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.

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 to enable the discovery and development of breakthrough medical innovations, to facilitate their delivery to the patients who need them, and to advance scientific, medical 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] The patents covering our medicines reflect solutions to the complex scientific challenges that must be overcome, and the many technological problems that must be solved, to navigate this process and arrive at a single safe and effective medicine.

Nearly every modern medicine has come from the R&D efforts of biopharmaceutical companies, enabled by the IP system. Over the past 30 years, more than 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 9 years (2015-2023), Novartis alone has secured 28 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] Each new approval brings new treatment options to patients, including for diseases for which few or no treatments existed before. 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 advance medical progress and 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 generic medicines. 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.

IP rights do not determine a medicine's price

We aim to price our medicines according to the value they deliver to patients, healthcare systems and society. We believe this incentivizes health systems to focus on interventions that deliver the most effective, efficient and sustainable outcomes. While IP rights provide the opportunity to seek prices that reflect this value, they do not determine what a value-based price is or should be. In addition to value, when pricing our medicines, we use innovative access and pricing models, taking into account local income levels, affordability barriers and economic realities. We also implement a global access strategy for every new medicine we launch. Ultimately, the price of a medicine is determined in consultation with payors, according to the rules and policies of a given country's healthcare system.

Trademarks advance public health

Trademarks play a variety of important roles that advance public health. We register and enforce our trademark rights not merely to protect our brand identity, but to help enhance product name recall and to assure patients of the quality of our medicines. We also believe strongly in the essential role that trademarks play in patient safety. Trademarks are crucial tools in helping to reduce medication errors, and, along with our security measures, are instrumental in helping to combat counterfeit medicines.

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, the TRIPS Agreement, and the Doha Declaration:** 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 local infrastructure and knowledge necessary to successfully launch new medicines. To help enable these local activities and maintain the conditions necessary to advance innovative R&D on a global scale, we believe it is imperative for all countries to respect IP rights. We support the World Trade Organization (WTO) Agreement on Trade Related Aspects of Intellectual Property (TRIPS), which sets forth minimum IP standards and obligations that WTO member countries are required to implement, and believe that all countries have a sovereign right to decide for themselves whether to adopt stronger standards. We also recognize and support the balances and "flexibilities" built into the TRIPS agreement, as reaffirmed in the 2001 Doha Declaration on TRIPS and Public Health, provided such flexibilities are properly used for their intended purposes and in compliance with their associated rules. These include time-based transition periods that allow UN-designated Least Developed Countries (LDCs) to postpone implementation of their TRIPS IP obligations; the "Bolar" exemption, which exempts certain research activities from patent infringement; the use of compulsory licenses in the limited, exceptional circumstances for which they were designed; and the use of the "Paragraph 6" (Art. 31bis) framework for such licenses under the Doha Declaration where countries lack sufficient local manufacturing capacity.

- **Patent eligibility and technological neutrality:** We believe that all forms of technology should be eligible for patent protection. This includes, among other things, new 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.

With respect to upper-middle-income countries (UMICs, as designated by the World Bank), our approach to patent filing and enforcement depends on the individual circumstances of the countries that make up this diverse group. Currently, we do not seek or enforce patents in over half of the UMICs.

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[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; Dean G. Brown, Heike J. Wobst, Abhijeet Kapoor, Leslie A. Kenna and Noel Southall, *Clinical development times for innovative drugs*, Nature Reviews Drug Discovery 21, 793-794 (2022).

[ii] DiMasi, et. al. *Innovation in the pharmaceutical industry*, 20-33; Congressional Budget Office, *Research and Development in the Pharmaceutical Industry* | (cbo.gov), April 2021.

[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] 2023 FDA approvals (nature.com); Novel Drug Approvals for 2023 | FDA

[v] 2015-2023 annual reports.

[vi] 2023 FDA approvals (nature.com)

[vii] Cockburn, Iain M., Jean O. Lanjouw, and Mark Schankerman. 2016. *Patents and the Global Diffusion of New Drugs*, American Economic Review, 106 (1): 136-64; Berndt, Ernst R. 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; Kyle, Margaret and- Yi Qian, *Intellectual Property Rights and Access to Innovation: Evidence from TRIPS* (National Bureau of Economic Research, 2014); 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.