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.

For a granted patent, one of the most important IP rights for the biopharmaceutical industry, the inventor has 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 is required for commercialization.

Society relies on the biopharmaceutical industry to develop and provide new medicines. There is increasing stakeholder debate on the role of IP in sustaining private sector research while providing broad access to medicines.

Novartis Position

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

The IP system is essential to Novartis' central mission of improving and extending people's lives. In this 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. Over the past 20 years (1997-2016), 595 new molecules have been approved by the US Food and Drug Administration and the European Medicines Agency.[iv] In 2015 and 2016, Novartis alone secured 9 new molecular entity (NME) approvals.[v] Industrywide, the number of novel drug approvals continues to increase over time, with 2015 witnessing the second highest number in history.[vi] Private sector companies like Novartis continue to invest billions of dollars in innovative R&D each year to maintain this upward trend. In fact, the private sector fully invents around 76% of all medicines, and, working in collaboration with universities and similar institutions, is responsible for developing the other 24%.[vii]

NOVARTIS

As a world leader in the discovery and development of new medicines, Novartis seeks patent protection for new chemical entities and new biologics in countries where patents play, or are expected to play, a significant role in helping to generate the global returns needed to sustain the R&D cycle, and/or to support the local investments necessary to successfully launch and deliver our medicines to the patients who need them.

IP rights are fundamental in facilitating access to medicines

At the same time, the IP system 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. 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. [viii] 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 biosimiliar 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 takes the following positions on key IP topics:

- **Patents in Least Developed Countries (LDCs) and Low-Income Countries (LICs):** Novartis does not file or enforce patents in LDCs or in LICs. We will grant non-exclusive licenses to qualified third parties to supply our patented products exclusively to LDCs and LICs.

- **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, many of which 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.

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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.

[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] http://www.accessdata.fda.gov/scripts/cder/daf/

[v] 2015 and 2016 annual reports.

[vi] USFDA, 2015 Novel New Drugs Summary Report

[vii] Nature Reviews Drug Discovery 9, 867-882 (Nov. 2010)

[viii] 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.