Novartis Public Affairs

Novartis Position on Intellectual Property

Intellectual Property (IP) refers to a variety of different creations of the mind. The IP system is a long-established network of laws that aims to promote the activities that lead to these creations in order to advance knowledge and human progress. The system works by providing a variety of market-based incentives (IP rights) to inventors and creators, each designed to encourage the creation and dissemination of different forms of human ingenuity. Patents extend to new and useful inventions; copyrights to works of art and authorship; trade secrets and regulatory data protection (RDP) to certain forms of proprietary information; and trademarks and trade names to a variety of names and symbols used in commerce. For each type of IP right, the system contains important limitations, such as strict grant criteria and fixed terms of protection, that work to ensure a fair balance between promoting creative and innovative activity and returning value to society.

Patents are one of the most important IP rights for the biopharmaceutical industry. A granted patent provides its inventor/holder with the right to exclude others from making, using or selling the covered invention for a limited time, in exchange for providing the public with information on how to make and use the invention. At the end of the patent term, the covered invention enters the public domain. A patent itself does not give the inventor/holder the right to commercialize the invention. In the case of pharmaceuticals, a marketing authorization from a health authority is required for commercialization.

The IP system is the foundation of the modern biopharmaceutical innovation ecosystem, but it is frequently misunderstood, and has been increasingly attacked as a barrier to access-to-medicine, when in fact the opposite is true: Strong and predictable IP rights enable the invention and development of new medicines, and play an important role in facilitating their broad and timely delivery to the patients that need them around the world.

Novartis Position

Our approach to intellectual property (IP) derives from our broader purpose to reimagine medicine to improve and extend people's lives. We use patents and other IP rights as a means to enable the discovery and development of breakthrough medical innovations, to facilitate their delivery to the patients who need them, and to promote scientific and technological progress for patients and society.

IP rights are fundamental for investment in the research and development (R&D) that leads to new medicines

The IP system is central to Novartis' efforts to discover and develop breakthrough treatments that address some of society's most challenging healthcare issues. In

our research-intensive field, the IP system provides a proven, practical means to attract the massive investments needed to conduct and sustainably finance R&D.

Biopharmaceutical R&D is a lengthy, costly, and high-risk endeavor, with an average development timeline of 10-15 years per medicine[i] and a high rate of failure. For chemistry-based pharmaceuticals, as few as 1 in 10,000 substances tested in the laboratory will ultimately be approved as a medicine. Even when a substance shows sufficient promise to begin clinical testing, less than 12% of these will succeed,[ii] and of those that do, only 2 in 10 will ever return revenues that equal or exceed R&D costs.[iii]

Nearly every modern medicine has come from the R&D efforts of biopharmaceutical companies, enabled by the IP system. Over the past 25 years, nearly 1000 new industry-developed chemical and biologic molecules have been approved by the US Food and Drug Administration and the European Medicines Agency.[iv] In the past 7 years (2015-2021), Novartis alone secured 26 novel drug approvals.[v] Industrywide, the number of novel drug approvals continues to increase over time, with the last five years witnessing some of the highest annual figures in history.[vi] With IP rights serving as a critical incentive, private sector companies like Novartis continue to invest billions of dollars in innovative R&D each year to maintain this upward trend.

IP rights are fundamental in facilitating access to medicines

The IP system also plays an important role in enabling the local investments needed to secure approvals and conduct the activities that lead to successful launches and use of medicines around the world. Strong IP rights create incentives for innovators to seek local regulatory approval, a prerequisite for selling medicines in most markets. With such incentives in place, innovators are also more likely to invest in building distribution chains, improving infrastructure, and educating doctors and patients about the existence and proper use of a new medicine, all of which contribute to improving access and helping to achieve better patient outcomes.[vii] The IP system also plays a central role in enabling the generic medicines that are so important to budget-conscious healthcare systems. To provide medicines at lower cost, generic and biosimilar makers copy innovative medicines once valid patents expire, relying on innovators to continue conducting R&D to develop new medicines.

While IP rights offer the opportunity for a medicine to succeed, a commercially successful medicine is only realized if patients, physicians and payors deem the medicine to be useful, judged on the basis of the value the treatment provides. Further, IP rights do not guarantee the medicine any specific or predetermined price, nor do they guarantee reimbursement by any health care system.

Novartis' positions and approaches to IP include the following:

- **Our patient-centric approach to IP:** Consistent with our broader purpose, Novartis embraces patient and societal benefit as guiding principles in our IP policies and practices. We are proud to be a founding member and signatory of the IP Principles for Advancing Cures and Therapies (IP PACT), a public statement of our patient-centric approach to, and commitments around IP, launched in 2021.

- **Accessibility of patent information:** Novartis believes that basic information about patented inventions should be publicly accessible. While patent offices have primary responsibility, Novartis is proud to be one of the founders of the Patent Information Initiative for Medicines (Pat-INFORMED), which helps to facilitate access to basic patent information about approved medicines.

- **Accessibility of the patent system:** Novartis believes that innovation happens everywhere, and that IP systems should be accessible to all, without regard to

socioeconomic status, geography or financial means. For this reason, Novartis is a founder and sponsor of the WIPO-WEF Inventors Assistance Program (IAP).

- **IP, globalization and trade:** Novartis operates globally to meet worldwide demand for our medicines. We invest in countries around the world, build facilities, collaborate and work with local companies and universities, conduct local clinical trials, and ultimately develop the infrastructure and knowledge necessary to successfully launch new medicines. We believe it is imperative for all countries to contribute to the costs of innovative R&D by respecting IP and creating the conditions for effective grant and enforcement of IP rights. Countries that are members of the World Trade Organization should at minimum adopt and fully implement all IP obligations contained in the Agreement on Trade Related Aspects of Intellectual Property (TRIPS). We believe that countries also have a sovereign right to decide for themselves whether more stringent standards for IP protection are in their interests, and to execute other agreements accordingly.

- **Patent eligibility and technological neutrality:** We believe that all forms of technology should be eligible for patent protection. This includes, among other things, human applications of nature, new forms of existing substances, new formulations, and new uses of existing medicines, which can significantly enhance patient life and health. Consistent with TRIPS, we likewise believe that patent systems should not discriminate against any field of technology in the grant, exercise, utilization or enforcement of any patent rights.

- **Our approach to patents in the world's poorest countries:** Novartis recognizes the unique socio-economic challenges faced by the world's poorest countries, including challenges that may interfere with the proper functioning of market-based incentives like IP rights. Accordingly, we do not seek or enforce patents in least developed countries (LDCs, as designated by the United Nations), low-income countries (LICs, as designated by the World Bank), or in around 80% of the lower-middle income countries (LMICs, as designated by the World Bank). In the small number of LMICs where we do seek or enforce patents, we aim to limit them to those patent applications covering new molecular entities. In addition, we are committed to granting non-exclusive licenses to qualified third parties for supply of our patented products exclusively to LDCs or to LICs.

Last updated November 2022

---

[i] DiMasi JA, Grabowski HG, Hansen RW. Innovation in the pharmaceutical industry: New estimates of R&D costs. J Health Econ. 2016;47:20-33.
[ii] *Ibid*.
[iii] Vernon JA, Golec JH, DiMasi JA. Drug development costs when financial risk is measured using the fama-french three-factor model. Health Econ.2010;19(8):1002-05.
[iv] https://www.nature.com/articles/d41573-022-00001-9; https://www.fda.gov/drugs/development-approval-process-drugs/new-drugs-fda-cders-new-molecular-entities-and-new-therapeutic-biological-products
[v] 2015-2021 annual reports.
[vi] https://www.nature.com/articles/d41573-022-00001-9
[vii] Wilsdon, Tim and Glyn Chambers, "The role of the innovative industry in 'developing' the market for new medicines in emerging markets," Charles River Associates, April 2013; Cockburn, I.M. et al., "Patents and the Global Diffusion of New Drugs," National Bureau of Economic Research, September 2014, available at http://nber.org/papers/w20492; Ernst R. Berndt and Iain M. Cockburn, "The Hidden Cost of Low Prices: Limited Access to New Drugs in India," Health Affairs 33, no. 9 (2014): 1567–75; Margaret Kyle and Yi Qian, "Intellectual Property Rights and Access to Innovation: Evidence from TRIPS" (National Bureau of Economic Research, 2014), http://www.nber.org/papers/w20799.