

August 15, 2018

Re: Docket No. FTC-2018-0048: Competition and Consumer Protection in the 21st Century Hearings,
Project Number P181201

Dear FTC Hearing Organizers:

As part of your evaluation into the role of intellectual property and competition policy in promoting innovation, I submit for consideration my article, *Disrupting the Balance: The Conflict between Hatch-Waxman and Inter Partes Review*, 6 NYU JOURNAL OF INTELLECTUAL PROPERTY AND ENTERTAINMENT Law 14 (2016).

This Article discusses the administrative proceeding to challenge patents—Inter Partes Review (IPR)—created under the America Invents Act in 2012. For patents in most industries, IPR offers a new, efficient alternative to challenge patents of dubious quality. However, for pharmaceutical patents, IPR is a means to avoid the litigation pathway created under the Hatch-Waxman Act over thirty years ago.

In this Article, I explain the critical differences between district court litigation in Hatch-Waxman proceedings and IPR administrative proceedings that jeopardize the delicate balance Hatch-Waxman sought to achieve between patent holders and patent challengers. The PTAB applies a lower standard of proof for invalidity than do district courts in Hatch-Waxman litigation. In addition to the lower burden, it is also easier to meet the standard of proof in a PTAB trial because of a more lenient claim construction standard. Moreover, on appeal, PTAB decisions in IPR proceedings are given more deference than lower district court decisions. Finally, while patent challengers in district court must establish sufficient Article III standing, IPR proceedings do not have a standing requirement. This has led to the exploitation of the IPR process by entities that would never be granted standing in traditional patent litigation—hedge funds betting against a company, then filing an IPR challenge in hopes of crashing the stock and profiting from the bet. These differences between district court litigation and IPR proceedings are creating significant deviation in patent invalidation rates under the two pathways; compared to district court challenges, patents are twice as likely to be found invalid in IPR challenges.

This Article explains why the disparities between IPR proceedings and Hatch-Waxman litigation must be reduced to preserve innovation in the pharmaceutical industry. The high patent invalidation rate in IPR proceedings creates significant uncertainty in intellectual property rights. Uncertain patent rights will, in turn, disrupt the nature of competition in the pharmaceutical industry, drug innovation, and consumers' access to life-saving drugs.

Thank you for considering this important topic.

Sincerely,
Joanna Shepherd