ANDA filers have been using the IPR proceedings to cancel patents on the Orange book given that it is more cost effective and decisions are issued within 18 months. As a result, this can create scenarios where patents listed on the Orange Book that are cancelled by the PTAB can impact the 30-month stay which NDA holders currently enjoy under the litigation route of Hatch-Waxman.

Under the current statutory language of Hatch-Waxman, only a district court decision, or an appellate decision based on a district court decision, holding that the patent(s) is invalid will end the 30-month stay.

We believe that the FDA should work with Congress to amend Hatch-Waxman to clarify the interplay between IPRs and ANDA litigation. Specifically, Congress should be asked to tie the termination of the 30-month stay to also include any patent resolution at the PTAB. By doing so, this could help accelerate generic entry much earlier (given that decisions are handed down within 18 months) in cases where all relevant Orange Book patents on a drug are cancelled under the IPR process.

The benefits of tying resolutions of Orange Book patents at the PTAB to ANDA litigation can also help accelerate generic entry where it concerns the first-filers' 180 day exclusivity. It is well documented that many first ANDA filers accept settlement agreements, or "pay for delay" agreements rather than seeing litigation through to the end. By allowing PTAB decisions to be recognized as validly cancelling Orange Book patents, this would trigger the 180 day exclusivity much sooner and allow other follow on generic ANDA filers to enter the market earlier. This would create more competition in the marketplace and, therefore, lower prices.

We encourage the FDA to work with Congress to integrate the PTAB proceedings into the Hatch-Waxman Act. These changes could significantly alter how quickly generic entry can happen so as to increase competition and lower drug prices. It would also help curb the over-patenting problem and "pay for delay" agreements that NDA holders and some first ANDA filers seek to prevent early competition.

2. Limiting the types of patents that can be listed on the Orange Book

Currently 21 CFR 314.53 requires the NDA applicant to submit information for each patent that covers the drug, including the specific therapeutic area that it will be used for. The NDA applicant must list all relevant patents that it would rely upon to claim patent infringement of its product.

The types of patents that are required to be listed for a drug product include those that cover:
a) the active substance;
b) the formulation and composition;
c) its methods of use; and
d) other compound forms of the active substance, also known as polymorphs.

We recommend that the FDA seek an amendment to 21 CFR 314.5, whereby patents on formulation and compositions, methods of use, and polymorphs are not permitted on the Orange Book. As stated earlier, evidence shows that these types of patents when challenged are often found invalid and are being used to extract "pay for delay" settlements.

Accordingly, these types of patents should be presumed obvious from a legal standpoint and not be permitted on the Orange Book, as they only serve to delay approval of ANDAs and early generic entry.

3. Raising the bar for how we define innovation and grant patents:

While it is necessary to strike an effective balance between rewarding innovation and getting people the medicine they need, the current patent system and Hatch-Waxman Act fails to achieve this balance.

Since Hatch-Waxman was introduced in 1984, the data shows the number of patents on approved medicines has doubled. In the face of competition, pharmaceutical companies are more intent on using patents as a defensive weapon and business strategy to prevent competition, rather than one for making genuine progress and innovation. Put simply, there is a serious over-patenting problem in the pharmaceutical sector that is a root cause of the high drug prices we see today.

The introduction of the PTAB proceedings and IPRs is a first step in the right direction to redress some of these problems and how the industry abuses the patent system for its own gain. However, what is really needed is to ensure that the standard for obtaining a patent is made more stringent in the first place. Our government should strengthen patent examination and reject patent applications that do not meet the legal requirements of patentability.

4. Making the system more accessible to patients:

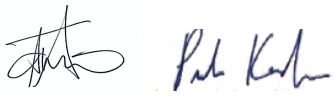
To increase accessibility for patients, consumer advocates and non-profits, the government should also remove overly burdensome fees for filing patent reviews. Such fees stand as a barrier in the way of patients and consumers participating in the patent system, which has a direct impact on their health and lives.

Moreover, access to the courts in pharmaceutical patent cases should not be limited only to parties that are being sued for infringement. Non-commercial actors should be allowed standing in courts to challenge patents, like they are for IPRs.

Setting a higher bar for patentability and making the patent system more open and accessible to scrutiny is critical. These steps give policy-makers tools that will incentivize industry to redirect investments towards the achievement of legitimate innovation, advance medical care, and addresses public health needs.

In conclusion, thank you for your commitment to improving public health by ensuring access to medicines and protecting a competitive marketplace. We would welcome the opportunity to discuss with you further our ideas for how best to modernize the patent system, and the efforts by I-MAK and its partners to challenge meritless patents that are creating harmful barriers to treatment for millions of people.

Sincerely,



Tahir Amin and Priti Krishtel

Initiative for Medicines Access & Knowledge (I-MAK)