FACTS ABOUT PATENTS

Debunking the False Narrative About Biopharmaceutical Patents

America's biopharmaceutical research ecosystem is the global leader in the development of innovative medicines, allowing patients in the U.S. to access new medicines faster than the rest of the world. This is the result of a carefully balanced policy environment that includes robust intellectual property (IP) protections that foster investment in groundbreaking research and development (R&D), while also promoting access for patients and the sustainability of the U.S. health care system. Below are the real facts about how patents help drive innovation and access, contrary to what some claim.

MYTH	FACT
Biopharmaceutical companies file many patents on the same medicine to block competition.	Medicines are much more than just their active ingredients. They involve highly complex manufacturing processes and often significant R&D long after a medicine's active ingredient is patented and initially approved by the Food and Drug Administration (FDA), leading to important advances for patients. A medicine is often associated with multiple patents that cover other innovative aspects, including the composition of dosage forms, methods of manufacturing and use in a particular therapeutic indication. Patents incentivize continued R&D into these important aspects of medicines, which can play a critical role in making a treatment safe and effective for use by patients and result in improved health outcomes.
Patent protection for medicines lasts much longer than 20 years.	Unlike products from other industries, medicines must go through lengthy and costly clinical trials to confirm their safety and efficacy before they are allowed to come to market. With an average of 10 to 15 years and $2.6 billion needed to develop one FDA-approved treatment, many medicines will reach the market with less than half of their original patent life remaining, during which time biopharmaceutical companies can attempt to recoup R&D costs and fund future innovation.[1] Today, on average, there is generic competition against a patented medicine after it has been on the market for around 13 years, which is substantially less than the 20 years afforded other products by the patent system generally.[2]
Not all patents are inventive.	Innovation does not stop the minute a medicine is first approved. In reality, R&D investment on a medicine is an ongoing process that continues long past initial FDA approval, resulting in innovations that improve the lives of patients, including new uses, novel delivery mechanisms and new dosing schedules. These advances, which generally are the result of lengthy and resource-intensive clinical trials, can expand treatment options for patients and lead to better adherence to medicines and improvements in quality of life, as well as savings to the health care system from fewer unnecessary hospitalizations.
More patents do not mean more innovation.	By law, inventors must demonstrate that their inventions are *new, useful, and non-obvious* for the U.S. Patent and Trademark Office to grant a patent. As a result, patent activity is a strong indicator of the scale and pace of R&D underway to generate new innovations. Even after a medicine's initial approval, biopharmaceutical companies continue to invest in R&D that can improve its manufacturing process or lead to additional uses of the medicine. While these additional innovations can be covered by additional patents, these patents do not block generic or biosimilar competitors of the original version of a medicine, nor do they block brand competitors from developing treatment alternatives. These alternative versions increase patient and physician choice and create competition by providing payers with additional leverage to negotiate rebates and other discounts.
Public funding is responsible for biopharmaceutical innovation.	The biopharmaceutical industry spends, on average, three times as much on R&D each year than the total annual budget of the National Institutes of Health (NIH).[3] Furthermore, only a small portion of the NIH's total budget–8% in 2018–is dedicated to actual medicine development.[4] This is because the NIH is largely focused on basic research that accelerates scientific progress more broadly, while biopharmaceutical companies provide the specific expertise, infrastructure, capabilities, and financial resources needed to develop new medicines. As one study found, 90% of NIH-funded publications connected to new medicines are related to the underlying drug target, not the actual therapy itself.[5] Without the investment and expertise of the biopharmaceutical industry, the knowledge resulting from basic research would generate many ideas for potential drugs and drug targets–but very few new medicines for patients.

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