

# Boehringer Ingelheim: Policy on Access to Healthcare and Property Patent Rights in Developing Countries

Status: 2022

Since 1885 Boehringer Ingelheim has been creating value through innovation, driven by the desire to serve patients worldwide. Boehringer Ingelheim is therefore acutely aware that almost **half of the world's population lack access to essential health services**<sup>1</sup>. A large number of people in developing countries lack universal health coverage and are confronted with weak health systems on a regular basis. What is more, low-income patients who are forced to pay for medicines out of pocket may be driven into poverty and destitution due to illness.<sup>2</sup> In some contexts, regulatory and supply chain hurdles and markups can inflate the original prices of needed medication.

This is why, in recent months, we have been engaged in internal and external discussions around access to healthcare and have developed a new and **innovative Access to Healthcare Strategy** to facilitate reaching our patients in developing countries. With this renewed strategy we aspire to sustainably deliver more health by building distinctive initiatives and partnerships. In the the context of pharmaceutical products for human patients specifically, we want to develop **breakthrough therapies and health care solutions in the area of unmet medical need**.

This document outlines our approach to ensuring access to healthcare, and in particular medicines, for low-income populations by focusing on property patent rights in developing countries. When discussing our commitment to a **responsible and sustainable approach to intellectual property (IP) in developing countries** we highlight our collaborative approach; our commitment to not filing or enforcing patents in many low-, middle- and upper-middle income countries; facilitating competition in these markets; and our commitment to public-health safeguarding concessions within global and local trade frameworks.

## Our Approach to Access To Healthcare

Through various programmes and activities alongside the continuum of care, Boehringer Ingelheim provides **healthcare solutions to patients in resource-constrained settings** and contributes to strengthening healthcare systems in low and middle-income countries. Our activities range from awareness building and working to prevent disease, to training and education of healthcare personnel, technology transfer and local capacity building up to post-treatment patient services.

Our Access to Healthcare Strategy is based on a holistic approach including three strategic pillars: (1) increasing availability, (2) delivering sustainable access models and (3) creating innovative solutions for awareness and adherence. The Strategy **addresses access barriers from a global cross-functional perspective** including research, registration, pricing, manufacturing, distribution,licensing and patents, among others.

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<sup>1</sup> Joint WHO/World Bank Group report, 13. December 2017

<sup>2</sup> <http://www.who.int/management/programme/ncd/TheBurdenCostsChronicDiseaseLICs.pdf>

## A locally-responsive approach to Intellectual Property in Developing Countries

We acknowledge the challenges around protecting IP in developing countries. Where possible, Boehringer Ingelheim strives to **adopt a locally appropriate approach to IP management** in countries and situations involving access challenges. This is true for our entire product portfolio. We acknowledge that, in order to effectively provide access to health in underserved markets, we have a responsibility to share and develop sustainable models together with partners and other stakeholders. Only through an innovative approach in the way we do business can a shift in the right direction be made for global health access to become reality.

### 1) Working with partners to identify responsible, sustainable solutions

We believe that **collaboration and co-creation with an array of partners for research and development (R&D)** brings together expertise to tackle product development challenges and respond to patient needs. This can accelerate and enhance the development of innovative solutions to healthcare challenges, including those that disproportionately affect people in developing countries. We continue to invest in partnerships with a range of organisations to overcome the formidable challenges of product discovery and development like the Innovative Medicines Initiative (<https://www.boehringer-ingelheim.com/our-company/corporate-citizenship/partnerships>) or our comprehensive partnership with Peking University (<https://www.boehringer-ingelheim.com/press-release/comprehensive-peking-university-partnership>)

Once products are successfully launched, ensuring patients have access to them globally is challenging and complicated, with a diverse array of stakeholders having a responsibility. To reflect this, Boehringer Ingelheim strives to work with many diverse partners to share learnings on improving access. For example the decision to waive enforcement of Boehringer Ingelheim's patent rights for nevirapine use in a total of 135 low- and middle-income countries is the result of a close cooperation between Boehringer Ingelheim and the **Medicines Patent Pool (MPP)** (<https://www.boehringer-ingelheim.com/press-release/boehringer-ingelheim-increases-access-medication-treatment-hiv-aids>)

### 2) Balancing the vital need of patients for our business with efforts to not impede access to high-need products.

Boehringer Ingelheim has a strong history of **committing to not file or enforce patents** in a broad range of countries for certain high-need products. We abstain from enforcing patents in most low income and low-development countries, and **many middle income countries** – including many upper middle income countries – **across our entire human pharma portfolio. In Appendix A** we provide a map and list of countries where **Boehringer Ingelheim abstains from applying for or enforcing patent rights**. Additionally we commit to being **open to discuss** other possibilities on a case-by-case basis.

In addition to not enforcing patents rights, we continue to work with other industry partners, towards disclosure of patent rights. Transparency on what patent rights we hold in various jurisdictions for our products can assist the functioning of free markets. The support of competitive and well-functioning pharmaceutical markets –globally – is in the interests of all stakeholders.

### 3) Facilitating competition in global pharmaceutical markets

Boehringer Ingelheim believes that competitive and **well-functioning global pharmaceutical markets** are in the interests of all stakeholders, not least patients. BI has robust internal mechanisms to ensure the company remains compliant with competition laws in all countries where BI products are

sold.

What is more, with the decision to waive enforcement of its patent rights for nevirapine use in a total of 135 low- and middle-income countries, Boehringer Ingelheim is facilitating access to its products by allowing other manufacturers (generic or other research-based companies) to produce them. (<https://www.boehringer-ingelheim.com/press-release/boehringer-ingelheim-increases-access-medication-treatment-hiv-aids>)

#### 4) Committing to global and local frameworks on trade

Boehringer Ingelheim, conducts its operations consistent with all **global and local legal frameworks**. Boehringer Ingelheim maintains a Code of Conduct and internal compliance procedures to ensure the whole of our business is conducted in accordance with applicable legal and ethical standards wherever we operate around the world. ([https://www.boehringer-ingelheim.com/who-we-are/ethics\\_compliance](https://www.boehringer-ingelheim.com/who-we-are/ethics_compliance))

An example of global framework on trade is the Agreement on **Trade-Related Aspects of Intellectual Property Rights (TRIPS)**. Boehringer Ingelheim is supportive of the principles enshrined within TRIPS as well as the public health safeguards (so called 'TRIPS flexibilities') that were clarified in the 2001 Doha Declaration.

#### 5) Why protecting IP is essential for both our business and for access to healthcare

As a privately owned pharmaceutical company that is dedicated to engage in research, development and commercialisation of innovative drug products, Boehringer Ingelheim considers IP rights as an indispensable means to successfully improve global healthcare. Among such IP rights, patent rights, regulatory data protection and trademarks play an essential role in encouraging investment decisions in innovation.

As an originator pharmaceutical company we fully support the concept of IP rights and acknowledge its positive influence on global healthcare, specifically in the field of Human Pharma:

- For a privately owned company, such as Boehringer Ingelheim, the promise of IP rights to protect intellectual property is the foundation for making long term commitments for the high risk investment decisions in innovative drug product research, development, and international commercialisation.
- Patent rights allow the sharing of competitive and commercially-sensitive information throughout all stages of innovative drug product development from early research to commercialization. In particular, patent rights allow sharing information about new drug products with physicians and patients as early as in the preclinical and clinical development phase.
- Due to the legal prerequisite to publish patent applications and related know-how, patent rights foster innovation by providing the platform for the investigation into next generation of innovative drug products.

*Why are IP rights required for an investment decision into innovative drug products?*

As a research and development pharmaceutical company we understand the demands and timeline pressures of developing new and innovative drug products.

The timeline needed for research and development resulting in the commercialization of an innovative drug for the benefit of human patients ranges from 15 – 20 years. Five to 10 years are needed for research while more than 10 years are required for non-clinical and clinical development.

The risk of failure is immense – estimates are that less than 5 % of any such development effort will result in a new marketplace product. The remaining development efforts fail for various reasons. The related costs for the development of a new human drug product is around 2.9 billion USD<sup>3</sup>.

As patent applications for innovative drugs are filed many years before the drug product will reach the market, the exclusivity term provided by the patent is rather short compared to other industry sectors. In addition, once the challenges for bringing a new innovative drug product into the market are overcome, the technical barriers for copying the products are comparably low and also the regulatory requirements are reduced, since in general no comparably huge investment into non-clinical and clinical studies is necessary.

The immense investment risks, the long term commitment in development, and the ease with which innovative drug products can be copied are among the reasons why IP rights are so essential in the development of innovative drug products for the benefit of patients.

*Why do patent rights allow the sharing of competitive and sensitive information with physicians and patients early on?*

Once a new and inventive drug product is subject to a patent application, the mechanism of patent protection starts. Under this initially preliminary and later actual protection umbrella, even competitive and commercially sensitive information can be shared.

*How can patent rights foster innovation?*

Patent applications are published in accordance with the requirements of patent law in such a way that a skilled person in the art is able to understand and work the claimed invention. Starting from this basis of understanding and realisation of the claimed invention, subsequent innovation can be conceived and realized.

Taken together these are the reasons why Boehringer Ingelheim places trust in the value of IP rights as the foundation of its efforts to make innovative drug products globally available.

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<sup>3</sup> Dimasi, Joseph A., Henry G. Grabowski, and Ronald W. Hansen. "Innovation in the Pharmaceutical Industry: New Estimates of R&D Costs." *Journal of Health Economics* 47 (2016)

**Appendix A: countries where Boehringer Ingelheim abstains from applying for or enforcing patent rights. (Status 2022)**

**East Asia & Pacific**

Kiribati  
Korea, Dem. People's Rep.  
Lao PDR  
Micronesia, Fed. Sts.  
Mongolia  
Papua New Guinea  
Samoa  
Solomon Islands  
Timor-Leste  
Tonga  
Tuvalu  
Vanuatu

**Middle East & North Africa**

Djibouti  
Syria  
Yemen, Rep.

**South Asia**

Afghanistan  
Bhutan  
Maldives

**Europe & Central Asia**

Tajikistan  
Turkmenistan

**Latin America & Caribbean**

Belize  
Bolivia  
El Salvador  
Guyana  
Haiti  
Suriname

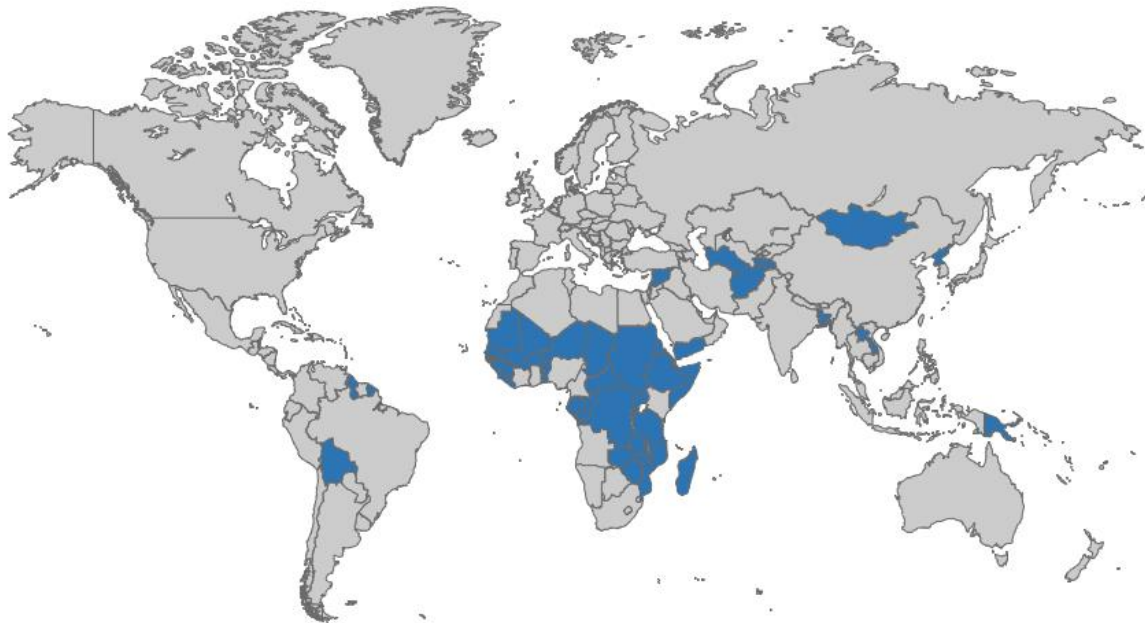
**Sub-Saharan Africa**

Benin  
Burkina Faso  
Burundi  
Cabo Verde  
Central African Republic  
Chad  
Comoros  
Congo, Dem. Rep.  
Congo, Rep.  
Equatorial Guinea  
Eritrea  
Ethiopia  
Gabon  
Gambia  
Guinea  
Guinea-Bissau

Liberia  
Madagascar  
Malawi  
Mali  
Mauritania  
Mozambique  
Niger  
Rwanda  
São Tomé and Príncipe  
Senegal  
Sierra Leone  
Somalia  
South Sudan  
Sudan  
Tanzania  
Togo  
Uganda  
Zambia  
Zimbabwe

## Countries and national patent rights of Boehringer Ingelheim

Countries where Boehringer Ingelheim does not file or enforce national patent rights (in blue)\*



\*Status 2022.