



December 3, 2020

Attn: Scott C. Weidenfeller
Vice Chief Administrative Patent Judge
U.S. Patent and Trademark Office
PO Box 1450
Alexandria, VA 22314

Re: Patent Trial & Appeal Board - inter partes review - discretionary denials
Docket No. PTO-C-2020-0055
Document Citation: 85 Fed. Reg. 73437
Document Number: 2020-25490

Maryland PIRG is an advocate for the public interest. We speak out for a healthier, safer world in which we're freer to pursue our own individual well-being and the common good.

Prescription drugs are an important element of our health care system and yet is one of the most expensive parts of it. The patent system is intended to encourage innovation by ensuring drug manufacturers will have exclusive rights to sell new drugs for many years, but patents also expire so that this new knowledge eventually can benefit all of society. The U.S. spends far more on prescription drugs than do other countries, largely because we pay higher prices. One reason drug prices are higher in the U.S. is that the drug market involves anti-competitive practices and policies. Drugmakers have twisted and abused patent laws to increase the life of their patents and drive up prices. Activities such as "evergreening," allow pharmaceutical companies to use the patent system to extend their market exclusivity, such as by patenting a drug's secondary aspects (such as dosing schedule or production techniques), in addition to the active ingredients.¹ The patent system allows interested parties to challenge patents that were erroneously granted. This is a vital component of our patent system and yet, it has the potential to add costs to the system when it means drawn-out court challenges. This is one reason why *inter partes* review (IPR) was created - to identify a more efficient way to allow competitors to challenge patents.

We urge the U.S. Patent and Trademark Office ("USPTO") not to proceed with rulemaking that would make discretionary denial of petitions by the Patent Trial and Appeal Board ("PTAB") more common. The goal of the IPR process was to find a swifter, less expensive way to allow a second look at patents than a

¹ <https://law.uoregon.edu/images/uploads/entries/Marrs.pdf>

long-delayed and expensive court trial. Allowing for greater use of discretionary denials that allow for the denial of valid petitions not based on the merits of the petition will result in delaying entry into the market of competitors offering less expensive generic and biosimilar drugs.

The harm of erroneous patents is well-established: raising drug prices and making medicines unaffordable. The USPTO should preserve the benefit of the IPR process. This quick, efficient, and less expensive means of challenging potentially erroneously granted pharmaceutical patents is especially important to speed up the entry of competition and reduce drug costs for American patients and payers.