# Innovation DA

## Generic

#### The risks associated with creating new drugs means that patents are key to biopharmaceutical innovation

**Cockburn & Long 15 [**Iain Cockburn, Richard C. Shipley Professor of Management. Genia Long, senior advisor and part of analysis group. “The importance of patents to innovation: updates cross-industry comparison with biopharmaceuticals.” Taylor & Francis online, Volume 25, Issue 7, 2015. Published online: 30 April 2015. Link: <https://www.tandfonline.com/doi/full/10.1517/13543776.2015.1040762>] JV

Due to distinctive economic characteristics, patents and regulatory exclusivity have long been considered essential to prescription drug development. These characteristics include the costly, lengthy, and risky nature of innovative research and development (R&D) and the much lower investment required for generic drugs. Because of this disparity, without patent protection and regulatory exclusivity, particularly in the USA, innovators would be unlikely to make the substantial investments required to bring new drugs to market. Whereas drug development is global, patent law and regulation are country-specific. In the USA, regulatory exclusivity operates in parallel with patents, defining when generics or biosimilars may not submit abbreviated applications and/or enter the market. Generic imitation may require several million dollars, whereas the cost to bring a single FDA-approved drug to market (including the cost of failed attempts) has been estimated at $1.4 billion in out-of-pocket costs and $2.6 billion including the cost of capital [[1,2]](https://www.tandfonline.com/doi/full/10.1517/13543776.2015.1040762). New drug R&D requires more than a decade, including pre-clinical testing, clinical trials, and US regulatory approval [[1,2]](https://www.tandfonline.com/doi/full/10.1517/13543776.2015.1040762). In comparison, clinical testing is not required for generics; manufacturers need only demonstrate bioequivalence to an already-approved drug. Risk is also high; the vast majority of candidates are eliminated, most before clinical testing. For those that begin clinical testing, the probability of proceeding to approval averages only 12% [[2,3]](https://www.tandfonline.com/doi/full/10.1517/13543776.2015.1040762). Therefore, R&D must be funded by a few successful, on-market medicines [[4]](https://www.tandfonline.com/doi/full/10.1517/13543776.2015.1040762). Generally, in the USA, once patent protection and any 180-day generic exclusivity end, multiple generics launch, and generic share increases rapidly. For all new molecular entities experiencing first generic entry in 2011–12, the average brand’s unit share of molecule sales declined to 16% 12 months after generic entry, versus 44% in 1999–00 [[5]](https://www.tandfonline.com/doi/full/10.1517/13543776.2015.1040762). In 2013, generics represented 86% of all US prescriptions [[6]](https://www.tandfonline.com/doi/full/10.1517/13543776.2015.1040762). In addition to distinctive R&D and market competition economic characteristics, biopharmaceuticals are also distinguished from other industries by a large gap between the statutory patent term (20 years from the effective patent filing date) and the effective patent term (years remaining at launch), even after any patent term restoration and additional regulatory exclusivity (e.g., for pediatric studies). The average time between brand launch and first generic sale for drugs experiencing initial generic entry in 2011–12 was 12.6 years for drugs with sales greater than $100 million (in 2008 dollars) in the year prior to generic entry, and 12.9 years overall [[5]](https://www.tandfonline.com/doi/full/10.1517/13543776.2015.1040762). In contrast, assuming < 3 years for the US Patent and Trademark Office to examine and approve a patent application (overall average of 29 months for FY2013), the remaining duration (assuming 20 years from the effective patent filing date) would be > 17 years in other industries [[7]](https://www.tandfonline.com/doi/full/10.1517/13543776.2015.1040762).

#### Patents ensure that new biopharmaceutical research gain funding

**Cockburn & Long 15 [**Iain Cockburn, Richard C. Shipley Professor of Management. Genia Long, senior advisor and part of analysis group. “The importance of patents to innovation: updates cross-industry comparison with biopharmaceuticals.” Taylor & Francis online, Volume 25, Issue 7, 2015. Published online: 30 April 2015. Link: <https://www.tandfonline.com/doi/full/10.1517/13543776.2015.1040762>] JV

Finally, patents serve other particularly important economic functions in biopharmaceuticals, developing robust markets for technology and ‘signaling’ to potential investors the quality of pre-market assets [[8]](https://www.tandfonline.com/doi/full/10.1517/13543776.2015.1040762). Since the 1980s, a number of scientific, economic, and legal developments have created the modern-day US biopharmaceutical sector [[9]](https://www.tandfonline.com/doi/full/10.1517/13543776.2015.1040762). In addition to scientific discoveries creating new areas of life sciences research, patent law developments made obtaining and enforcing patents for genes and recombinant entities possible, the Bayh-Dole Act encouraged university licensing of government-sponsored research, and a venture capital industry emerged, supporting early phase companies. Between 1980 and 2012, life sciences venture investments totaled $108 billion in 4,600 start-ups (19% of all US venture investment then) [[10]](https://www.tandfonline.com/doi/full/10.1517/13543776.2015.1040762). Potential start-up investors weigh patents heavily, including expected effective patent terms of molecules in development, and patent strength for proprietary technology.

#### Patents are crucial to the economy and the development of new drugs

**Grabowski et al 15** [Henry G. Grabowski: professor of economics at Duke University, in Durham, North Carolina. Joseph A. DiMasi: director of economic analysis at the Tufts Center for the Study of Drug Development, Tufts University, in Boston, Massachusetts. Genia Long: senior advisor at the Analysis Group, in Boston, Massachusetts. “The roles of patents and research and development incentives in biopharmaceutical innovation” Health Affairs. Vol. 34, No.2: Biomedical Innovation. Published: February 2015. Link: <https://www.healthaffairs.org/doi/10.1377/hlthaff.2014.1047>] JV

The essential rationale for patent protection for biopharmaceuticals is that long-term benefits in the form of continued future innovation by pioneer or brand-name drug manufacturers outweigh the relatively short-term restrictions on imitative cost competition associated with market exclusivity. Regardless, the entry of other branded agents remains an important source of therapeutic competition during the patent term. Several economic characteristics make patents and intellectual property protection particularly important to innovation incentives for the biopharmaceutical industry. [5](https://www.healthaffairs.org/doi/10.1377/hlthaff.2014.1047#B5) The R&D process often takes more than a decade to complete, and according to a recent analysis by Joseph DiMasi and colleagues, per new drug approval (including failed attempts), it involves more than a billion dollars in out-of-pocket costs. [6](https://www.healthaffairs.org/doi/10.1377/hlthaff.2014.1047#B6) Only approximately one in eight drug candidates survive clinical testing. [6](https://www.healthaffairs.org/doi/10.1377/hlthaff.2014.1047#B6) As a result of the high risks of failure and the high costs, research and development must be funded by the few successful, on-market products (the top quintile of marketed products provide the dominant share of R&D returns). [7](https://www.healthaffairs.org/doi/10.1377/hlthaff.2014.1047#B7),[8](https://www.healthaffairs.org/doi/10.1377/hlthaff.2014.1047#B8) Once a new drug’s patent term and any regulatory exclusivity provisions have expired, competing manufacturers are allowed to sell generic equivalents that require the investment of only several million dollars and that have a high likelihood of commercial success. Absent intellectual property protections that allow marketing exclusivity, innovative firms would be unlikely to make the costly and risky investments needed to bring a new drug to market. Patents confer the right to exclude competitors for a limited time within a given scope, as defined by patent claims. However, they do not guarantee demand, nor do they prevent competition from nonidentical drugs that treat the same diseases and fall outside the protection of the patents. New products may enter the same therapeutic class with common mechanisms of action but different molecular structures (for example, different statins) or with differing mechanisms of action (such as calcium channel blockers and angiotensin receptor blockers). [9](https://www.healthaffairs.org/doi/10.1377/hlthaff.2014.1047#B9) Joseph DiMasi and Laura Faden have found that the time between a first-in-class new drug and subsequent new drugs in the same therapeutic class has been dramatically reduced, from a median of 10.2 years in the 1970s to 2.5 years in the early 2000s. [10](https://www.healthaffairs.org/doi/10.1377/hlthaff.2014.1047#B10) Drugs in the same class compete through quality and price for preferred placement on drug formularies and physicians’ choices for patient treatment. Patents play an essential role in the economic “ecosystem” of discovery and investment that has developed since the 1980s. Hundreds of start-up firms, often backed by venture capital, have been launched, and a robust innovation market has emerged. [11](https://www.healthaffairs.org/doi/10.1377/hlthaff.2014.1047#B11) The value of these development-stage firms is largely determined by their proprietary technologies and the candidate drugs they have in development. As a result, the strength of intellectual property protection plays a key role in funding and partnership opportunities for such firms.

## COVID Vaccine

#### Waiving patents on the COVID-19 vaccine would not guarantee generic production and could go on to hurt current production and distribution of the vaccine

**Okutsu & Sharma 21** [Akane Okutsu: Japan based reporter. Kiran Sharma: India based reporter. “Vaccine patent waiver: COVID stopper or innovation killer?” Nikkei Asia. 14 May 2021. Link: <https://asia.nikkei.com/Spotlight/Coronavirus/COVID-vaccines/Vaccine-patent-waiver-COVID-stopper-or-innovation-killer>] JV

There is a precedent for this. In the case of AIDS and HIV drugs, prices did drop thanks to relaxed intellectual property protections under the WTO Doha Declaration in 2001 and a related agreement in 2003. Countries suffering from health emergencies were allowed to make patented products without the consent of the patent owners. Countries lacking their own production capabilities were given the option of importing cheaper generics made in places such as India. But in the case of COVID-19 vaccines, information not included in the patents is needed to copy them. And pharmaceutical companies argue the waiver would not immediately mean better access. "Waiving intellectual property rights cannot assure the production of comparable vaccines," George Nakayama, president of the Japan Pharmaceutical Manufacturers Association (JPMA), said in a statement. Nakayama warned that production by more players "may accelerate the shortage of raw materials" and other necessary equipment such as vials -- with no guarantee that the alternative shots would match the originals' quality. Critics also say that materials shortages could make it harder for existing players to increase output, potentially even pushing prices up.

#### Waiving patent on COVID-19 vaccine could hurt innovation needed to combat future pandemics

**Okutsu & Sharma 21** [Akane Okutsu: Japan based reporter. Kiran Sharma: India based reporter. “Vaccine patent waiver: COVID stopper or innovation killer?” Nikkei Asia. 14 May 2021. Link: <https://asia.nikkei.com/Spotlight/Coronavirus/COVID-vaccines/Vaccine-patent-waiver-COVID-stopper-or-innovation-killer>] JV

One major concern is a loss of incentives for costly research and development. Pharmaceutical research has a low success rate and requires enormous sums of money. Without the profits generated from intellectual property rights, "there would be no new drugs," as companies would have no hope of recouping their investments, a JPMA spokesperson said. Ito said this raises "concerns about how to respond to future pandemics." Speedy vaccine development, he said, is driven in part by the chance to corner the market. If the patents are to be waived, Ito suggested other steps to spur innovation will be needed, such as establishing a fund to buy such knowledge. But setting prices and deciding how to deal with the technical secrets would be no easy task. Ito said a quicker solution might be for Group of Seven countries to "consider policies to expand production capacity and strengthen the [World Health Organization's] COVAX initiative to purchase and distribute vaccines to developing countries."

#### COVID-19 vaccine patent waivers would destroy innovation in cancer treatment

**Spiegel 21** [Andrew Spiegel: Temple University of Philadelphia. Attorney. Co-founder of Colorectal Cancer Alliance and Global Colon Cancer Association. “How the COVID IP-waiver could sabotage crucial cancer research” Delaware Online. 5 August 2021. Link: <https://www.delawareonline.com/story/opinion/2021/08/05/covid-vaccine-patent-waiver-endangers-crucial-cancer-research/5487664001/>] JV

President Joe Biden craves a cure for cancer. In a speech to Congress this spring, he vowed to ["end cancer as we know it."](https://www.delawareonline.com/story/news/health/2021/05/09/national-cancer-institute-ned-sharpless-helps-lead-biden-cancer-effort/7391767002/" \t "_blank) And as Vice President, he helped start the Cancer Moonshot initiative. Yet by giving his backing to[a global waiver of intellectual property rights for COVID-19 vaccines,](https://www.delawareonline.com/story/news/health/2021/05/05/covid-vaccine-distribution-variants-mask-cdc-biden-india/4947182001/) Biden may have endangered millions of Americans living with cancer. The Biden administration has said that it would join a World Trade Organization move to suspend IP safeguards for the vaccines. Its intentions are no doubt sincere, founded in the belief that a waiver will help rid the world of COVID-19. Yet the setting aside of IP protections has consequences that the administration seems to have overlooked. If adopted, the waiver won't galvanize the supply of vaccines bound for the developing world — certainly not in the immediate term. What it will do is threaten scientific innovation that could lead to cures for cancer and other diseases. When the news that Biden would support the waiver broke, I received agitated call after agitated call from friends and colleagues in the cancer patient community. They wanted to know what the move would mean for them. I had to be honest with them. I said I had a bad feeling. I'll explain why. Technically, the waiver supported by the United States would only apply to IP on COVID-19 vaccines. So what has this got to do with cancer? There are two consequences. First, intellectual property underpins scientists' incentives to make discoveries. Without proprietary "armor" to protect research, rivals could blithely — and lawfully — use scientists' know-how, data, or manufacturing processes. Second, waiving IP on underlying vaccine technology has ramifications for drug innovation. Since the same technologies are used for potential treatments for other diseases, vaccine-makers would have to give up IP on those projects too. Consider the Pfizer-BioNTech and Moderna vaccines. They use "mRNA" to promote an immune response to Covid-19, a technology that took decades to develop. The only people who really understand it are with American firms like Moderna and German companies like BioNTech, the firm that partnered with Pfizer for its mRNA vaccine. With the successful rollout of mRNA Covid-19 vaccines, researchers in the United States and Germany now hope they can use mRNA to fight other viruses. Moderna has active trials for mRNA vaccines for Zika, HIV, and the flu.  Cancer doctors and patients pray that mRNA is the key to a cure. Moderna, in fact, has two mRNA vaccine candidates for cancer. Researchers hope that mRNA could instruct the body to combat cancerous tumors like it fights a virus. With the IP waiver, Moderna's mRNA technology could end up with rivals, leaving the company with greatly diminished incentives — and greatly diminished investment dollars — to continue with mRNA clinical trials, including ones for cancer. Advanced drug innovation could come to a halt. What investor would fund biotech startups if copycats can swoop in?

## Impacts/IL

#### Medical innovation is a key part of the American economy

**Wright 13** [Rob Wright– Chief editor and Life Science Leader. “How important is medical innovation to the US economy?” Life Science Leader. 11 March 2013. Link: <https://www.lifescienceleader.com/doc/how-important-is-medical-innovation-economy-0001>] JV

According to University of Chicago economists Kevin Murphy, Ph.D., and Robert Topel, Ph.D., who calculated cumulative gains in life expectancy after 1900 to be worth over $1.2 million to the representative American in the year 2000. Further, in the 30 years between 1970 to the year 2000, life expectancy gains added approximately $3.2 trillion per year to the national wealth of the United States. But medical innovation contributes more than just living longer and accumulation of wealth. Medical Innovation Economics 101 Over the past 50 years, medical innovation has been the source of more than 50% of all economic growth in the United States. It is estimated that there are more than 650,000 jobs in the U.S. biopharmaceutical sector, with each of these jobs supporting an additional five jobs in other sectors. In a report by Battelle, a nonprofit R&D organization, the overall economic impact of the biopharmaceutical sector on the U.S. economy in 2009 (as measured by output) was estimated to be more than $917 billion on an annual basis. Further, the biopharmaceutical sector generated nearly $85 billion in state, local, and federal tax revenues for 2009. The annual average personal income of a biopharmaceutical worker in 2009 was nearly twice the average across all private sector industries ($118,690 vs. $64,278). When you compare export numbers among industries, you may be surprised to learn that in 2010 the U.S. biopharmaceutical industry exported $46.7 billion, which is more than automobiles ($38.4 billion), plastics and rubber products ($25.9 billion), communications equipment ($27 billion), and computers ($12.5 billion). With all of these positive U.S. economic attributes, why then does it seem everyone is intent on killing the golden goose that medical innovation represents? The Obama administration is pushing for policy changes to Medicare Part D, which if enacted will most likely result in decreased pharmaceutical R&D spending, as well as the loss of possibly 250,000 high wage jobs. So Paul, to answer your question, the pharmaceutical industry is BIG. How important is medical innovation to the U.S. economy – VERY!

#### Innovation crucial to solve diseases

**George 17** [Bill George– Senior Fellow, Harvard Business School and Former Chairman and Chief Executive Officer, Medtronic, Inc. “Innovation is key to solving America’s health-care problems” CNBC . 7 December 2017. Link: <https://www.cnbc.com/2017/12/07/innovation-is-key-to-solving-americas-health-care-problems.html>] JV

As politicians debate who should pay for America’s declining health and ever-increasing cost of health care, they are overlooking the

key to simultaneously improving the health of Americans and cutting costs: innovation. Innovation can solve many of our most pressing health-care problems by transforming lives, preventing disease, restoring people to full health and making the health-care delivery system more efficient. To address these long-standing issues, innovation is required in five areas: Medical technology innovation to restore health to people suffering from chronic disease. Scientific breakthroughs in drugs that treat and cure the most debilitating diseases. Delivery of health care outside of the hospital setting, letting hospitals focus on the most seriously ill patients. Innovative use of information to improve diagnosis, treatment and after-care. Moving upstream to prevent disease occurrence with innovative approaches that enable people to lead healthy lives. Medical technology innovation In the last 30 years, breakthroughs in medical technology have transformed the treatment of cardiovascular disease with implantable defibrillators and drug-coated stents, of Type I diabetes with the sensor-based pumps and the advent of the artificial pancreas, and of spine, hip and knee surgery with implantable prostheses. Now, advancements in medical technology are addressing debilitating neurological diseases like Parkinson’s, incontinence and sleep apnea. With investment and imagination, the future of medical technology to help people seems almost unlimited. Breakthrough drugs Decades of scientific investment in genetics, genomics and proteomics have led to treating the immune system as the most promising way to cure cancer and other debilitating diseases. Breakthroughs in personalized medicine like immunotherapy and CAR-T therapy hold the potential for genuine cures, not just palliative treatments. To make these high-priced treatments more affordable, they should be offered on a sliding scale based on ability to pay. Meanwhile, a wider array of generic drugs should be approved for traditional drugs such as statins to lower the overall cost of drug therapy. In addition, the multiple layers of drug distribution should be creatively disintermediated by direct-to-consumer approaches, thus dramatically cutting the overall cost of drug therapy.

#### Medical innovation is crucial to prevent pandemic and mitigate economic harms during shut downs

**Mulligan 21** [Casey B. Mulligan– American economist and author. He is a Professor in Economics at the University of Chicago. “Economic activity and the value of medical innovation during a pandemic” Cambridge University Press. 9 June 2021. Link: <https://www.cambridge.org/core/journals/journal-of-benefit-cost-analysis/article/economic-activity-and-the-value-of-medical-innovation-during-a-pandemic/864F8042F794D4417E64C643999C9280>] JV

Medical innovation can reduce the duration and severity of pandemics. In doing so, innovation reduces the duration and severity of the direct health costs as well as the costs of economic shutdowns intended to mitigate the health costs. As long as it remains a major barrier to medical innovation, regulation will unnecessarily add to the economic and health costs of the current pandemic (Peltzman, 1973; Philipson & Sun, 2008). Innovation is not finished when scientists discover a new medicine, device, or technique and demonstrate its safety. Pandemic medicines and equipment need to be manufactured and distributed on a massive scale. Personnel need to be trained to administer new treatments. These processes can be slowed by regulatory barriers ranging from federal inspections of facilities manufacturing drugs and devices to state occupational licensure. Although not new, disease testing and contact tracing are essential techniques that are scalable in principle, but early in the pandemic were unavailable in the USA in more than small quantities. Regulatory barriers slow both the manufacturing of these devices and techniques as well as the development of more scalable methods for distributing them.

#### Pandemics destroy economies and widen inequalities among countries

**Shang et al 21** [Yunfeng Shang– Zhejiang Yuexiu University of Foreign Languages, Shaoxing, China. Haiwei Li– Tianjin University of Commerce, Tianjin, China. Ren Zhang– Texas State University, San Marcos, TX, United States. “Effects of pandemic out break on economies: Evidence from business history context” Frontiers in Public Health. 12 March 2021. Link: <https://www.frontiersin.org/articles/10.3389/fpubh.2021.632043/full>] JV

Covid-19 has impacted the societies in far more ways than impacting the health of the affected. It is affecting the societies as well as the economies at the core. The impact of the pandemic is severe and vary from country to country. It is likely to increase the economic costs among nations and increase the inequalities at a global level ([20](https://www.frontiersin.org/articles/10.3389/fpubh.2021.632043/full#B20)). The pandemic has disrupted the lives of people and affected world trade and movements, as seen in [Table 3](https://www.frontiersin.org/articles/10.3389/fpubh.2021.632043/full#T3). At this stage, the pandemics negatively affect the manufacturing sector. Various industries and sectors have slowed down because of the disease, such as tourism, pharmaceutical industry, solar power sector, information, and electronics industry. There have been short-term challenges like a halt in tourism and entertainment and long-term consequences such as disruptions in trade and investments ([21](https://www.frontiersin.org/articles/10.3389/fpubh.2021.632043/full#B21)). The disease has extensive consequences on the healthcare, economic, and social sector. Healthcare Impact The healthcare sector faces challenges in the pandemic regarding diagnosis, treatment, and disease prevention. The medical system's functioning has become a burden, and patients with other medical problems are getting neglected. The lives of doctors and other health professionals are at very high risk. Pharmaceutical shops are overloaded, and the medical supply chain is disrupted. Economic Impact Due to the lockdown and the risk of spreading the disease, the manufacturing of essential goods has slowed down. The supply chain of products has been disrupted, and national and international businesses face losses ([22](https://www.frontiersin.org/articles/10.3389/fpubh.2021.632043/full#B22)). The cash flow in the market is poor, slowing down the revenue growth in the economy. Millions of workers have lost their jobs as industries have shut down. The GDP of many economies have also been impacted due to production in industries being disrupted.