

IP INCENTIVES FUEL BIOPHARMACEUTICAL INNOVATION AND COMPETITION

Robust protection and enforcement of intellectual property (IP) rights are the driving force behind continued investments into the biopharmaceutical research and development (R&D) enterprise supporting continued innovation and competition. As we push the frontiers of science, patent rights and statutory data protection are critical to ensuring a favorable environment for continued innovation and achieving progress against the most complex and difficult to treat diseases of our time.

Intellectual Property Incentives Drive R&D Investments in Innovation

IP incentives, including both patents and statutory data protection, generate tremendous biopharmaceutical innovation benefits to both patients and society. In the last decade alone, the U.S. Food and Drug Administration (FDA) has approved nearly 900 new medicines, including the first medicine to treat the underlying cause of cystic fibrosis, the first vaccine to prevent cervical cancer, and the first ever gene therapies.^{ii,iii,iv} With sustained investments, our scientific understanding will continue to grow, creating new opportunities to further transform the treatment of disease.

R&D investment decisions are based on the rationale that most high-risk early stage investments will fail but that the strong returns on a few successful projects will be sufficient to justify investments that entail many losses. IP protections are critical incentives for innovation, given the unique attributes of the biopharmaceutical R&D process:

- The R&D process involves a high level of scientific and regulatory uncertainty. Only 12% of investigational medicines that reach clinical trials ultimately receive approval from the FDA.^v Patent protection and statutory data protection help support future innovation, including by providing the opportunity to earn revenue that can also compensate for the costly failures inherent in the R&D process.^v
- Research shows that R&D-intensive industries such as biopharmaceuticals are inherently riskier than non-R&D-intensive industries due to the uncertainty around R&D endeavors. The benefits, if they occur at all, are also realized over an extended time horizon, all of which increases the risk of such investments.^{vi}
- On average, it costs \$2.6 billion dollars and takes 10 to 15 years to develop a new medicine.^{vii} The growing cost of drug development is driven in part by increases in protocol requirements as well as manufacturing complexities, particularly for biologics.^{viii}

Intellectual Property Fosters Many Forms of Innovation

IP protections provide incentives to support the substantial efforts required to discover and develop new medicines. Patent protections provide inventors the exclusive right to sell an invention for a set period of time before others may copy and sell it. Statutory data protection provides protection, for a limited period of time, of clinical trial data submitted to the FDA by a brand manufacturer during which such data cannot be relied on by other companies to seek approval of another medicine. Other companies can generate their own data to obtain FDA approval during this period.

Once a new medicine's patent term and any statutory data protection provisions expire, generic equivalents and biosimilars, which require lower capital investments, can enter the market. In fact, 90% of all medicines dispensed in the United States are generic copies that cost a fraction of the price of the initial brand medicine.^{ix} In the absence of IP protections, biopharmaceutical companies would be unlikely to invest in developing innovative therapies.

New medicines play a central role in transforming the trajectory of many debilitating diseases, resulting in decreased death rates, improved health outcomes, and better quality of life for patients. Researchers are pursuing cutting-edge research and novel scientific strategies to continue to drive therapeutic advances for patients.^x Today there are about 8,000 medicines in clinical development globally with the potential to impact U.S. patients. And across the medicines in the pipeline, 74% have the potential to be first-in-class treatments.^{xi}

While the initial approval of a new medicine is a major milestone, based on rigorous demonstration of safety and efficacy, research does not stop at that point. Additional knowledge and understanding of a medicine continue to build over time, through additional R&D often requiring lengthy and costly phase III trials. This ongoing research can culminate in expanded uses of medicines, including through the FDA approval of an existing medicine for use in a completely different disease area or in a new patient population (e.g. pediatric populations, for use in an earlier stage of disease). Ongoing research can also result in new forms, such as extended release preparations, alternate delivery systems, dosage forms or combination products.

Improvements upon existing forms can have a profound effect on the clinical profile of a medicine and offer many benefits, not only by expanding treatment options for patients, but by providing less frequent dosing, greater convenience, reduced side effects and improved quality of life. These benefits in turn provide patients with the tools to successfully manage their condition and achieve better health outcomes. Likewise, by improving patient adherence and outcomes, these innovations can also provide benefits to the health system more broadly—including through the avoidance of disease complications, hospitalizations and associated health care costs.

Intellectual Property Drives Competition

Medicine costs have remained a small, stable share of health care spending even as new medicines reach patients year after year. That's because our market-based system leverages competition to control costs throughout the lifespan of a prescription medicine. IP protections do not impede competition in the United States. Rather, they drive biopharmaceutical companies to innovate by providing a degree of assurance that they may earn a return on an otherwise risky and costly investment in R&D.

As result of these incentives, multiple biopharmaceutical companies are often simultaneously researching and developing potential new medicines in order to be the first medicine to launch in a new therapeutic class, while recognizing they might ultimately be second or third, or fail altogether. Ultimately, it is this race to market that fuels competition amongst these products, not only to differentiate based on price but on the clinical effects, in order to address remaining unmet needs. Likewise, IP protections do not prevent competition from nonidentical drugs, but rather they encourage it while also fueling innovation to address unmet needs.

Similarly, patents and statutory data protection that cover new forms do not extend the patents or data protection on previously approved formulations, or otherwise delay or block generic copies of the earlier formulations. Rather, they incentivize R&D into improving upon products so as to provide greater clinical benefits and improved health outcomes to patients with unmet needs.

Importantly, these IP incentives lead to multiple products on the market, thereby providing payers with increased leverage to negotiate rebates and discounts on medicines in exchange for formulary placement or placement on lower cost-sharing tiers. For example, within a year of the introduction of the first major breakthrough treatment for hepatitis C, there were multiple competitors on the market resulting in lower prices, improved clinical effectiveness and a curative treatment option for patients with all forms of the disease. Owing to the success of this competitive market dynamic, evidence suggests that negotiated prices in the United States are typically lower than in most European countries.^{xii}

The current legal and regulatory framework successfully balances the need to encourage innovation with the interest in fostering competition through the timely market entry of additional brand, generic, and increasingly biosimilar competitors. As the lifeblood of the industry, IP rights in the form of patents and statutory data protection help ensure that innovative biopharmaceutical companies recoup the significant investments needed to bring new medicines to patients. Strong IP rights are a critical policy area that will enable the United States to maintain its role as the world leader in biopharmaceutical R&D and will sustain the future investments needed to transform cutting-edge science into tomorrow's life-saving treatments.

ⁱ US FDA. Summary of NDA approvals and receipts, 1938 to the present.

ⁱⁱ US FDA. Center for Drug Evaluation and Research (CDER) Advancing Health through Innovation, 2018 New Drug Therapy Approvals.

ⁱⁱⁱ US FDA. Center for Biologics Evaluation and Research. Biological Approvals by Year.

^{iv} DiMasi JA et al. Innovation in the Pharmaceutical Industry: New Estimates of R&D Costs. *Journal of Health Economics* 2016 (47):20-33.

^v DiMasi JA et al. Innovation in the Pharmaceutical Industry: New Estimates of R&D Costs. *Journal of Health Economics* 2016 (47):20-33.

^{vi} Pham ND et al. A comparison of profitability measurements between R&D-intensive industries and non-R&D-intensive industries. NDP Analytics. 2019.

^{vii} JA DiMasi, Grabowski, RW Hansen. Innovation in the pharmaceutical industry: New estimates of R&D costs. *J Health Econ.* 2016;47:20-33.

^{viii} See Getz, KA, and Campo RA. *New Benchmarks Characterizing Growth in Protocol Design Complexity.* Therapeutic Innovation & Regulatory Science. 2017.

^{ix} IQVIA Institute for Human Data Science. *Medicine use and spending in the U.S.: A review of 2018 and outlook to 2023.* April 2019.

^x Adis R&D Insight Database. Accessed June 2019.

^{xi} Analysis Group. "The Biopharmaceutical Pipeline: Innovative Therapies in Clinical Development," July 2017.

^{xii} IMS Health, "Comparison of Hepatitis C Treatment Costs," September 2016