Debunking Some Anti-Patent MYTHS

Throughout its history, the United States has led the world in protecting intellectual property (IP) rights. On that foundation, we've also led the world in artistic, commercial and scientific innovation, particularly with lifesaving medicines and vaccines. Yet patent rights are under increasing assault, with some charging biopharmaceutical manufacturers with "antitrust" violations for utilizing and building upon their patents for the greater good. Those false critiques under the guise of "antitrust" typically rely upon an array of misleading and pejorative labels, the most prominent of which we address and debunk below:

MYTH "Product Hopping" FACT

Anti-patent activists employ this deceptive term to describe when a manufacturer introduces a new, different drug that may compete with or replace an older version and provide expanded patient choice and access. They claim that by introducing a new product covered by new patents, biopharmaceutical manufacturers are somehow engaging in anticompetitive activity, fending off entry of generic or biosimilar competitors.

U.S. patent law rightfully grants patent rights for new and useful improvements to existing drugs. That incentivizes research and development and the multiple years of risk-taking and experimentation needed to make existing products even better. Such improvements open the door for reduced side effects, lower dosage requirements, improved potency, extended effectiveness or alternative uses. Additionally, as the COVID pandemic has illustrated, it's important to upgrade existing drugs to address potentially mutating microbes that cause disease. Depriving biopharmaceutical innovators of patent protections for those critical improvements or otherwise disincetivising such innovations would mean they're far less likely to be developed, resulting in decreased options for patients.

MYTH "Patent Thickets" FACT

Similarly, patent antagonists use this pejorative term to refer to what they claim are overlapping patent rights relating to a single product or product category. They additionally claim such patents are meaningless and superfluous, and somehow obstruct entry to some markets and impede innovation.

This claim doesn't withstand even initial scrutiny. First, the U.S. Patent and Trademark Office (USPTO) only grants patents for new, useful and non-obvious innovations following a robust and thorough examination process by the USPTO. Second, to claim the U.S. patent system "impedes innovation" ignores the fact that under our system of strong patent protections the U.S. creates two-thirds of all new drugs introduced to the world, with no close competitor. Weakening patent rights would reduce innovation and undermine that position.

MYTH "Evergreening" FACT

Biopharmaceutical patent holders have been accused of filing for new patents on trivial improvements to a medicine on which they already possess existing patents to fend off competition and extend patents, including from generics and biosimilars.

In reality, patents on an improvement to a medicine do not extend the term of any earlier patents on the medicine and do not prevent generic or biosimilar competition for the original medicine. Again, any new patents must clear USPTO scrutiny to be granted, so if the improvements described in any new patent applications are deemed frivolous, they'll fail the USPTO examination process.

MYTH "Pay-for-Delay Settlements" FACT

Anti-patent voices claim that when litigation arises between biopharmaceutical patent holders and generic or biosimilar producers, pretrial settlements should be restricted because they are anti-competitive and allow existing patent holders to continue charging unfairly high prices for their products by keeping generics or biosimilars out of the market.

The obvious problem with this critique is that historically patent settlements have not increased the duration for which brand medicines have market exclusivity. This is because patent settlements do not extend the patent term on a biopharmaceutical manufacturer's patents and do not by themselves prevent generic or biosimilar entry after these patents expire. In fact, settlements actually often allow for market entry of generics or biosimilars earlier than they could otherwise achieve due to protracted litigation or loss at trial. Discouraging settlements would further only increase the amount of litigation in our already-overburdened judicial system, which would in turn divert critical resources from research, development, manufacturing, improvement and distribution to complex and costly litigation.

Americans and their elected leaders must recognize these deceptive terms and other similar talking points for what they are: mere rhetoric in the ongoing assault against strong patent protections for U.S. biopharmaceutical innovators. Those patent protections incentivize advancements and have created the foundation for our unparalleled record of creating lifesaving medicines and vaccines, as evidenced by the COVID pandemic. We cannot let that tragically be eroded by anti-patent voices.

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