As published in *National Journal* September 15, 2016
NationalJournal

Expanding Patient Access by Preserving Drug Patent Challenges

In so many drug cost conversations, two truths are constant; competition from generics and biosimilars lowers the cost of medicines; and, brand drug companies have proven time and again they will do anything they can to preserve their market monopolies at the expense of patients seeking access to affordable medicines.

One of the more complex ways that brand drug companies can hinder competition is by taking advantage of the patent process. Instances of brand company "evergreening," making minor changes to a product and pursuing a new patent with its requisite protection from competition are commonplace. When this results in more revenue for the protected brand products, patients lose out. Sometimes, these patent extension efforts lead to "weak" patents that the U.S. Patent and Trademark Office can invalidate if the "innovation" is not found to merit additional patent protection.

Congress approved a process to address these scenarios that allows generic and biosimilar manufacturers to challenge these weaker patents through a process called inter partes review (IPR). Successful IPR challenges are more efficient than the usual patent challenge procedures because they happen outside of the court system—and they are working.

It may not surprise some to learn that brand drug makers want to exempt pharmaceuticals from IPR and are asking Congress to make changes to a process that currently helps expedite patient access to more affordable generic drugs. The IPR process is allowed across many industries and a proposed pharmaceutical "carve out" would single out generic and biosimilar manufacturers.

The fact is, brands want to block IPR challenges because they promote generic and biosimilar competition.

Misguided efforts to exempt pharmaceuticals from the IPR process could be costly, and should be worrisome to anyone interested in holding down health costs. Exempting generic and biosimilar manufacturers from using the IPR process adds an estimated $1.3 billion in increased government spending on medicines.

Brands argue that IPR is abused and that third party investors such as hedge funds are manipulating the system. Distortion of the patent system by hedge fund managers should be prevented. But, in order to address isolated cases of these abuses, brand drug companies endorse the drastic measure of removing pharmaceutical patents from the IPR process altogether, which also conveniently shelters them from legitimate competition.

Eliminating bad actors from patent challenge processes is important but so is preserving legal avenues for generics and biosimilars to reach patients as quickly as possible. Some brand drug companies would assert that IPR disrupts the balance between competition and innovation that Hatch-Waxman and BPCIA establishes. In fact, the opposite is true. IPR is working in favor of patient access by expediting a path to invalidating weaker patents, promoting generic and biosimilar competition.

It's time for Congress to look for new ways to break down the barriers preventing patient access to affordable medicines. The Generic Pharmaceutical Association (GPhA) is proposing five policy prescriptions to boost drug competition and expand patient access to affordable medicines. Preserving legal avenues for patent challenges, such as IPR, is one such way to ensure that our nation's intellectual property framework balances innovation and competition while accelerating patient access to affordable medicines.

Nearly 9 of every 10 of the 12 million prescriptions taken each day is a generic. And despite their near universal usage, generics account for a mere 28 percent of the amount spent on prescriptions.

The bottom line is that generic drugs are saving the American healthcare system $5 billion per week, yet more can be done to expand patient access and grow these savings.

As policymakers evaluate their options, it is important to ensure that proposals do not have a chilling effect on competition and spur the market entry of more affordable medicines.

Generics and biosimilars create hundreds of billions of dollars in annual savings for our healthcare system, ensuring access to safe and effective medicines to millions who would otherwise go without. This is a foundation to build upon – not to inhibit or put at risk.

aam
Association for Accessible Medicines

The Biosimilars Council
A Division of the Association for Accessible Medicines