How the "Restoring the America Invents Act" lowers drug prices

Bad patents hold up generic and biosimilar drug competition and keep prices high, costing billions every year. Inter partes review (IPR) is a process created by the 2011 America Invents Act (AIA) that provides a low-cost and fast alternative to traditional patent litigation by using patent experts within the U.S. Patent and Trademark Office (USPTO) to take a second look at patents identified by the public as potentially granted in error. IPR is therefore a useful tool in weeding out bad patents used by drug companies to prevent competition.

How inter partes review is an efficient alternative to litigation

IPR is a popular and effective alternative to resolve disputes over whether a patent was properly granted. An IPR proceeding has statutory deadlines and takes 18 months from the filing of a petition to final written decision. This is much faster than district court litigation, which takes an average of about two and a half years just to make it to trial. IPRs are also typically less expensive than district court litigation. A survey by the AIPLA has shown that the median cost of filing an IPR through final written decision is $350,000. The cost to litigate these patent disputes in court is far more significant. The median litigation cost when more than $25 million is at risk, typical for a drug patent, was $4,000,000 in 2019. IPRs also benefit from public participation, like when the non-profit EFF successfully challenged a podcasting patent on behalf of the then nascent podcasting industry.

	IPRs	Court Litigation
Cost	~$350,000	~$4,000,000
Time	18 months	~2.5 years to trial

Why inter partes review is necessary to lower drug prices

Some drug companies use a strategy of filing up to hundreds of low quality patent applications to prevent generic competition on their older drugs. These patent applications are filed throughout the life of the drug's monopoly, especially towards the end, so that each patent extends the total monopoly period. This strategy works because the USPTO can and does make mistakes in issuing patents that should not have been granted. A key problem is that patent examiners are given an average of only 19 hours on each patent application, which includes the time spent reading the application, searching for prior art that would render the proposed patent invalid, interviewing the applicant's counsel, responding to the applicant's arguments, and rendering a decision. Patent applications are presumed valid unless a reason for rejecting them is found. One study found that approximately 27% of issued patents would be found at least partially invalid.

Brand-name drug companies seek dozens of patents and claims covering a single drug using second-, third-, and even fourth-generation patents to extend drug monopolies that can last decades and keep America's drug prices the highest on Earth. Prescription drugs like Humira (136 patents), Remicade (66 patents), and Lantus (49 patents) often receive decades of monopoly protection through over-patenting, which allow drug companies to raise prices on patients year after year.

A federal legislative solution

Federal legislation introduced by Senators Leahy (D-VT) and Cornyn (R-TX), Restoring the AIA, will strengthen IPR process and correct certain interpretations of the AIA in ways that will address tactics used by brand-name drug company to abuse the patent system. These changes will work to lower drug prices by improving the IPR process so that generic and biosimilar competition can come to market. While the fixes are largely technical, important changes include:

- Allowing IPRs to review a patent based on grounds of obviousness-type double patenting. This judicially created standard closes a loophole that sometimes allows patent holders to patent the same thing multiple times.
- Restricting the ability of the USPTO to dismiss petitions to institute an IPR on a patent for reasons other than the merits. This practice has been increasing in recent years and has prevented otherwise valid petitions from being considered.
- Resolving a transparency gap created by the U.S. Supreme Court's decision in *Arthrex*. The ruling in that case requires that the USPTO director is able to reverse any IPR decision. The bill adds the requirement that the USPTO must do so in a public written opinion.
- Providing clear deadlines to address concerns that it was taking far too long to address requests for reconsideration, sometimes delaying these requests for more than a year.
- Allowing meritorious appeals to proceed in instances where the Federal Circuit previously held that generic and biosimilar companies lacked the standing to appeal an adverse IPR decision.
- Other technical fixes to increase fairness and reduce gaming.

Restoring the AIA will also apply many of these changes to another process, called Post Grant Review, that is similar to IPR but must be filed within nine months of a patent being granted.