3 Myths Critics Get Wrong About Intellectual Property

Intellectual property (IP) protections are the foundation of U.S. global leadership in biopharmaceutical innovation.[1] Patents and other IP protections over the past 25 years have fueled the delivery of over 750 new medicines for debilitating and devastating illnesses, such as cancer, heart disease and many rare diseases, by giving innovators the legal protection and confidence they need to take on the significant costs and risks associated with drug development. On average, it costs $2.6 billion dollars and 10-15 years to bring a new medicine to patients and only 12% of potential medicines entering clinical trials are ultimately successful in reaching FDA approval.

Thanks to a system that balances innovation and affordability, U.S. patients have more medicine choices, with 90% of prescriptions filled by generics and biosimilars, and medicine costs making up only 14% of health care spending. Yet some in Congress are still pushing dangerous policy changes based on misleading narratives that could undermine the vital protections innovators need to develop future treatments and cures.

Here are three of the most egregious myths we're debunking.

MYTH #1

"Product Hopping" allows companies to make slight or clinically meaningless alterations to products and then market a new version to shift utilization away from the original.

REALITY:

"Product hopping" is a term coined by critics who wrongly claim that brand-name manufacturers make superficial changes to FDA approved medications to maintain market exclusivity.
These claims disregard the critical role of post-approval R&D which helps identify new ways of possibly treating disease, including possible new uses of existing treatments.2 Importantly, IP protections on post-approval advances do not prevent the approval of generic copies or biosimilars of earlier versions, and if the new version adds no additional value, generics or biosimilars of the original product are likely to be used instead.

MYTH #2

"Patent thickets" allow companies to layer on numerous patents to products.

REALITY:

Medicines are much more than just their active ingredients.
Patent thicket claims conveniently ignore that technologically advanced innovations like medicines often have multiple patents because, like any product, they are comprised of many different inventions. Even something as apparently simple as a golf ball can have as many as 68 patents covering different features.[3]

A recent USPTO report rebuts these common patent thicket claims by showing that the number of patents on a medicine is a poor indicator of a product's period of market exclusivity before generic entry, as patent volume does not determine how long this period lasts.[4]

MYTH #3

"Evergreening" allows companies to extend market exclusivity by making minor modifications to existing products and delaying entry of generics and biosimilars.

REALITY:

Innovation does not stop the minute a medicine is first approved. R&D is an ongoing process that continues long past initial FDA approval, resulting in innovations that improve the lives of patients. Patents covering new uses in different diseases, new dosing schedules, convenient dosage forms and manufacturing methods that are filed later in the product lifecycle do not extend the life of a drug's original patents. The term "evergreening" implies that companies are permitted to endlessly file frivolous patents on the same medicine, ignoring that inventors must demonstrate to the USPTO their inventions are new, useful and non-obvious. Though patents last 20 years from filing, brand-name medicines face generic competition after just 13 years, on average, significantly less than other products.

Before making sweeping changes to our IP system, policymakers should address root causes of patient affordability challenges driven by middlemen blocking access to generics and biosimilars.

The hyper-consolidated industry of insurers and pharmacy benefit managers (PBMs) controls which drugs are covered, who gets access to them and how much everyone pays.[5] These middlemen routinely keep lower-cost alternatives off their formularies that could reduce patient out-of-pocket costs. As PBM compensation is largely tied to the list prices of medicines, they are often incentivized to prefer medicines with higher list prices and large rebates over lower-cost alternatives.

In fact, the three largest PBMs, which control 80% of the U.S. market, have consistently excluded authorized generics and biosimilars from formularies in recent years. Most recently, these PBMs each have commercialized biosimilars produced through their own affiliates, preferencing coverage for these biosimilars while excluding non-PBM-affiliated biosimilars from formularies. By pushing patients to use PBM-affiliated biosimilars, these vertically integrated entities profit at multiple points along the supply chain—including when PBM-owned health plans cover the product and when the prescription is filled at a PBM-owned pharmacy.[6]

To improve patient access and reduce out-of-pocket costs, policymakers should prioritize protecting innovation and the IP ecosystem while advancing bipartisan reforms that address the root causes of access challenges, such as the anticompetitive behavior of insurers and PBMs, rather than dismantling the framework that fosters competition.

Sources:

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