SOLVING THE DRUG PATENT PROBLEM

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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 consumers. Abuse of the patent system is directly linked to skyrocketing drug prices: by gaming the patent system with tactics such as evergreening[1] and settlement agreements, pharmaceutical manufacturers delay generic competition and keep affordable medicines out of reach for too many Americans.

Today, one in four Americans report difficulty filling a prescription for themselves or family members,[2] and a majority of Americans believe that taking action to lower prescription drug prices should be the top priority for Congress.[3] Since 2008, the cost index for branded drug prices has nearly tripled,[4] and by 2025 prescription drug spending nationally is poised to double again.[5] At the same time, many pharmaceutical manufacturers secure scores of patents to protect and extend their market monopolies, far in excess of what is needed to incentivize drug development.

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.

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[1] '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".

[2] 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

[3] 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

[4] 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

[5] 2016-2025 Projections of National Health Expenditures. Centers for Medicare and Medicaid Services, Office of the Actuary. 15 Feb 2017

THE WAY FORWARD

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.

We recommend the following seven strategies as key prerequisites to solving the drug patent problem and restoring balance to the system:

1. Stop pharmaceutical manufacturers from over-patenting medicines

The problem

Every week, the U.S. Patent and Trademark Office (USPTO) grants 6,000 new patents.[6,7] A number of these patents enable pharmaceutical manufacturers to engage in 'evergreening', a tactic used to seek secondary and tertiary patents to extend the monopoly period on a medicine far beyond the original term of 20 years.[8] In many instances these secondary and tertiary patents are legally unmerited and form part of a business and legal strategy to stockpile additional patents on the same drug in order to create a defensive thicket to thwart competition- for years or even decades. In some cases, the problem goes even further upstream, with the primary patent(s) not meeting the law's requirements for patentability.

Recommended action

To stop pharmaceutical manufacturers from gaming the patent system, lawmakers, the federal court system, and the USPTO must ensure 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. Such legislation would help define the types of inventions in the

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[6] See https://patentlyo.com/patent/2017/09/fy2017-record-numbers.html

[7] Patents are government granted rights for inventions proven to be novel, non-obvious, useful, and which fully describe how to carry out the invention. All these requirements must be met in order to obtain a patent. Patent-holders receive a market monopoly for a period of 20 years for an invention. Too often, pharmaceutical manufacturers receive patents on inventions that do not hold up under the law's requirements, because they are based on previously published information and/or commonly practiced techniques in the field of pharmaceuticals.

[8] Secondary and tertiary patents are filed after the primary patent on the active ingredient that forms the basis of a new drug. Secondary patents cover other aspects of the active ingredient, such as dosage forms, formulations, different naturally occurring chemical forms of the main active ingredient and production methods. Tertiary patents usually relate to combining the active ingredient with a device, such as an inhaler or an injectable. Secondary and tertiary patents often represent commonly practiced incremental changes and tweaks on top of the primary patent. Since every additional patent grants 20 more years of protection, the practice of filing secondary and tertiary patents can in some cases lead to decades of market monopoly.

pharmaceutical and biologics field that would *prima facie* be considered obvious for examination purposes. This would help to strengthen 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 within the patent system

The problem

Patents, and the monopoly rights that come with them, have far-reaching drug pricing consequences that affect every American. However, participation in pharmaceutical patent cases is limited only to parties that are being sued for infringement. This means that non-commercial actors, such as patients, do not have "standing" in the courts to challenge patents.

Recommended action

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 (see below). 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 that is a vital 'check and balance' within the patent system and that is already reducing drug prices

The problem

The Patent Trial and Appeal Board (PTAB) was created to provide a streamlined process for challenging the validity of a patent in order to help reduce the time and cost of patent litigation, as well as enhancing patent quality. The IPR and Post Grant Review (PGR) systems administered by the PTAB are designed to protect against the proliferation of unmerited secondary and tertiary patents. The IPR/PGR processes ensure expeditious (within 18 months) and cost-efficient examination of challenged patents that are conducted by a knowledgeable panel of judges who are technical experts. Most importantly, these processes create a clear role and legal standing for the public (through any person) to petition to cancel one or more claims of an issued patent, even

though the current fee structure for filing an IPR is still prohibitive for many public interest groups and patients.

Since its creation, the PTAB has reviewed more than 4,500 cases and has laid a solid foundation for addressing high drug prices that are fueled by unmerited patents. Statistics from the USPTO show that nearly 50% of the IPR challenges relating to Orange Book patents[9] that had a final written decision had their claims invalidated in their entirety. However, federal legislation under discussion since 2015, especially the STRONGER Patents Act, would significantly undermine the PTAB as a mechanism to enhance patent quality. Moreover, there are concerns that the pharmaceutical industry will continue to seek exemption or place limitations on its patents from being challenged under the IPR/PGR process.

Recommended action

Proposed legislation that undermines the PTAB and which exempts or places limitations on pharmaceutical patents from being challenged should be rejected. Furthermore, in order to strengthen the IPR mechanism and increase participation for non-commercial actors who challenge patents, the filing fee should be significantly lowered.

4. Eliminate the practice of continuation applications

The problem

Unlike any other country, the U.S has a practice of continuation applications. This practice allows applicants who have had one or more patent applications rejected to overcome the refusal by paying a fee for a new filing. This means that the examiner who previously rejected the original application, or some other designated examiner, will have to start the examination afresh. This practice of allowing patent applicants to file continuation applications means that it is practically impossible for the U.S Patent and Trademark Office (USPTO) to finally reject a patent application.

Continuation applications generate a series of negative consequences. First, it creates inefficiency at the USPTO and reduces the quality of issued patents. Enabling patentees, such as pharmaceutical manufacturers, to refile patent applications without end can become a war of attrition with examiners and leads to overly broad patents being granted that were not merited in the first place.

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[9] The Orange Book, also known as the Approved Drug Products with Therapeutic Equivalence Evaluations, identifies drug products approved on the basis of safety and effectiveness by the Food and Drug Administration (FDA) and related patent and exclusivity information.

Second, continuation applications generate significant uncertainty for a patentee's competitors. The practice can introduce severe delays or block generic competition because many pharmaceutical manufacturers monitor generic company attempts to design around previously issued patents and then use continuation applications, often several years after the original patent application, to specifically block the generic entrants drug design.

Third, continuation applications can lead to multiple patents being issued for the same invention, which is an additional strategy companies can use to engage in patent evergreening. In some cases, granted patents resulting from continuing applications are used by pharmaceutical manufacturers to obtain sequential 30-month litigation stay periods under the Hatch-Waxman statute in order to further delay generic entry.

Recommended action

Continuation applications should be eliminated in their entirety by federal legislation. If an applicant believes that they deserve a patent on an application that has been finally rejected by an examiner, they already have the right to pursue an appeal to the PTAB and thereafter through the federal court system. Therefore, even without continuation applications, applicants would still be afforded plenty of opportunities to make their case for a patent. Furthermore, for applicants who are granted a patent, they should not be afforded the opportunity to file new applications directly targeted at generic drugs that were designed so as to not infringe the patent holder's original patent.

5. Update the Hatch-Waxman Act to recognize decisions from the PTAB to enable accelerated generic entry when patents are invalidated

The problem

Increasingly, generic competitors that seek to enter the market through an Abbreviated New Drug Application (ANDA) employ the PGR and IPR proceedings to cancel patents on the Orange Book, given that these mechanisms are timely and cost efficient. However, patents listed in the Orange Book under the Hatch-Waxman statute can only be invalidated through federal district or appellate court decisions, during which time the New Drug Application (NDA) holder receives a 30-month stay that prevents early generic competition. Therefore, a PTAB decision to invalidate a patent, affirmed on appeal, would invalidate a patent listing on the Orange Book. Yet for those patents cancelled by the PTAB that are not appealed, such decisions do not yet disrupt the 30-month stay, since the Hatch-Waxman statute does not compel invalidation of patents on the basis of a decision to invalidate a patent through IPR proceedings.

Recommended action

The Hatch-Waxman statute should be updated to include invalidating patents listed in the Orange Book on the sole basis of a PTAB decision that is not appealed. This could help accelerate generic entry if all relevant Orange Book 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. Harness the voice of the public to allow challenges, via a pre-grant opposition mechanism, prior to the issuance of patents

The problem

Too many secondary and tertiary patent applications - filed to extend monopolies and delay generic competition - slip through the cracks and are granted despite the best efforts of patent examiners. Pre-grant opposition mechanisms prevent this from happening by allowing for more rigorous examination before the patents are granted. This not only improves quality of the patents that are granted, it could also help reduce litigation after-the-fact. More importantly, by ensuring unmerited patents don't get granted in the first place, it could increase the speed of generics entering the market, improving competition and lowering drug prices. Granting patents that should not have been granted in the first place causes unnecessary costs and delays to generic entry – which is why a pre-grant mechanism is more effective than the current system in the United States that allows for challenges only after patents are granted.

Recommended action

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 permits 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. Promote transparency and scrutiny of the patent system by improving the process at the Food and Drug Administration (FDA) for allowing patents to be listed on the Orange Book

The problem

NDA holders often employ strategic patent listings on the Orange Book to delay generic entry. This is because any patent listed on the Orange Book enables an NDA holder to file a patent infringement suit against a competitor that files an ANDA and pursues market entry. The threat of a patent infringement suit can persuade a competitor to not pursue market entry until such patents expire, even if they are unmerited secondary and tertiary patents. In the event that an ANDA filer is willing to risk litigation, the legal proceedings that follow are lengthy and will delay generic entry.

Recommended action

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 patent attorney 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.

At all levels of government, there is recognition that steps must be taken to curb runaway drug prices. The strategies offered above are not a cure-all to the drug pricing crisis, but each recommendation is a significant step in the right direction. Until and unless policy-makers restore the patent system to its true purpose, to provide a time-limited exclusivity as a reward for an invention, life-saving medicines will continue to remain out of affordable reach for too many Americans.