Patent Policy Prescriptions

The epidemic of overpatenting

Filing hundreds of secondary and tertiary patent applications allows a brand-name drug manufacturer to unfairly extend monopoly protection and keep drug prices high. Some potential policy options to address the problem of overpatenting are:

- **Modify the "inventiveness" standard for patents** so that non-inventive and commonly practiced techniques in the pharmaceutical field cannot be patented. Raising the bar for the inventiveness standard will likely help curb non-inventive patenting, reduce litigation, and accelerate competition after the intended 20 years of protection that could drive down drug prices.
- **Eliminate continuation applications at the USPTO** so that a patent applicant does not have unlimited attempts to gain a patent on the same invention even when the USPTO may have made initial rejections. Drugmakers deliberately file continuation applications so they linger in the system as a deterrent for potential generic drug competitors and can eventually lead to multiple patents being granted for the same invention. Removing continuation applications would address a key anticompetitive behavior of brand-name drug manufacturers.

Public participation in the patent system

Unless non-commercial actors and other interested parties are sued for patent infringement, they do not have legal standing to challenge patents in federal court. This means that the only recourse for non-commercial actors and other interested parties in the patent system lies at the USPTO. Some potential policy options to allow for greater involvement of the public in the patent system to help improve transparency and address patent abuse are:

- **Maintain and improve the existing patent challenge system**, which includes the Inter Partes Review (IPR) process. This process is more efficient, cost effective and serves as an important check in the system to reverse mistakes, improve patent quality, and save money by allowing earlier generic drug competition. The IPR process could be improved by expanding the grounds for a challenge to a patent to include the lack of written description of a patent.

- **Create a pre-grant opposition system similar to the one used for trademarks.** Such a system could permit third parties to file legal challenges based on all available grounds used during examination to determine whether a patent application is valid. Pre-grant opposition systems permit knowledgeable experts to weigh in on the merits of a new patent application while it is still under review.

Unmerited patents listed in the Orange Book

Drugmakers typically file a series of strategic sequential patents in addition to the main patents covering the active ingredient in order to delay generic entry. These secondary and tertiary patents, which can cover formulations, polymorphs, new indications and medical devices combined with off patent active ingredients, are often found unmerited or result in settlement agreements when litigated. Some potential policy options to improve the administration of the FDA's Orange Book, speed up generic entry and reduce litigation are:

- **Update existing legislation which allows the removal of a patent from the Orange Book if it is invalidated using the Post Grant Review (PGR) or IPR processes.** Currently, the language of the law requires the decision of a federal or appellate court to remove an invalidated patent.
- **Improve the quality and transparency of the Orange Book.** FDA should be given greater authority for assessing which patents can be listed on the Orange Book to ensure that only necessary patents are included and it is not used by manufacturers to strategically delay competition. For example, FDA could require brand-name drug manufacturers to provide a patent attorney opinion letter explaining why a patent should be listed in the Orange Book and the letter could be publicly displayed on the Orange Book.