



## **Roche's Position on Intellectual Property<sup>1</sup> Fueling Innovation & Advancing Healthcare**

At Roche, we are turning advances in medical and data science into innovative diagnostics and life-changing treatments for patients. We are constantly innovating to develop and deliver products for the benefit of millions of people around the world.

We strongly believe that robust intellectual property (IP) systems stimulate innovation and economic growth for the benefit of society as a whole.

IP protection is essential for medical innovation and is needed to address the healthcare challenges we face today. Strong IP systems support and protect our development of new diagnostics and treatments for cancer, Alzheimer's Disease, multiple sclerosis and many more.

We are proud of our contribution to improvements in public health, and strive to do what patients need next by developing new and better diagnostics and pharmaceuticals.

### **Promoting Innovation through Intellectual Property**

Innovation is central to social, cultural and economic development. The generation of new ideas and their practical application has fueled advancement throughout history.

The recognition and protection of innovation through patents, designs, trademarks, copyright and other mechanisms reflects the value of such progress and is crucial for its continuation.

Effective IP systems protect the inherent right of the innovator to benefit from his/her work. They provide a fixed period of time after which others can use and freely benefit from the advance. This guarantee enables individuals, organizations and companies to make the commitment and investment necessary to develop new products and technologies. IP rights assure the sharing of new ideas in exchange for protection and by that enable others to build upon and to create further innovations.

Effective protection of innovation benefits economies. Countries with strong IP systems experience greater creative output across multiple fields, increased access to innovation, and higher employment in knowledge-based industries<sup>2</sup>.

In the United States, IP-intensive industries account for more than 40 million jobs – approximately 27% of total employment<sup>3</sup>. In the EU, that number is even higher with more than 82 million jobs, or nearly 40% of employment<sup>4</sup>.

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<sup>1</sup> Intellectual Property includes patents, designs, trademarks and copyrights.

<sup>2</sup> US Chamber of Commerce IP Index, Sixth Edition, February 2018

<sup>3</sup> *Intellectual Property and the US Economy: 2016 update*. Economics and Statistics Administration and US Patent & Trademark Office.

<sup>4</sup> *Intellectual property rights intensive industries and economic performance in the European Union: industry-level analysis report*. Second Edition, October 2016. European Patent Office & European Union Intellectual Property Office.

In developing economies, the application of effective IP systems contributes to sustainable economic growth and supports continuous improvement in living standards. Over the last 20 years, China has experienced impressive economic growth and a rise in its living standards. This evolution occurred in parallel with continuous improvements in its IP system<sup>5</sup>.

### **Advancing Healthcare through Intellectual Property**

IP, by the innovation it enables, has supported transformational advances in healthcare.

Life expectancy in Europe has risen by up to three decades over the last century<sup>6</sup>. Cancer mortality rate has declined by 21% since its peak in 1991 in Europe and HIV has been transformed from a death sentence to a manageable disease<sup>7</sup>.

In the past 30 years alone, more than 1100 new medicines have been introduced in Europe. These medicines have protected, improved and extended many lives<sup>8</sup>.

#### *Innovation requires investment*

Research and development of new medicines demand many years of intensive effort, considerable investment, and a willingness to accept significant risk. On average, only one to two of every 10'000 molecules complete the journey from lab bench to bedside<sup>9</sup>. By providing a time limited protection, patents give innovators the degree of certainty they need to continue to invest in the future and to turn science into valuable medicines.

Patents have to be applied when the invention has been made, which for the basic patent of a new medicine, is early in the development process. Therefore, in contrast to many other industries, the long development timelines of new medicines lead to a significant reduction of the regular patent term of 20 years<sup>10</sup>. To compensate for this loss of protection time, patent systems in many countries allow for the extension of the patent term for up to five years. Roche believes that this is an important incentive for the development of new medicines.

Innovation is not only required at the point of discovery of a new molecule, but also when exploring new formulations, developing new manufacturing processes, determining the benefits of a combination, and so on. Without robust patent protection, these additional innovations would not exist. Patents for these additional innovations are often called "secondary patents" but they are anything but secondary for patients as they address important needs such as dosing frequency and mode of delivery. Secondary patents do not extend the patent term for the original invention (the new molecule) but only protect the specific new inventions. Roche believes that robust patent protection for those inventions should be available as well.

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<sup>5</sup> Tian, Lipu, *IP Development to Promote the Economic and Social Development*, Qiushi, 2011(1)

<sup>6</sup> EFPIA "The Pharmaceutical Industry in Figures – Key Data, 2018"

<sup>7</sup> WHO Mortality Database

<sup>8</sup> Evaluate Pharma Database (2017)

<sup>9</sup> EFPIA "The Pharmaceutical Industry in Figures – Key Data, 2018"

<sup>10</sup> The "Study on the economic impact of supplementary protection certificates, pharmaceutical incentives and rewards in Europe" published on May 2018 by Copenhagen Economics found that the time from patent filing to the authorization for marketing of a new medicament in the EU increased from 10 to 15 years during the last 20 years.



It is fair to say that, if there was no IP protection there would be virtually no new medicines. The new medicines of today are the generics of tomorrow. Bactrim, for example, an antibiotic combination, which has been commercialized by Roche since the late 60s has treated more than 1.8 billion people in the last over 40 years<sup>11</sup> and was added in 1977 to the WHO list of essential medicines.

There are still many diseases which lack proper treatment, like Alzheimer's disease, neurological disorders or currently untreated forms of cancer. Proper patent protection is essential to incentivize continued R&D for the development of these new medicines.

### **Improving Intellectual Property Systems**

For innovative companies, it is the existence of robust IP provisions that makes it possible to identify, develop and deliver innovative solutions to some of the world's most challenging health issues.

As such, we encourage governments with strong IP systems to maintain their commitment to protect innovation and to support international adoption of a robust and consistent IP framework. New incentives should also be considered for the development of medicines for the treatment of "Neglected Diseases" and new antibiotics for the treatment of multi-drug resistant germs.

We encourage governments of developing countries to consider the role of a strengthened IP system in encouraging the transition to an innovation based economy delivering societal benefits and economic growth.

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<sup>11</sup> Until 31.3.2011 1.884 Billion people have been treated. See "Lifesaver for Millions, Editions Roche 2012