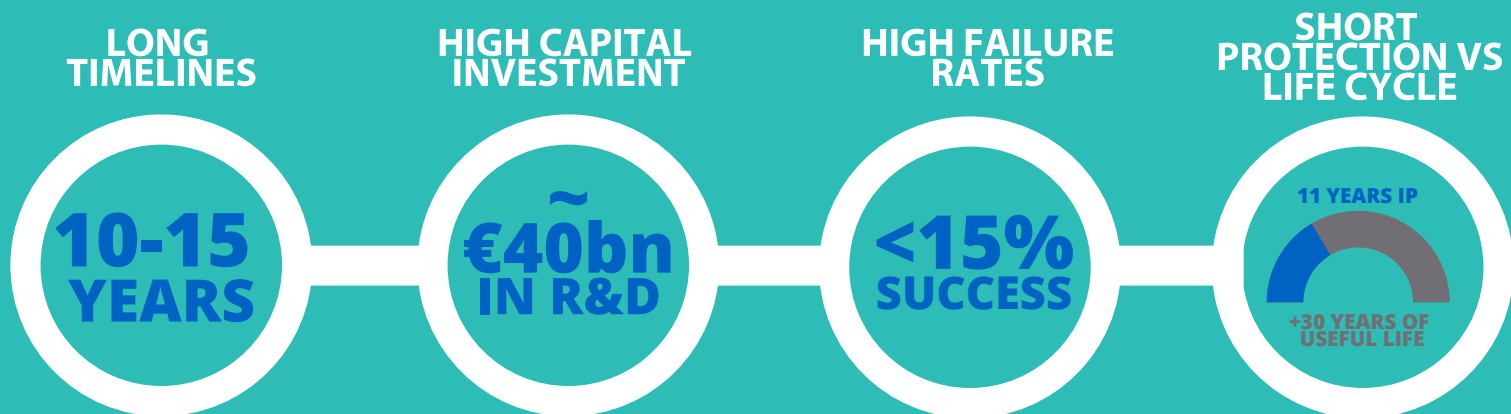


IP AND INNOVATION IN EUROPE

Amgen is committed to developing innovative medicines to answer unmet medical needs, improving the lives of patients and their families and benefiting healthcare systems and the broader society. Intellectual property (IP) rights and other mechanisms to incentivize research, development and commercialization of products are essential for the biopharmaceutical industry to keep bringing innovative treatments to patients.

FOSTERING INNOVATION AND IP

Recent biopharmaceutical innovation has resulted in the increase in the cure rates for both communicable diseases such as Hepatitis C, and non-communicable diseases such as cancer. However, this innovation is the product of large-scale, long-term and high-risk investments:



According to the OECD, developing a medicine takes on average 10-15 years. The long approval process is also reflected in estimated time period [1].

In 2019, the pharmaceutical industry spent approximately ~€40 billion on R&D across European countries [2].

On average, less than 14.6% of molecules that are patented make it to clinical trials, and only 4.1% of those that are tested in trials ever get approved [3].

An average drug has a useful life of +30 years [4]. The 11 years of intellectual property protection is a small part of this and yet makes the whole lifecycle possible.

AMGEN'S INVESTMENT IN INNOVATION

>\$4bn ^[5]
R&D SPEND

17% ^[5]
SALES INVESTED ON R&D

+40 ^[6]
MOLECULES IN THE PIPELINE

[1] OECD (2018). Pharmaceutical Innovation and Access to Medicines. Available at: <https://www.oecd.org/health/health-systems/Pharmaceutical-Innovation-and-Access-to-Medicines-Executive-Summary-ENGLISH.pdf>. Accessed April 11 2022.

[2] EFPIA (2021). The Pharmaceutical Industry in Figures. Available at: <https://www.efpia.eu/media/602709/the-pharmaceutical-industry-in-figures-2021.pdf>. Accessed April 11 2022.

[3] Dirk Calcoen, Laura Elias and Xiaomeng Y (2015). What does it take to produce a breakthrough drug? Nature Reviews Drug Discovery, 161-162.

[4] Hoyle, M. (2011). Accounting for the Drug Life Cycle and Future Drug Prices in Cost-Effectiveness Analysis. Pharmacoeconomics, 29, 1-15.

[5] Yahoo Finance (2021). Amgen - Big Bet on Biotech. Available at: <https://finance.yahoo.com/news/amgen-big-bet-biotech-100000357.html>. Data of 2020, Accessed April 11 2022

[6] Amgen (2021). Amgen Pipeline. Available at: <https://www.amgenpipeline.com/~media/themes/amgen/amgenpipeline-com/amgenpipeline-com/pdf/amgen-pipeline-chart.pdf>. Accessed April 11 2022.

AMGEN'S POSITION ON IP RIGHTS AND INNOVATION

IP rights are a critical foundation of the entire biopharmaceutical innovation ecosystem, as companies rely on them to attract investment capital and to encourage scientists to develop new medicines. However, these have been increasingly challenged in recent years.

EFFECTIVE IP RIGHTS PROVIDE INCENTIVES SPURRING R&D

The EU has laid down a system of incentives to support IP rights. This includes tools such as patents and regulatory data protection, supplementary protection certificates and market exclusivity for Orphan Medicinal Products and pediatric rewards, which have been successful in delivering innovation and are working as intended, promoting also investments in EU economies.

COMPULSORY LICENSING IS NOT A SOLUTION

Patents play a key role in enhancing competition amongst innovator companies during the patent protection term. In many product classes, there is now intense competition to bring products to market as early as possible, while maintaining patient safety. IP protection is essential for innovation and can ultimately help drive prices down and support affordability.

AFFORDABILITY AND SUSTAINABILITY ARE COMPATIBLE WITH INCENTIVES

1

Risk and rewards are inherent to the biopharmaceutical business model. Robust IP protections ensure the long-term viability of the ecosystem which makes drug development sustainable.

2

IP AND REGULATORY INCENTIVES ARE CRUCIAL FOR INNOVATION

Some policy makers are considering expropriating patent rights via Compulsory licenses (CL). CL is not an effective or sustainable way to improve access to medicines or achieve other critical public health goals, as patents drive and enable the research and development that delivers new treatments and cures. Furthermore, these limited and temporary intellectual property rights are not a barrier to access to medicines.

3

4

COMPETITION & INNOVATION ARE PROMOTED BY STRONG IP

Incentives favoring the development of innovative medicines should be seen as part of the solution rather than part of the problem as they can generate significant savings across the entire healthcare system (e.g., reduce hospitalization, more active labor force etc). This is because the real threat to the sustainability of healthcare systems lies in demographic trends, including an ageing population and increased prevalence of chronic diseases, rather than in the cost of medicines.

5