

Takeda's Position on Intellectual Property for Access to Medicine

Summary

Takeda's position on intellectual property (IP) for access to medicine is aimed at expanding access to innovative medicines and vaccines in Least Developed Countries (LDCs)ⁱⁱ and / or Low Income Countries (LICs)ⁱⁱ.

In LDCs and LICs, Takeda will:

- 1) Either not file a patent or not enforce it.
- 2) Support voluntary licenses and non-assertion declarations or clauses where necessary to improve access to medicine.
- 3) Offer, under appropriate terms, licenses to manufacturers that can provide low-cost access to our medicines, on a selective basis.
- 4) Make our patent information available upon request to the public.

Takeda is committed to providing the broadest possible access for its innovative medicines and vaccines through its <u>access to medicine initiatives</u>. We believe that IP should not be a barrier to access.

BACKGROUND

Our mission is striving towards better health and a brighter future for people worldwide through leading innovation in medicine and vaccines. Takeda is committed to addressing unmet medical needs through continuous innovation and ensuring access to high quality healthcare.

The intellectual property (IP) system has encouraged the creation of new technologies, including medicines and vaccines. The IP system discloses the latest inventions to the public in return for a defined period of exclusivity and encourages innovation. This creates an ecosystem for further investments in future medicines and vaccines while ensuring the diffusion of innovation that

benefits society as a whole. This ecosystem is critical for medicines and vaccines due to the extremely challenging and costly nature of drug discovery and clinical development, which takes, on average, more than 10 years of dedicated investment.

Innovation in medicines and vaccines has always driven the fulfillment of unmet medical needs, increases in life expectancy, and improvements in quality of life for patients. It has significantly reduced health and economic burden by preventing illness, premature disability and death due to infectious and chronic diseases. Without the encouragement provided by the intellectual property system, the world would not have many of the remarkable, life-saving medicines and vaccines that it has today.

There are still significant challenges to providing access to medicine in less developed countries with limited healthcare resources and infrastructure. Even though the majority of medicines and vaccines on the WHO's essential medicine list are off-patent, there are many other barriers to access such as regulatory shortcomings, supply chain problems, and lack of healthcare system financing. These factors seriously limit access even to generic medicines and vaccines. Patents in themselves are not a barrier to access. Ensuring access to medicine in these countries is a shared responsibility among governments, civil society and the private sector, and each can contribute in their own way.

Takeda is committed to contributing through our comprehensive access to medicine initiatives to strengthen global Health systems, which covers programs such as capacity building, patient assistance and corporate social responsibility as well as our approach to Intellectual Property. (Learn more about our access to medicine initiatives here)

POSITION

In line with our corporate mission, Takeda's approach to IP aims to accelerate patient access to medicines while fostering the development of new, potentially life-saving medicines and vaccines over the long-term. Here is Takeda's position on IP for improving access to medicine in Least Developed Countries (LDCs)[†] and / or Low Income Countries (LICs)[†], covering products already on the market as well as future products:

In LDCs and LICs, Takeda will:

- 1) Either not file a patent or not enforce it.
- 2) Support voluntary license and non-assertion declarations or clauses where necessary to improve access to medicine.

- 3) Offer, under appropriate terms, licenses to manufacturers that can provide low-cost access to our medicines, on a selective basis.
- 4) Make our patent information available upon request to the public.

Takeda aims to improve access to medicine where it is most needed. Least Developed Countries (LDCs) and Low Income Countries (LICs) are the world's most impoverished and economically vulnerable countries. Lack of healthcare resources, including medicines and vaccines, remains a key challenge and affects millions of lives.

Our position on patenting and licensing provides opportunities for qualified generic firms to manufacture and deliver our innovative medicines and vaccines. This is an important component of our access to medicine initiatives and provides a foundation for our ongoing efforts to deliver innovative medicines and vaccines to patients in these countries.

CLOSING

Intellectual property protection creates an ecosystem for continuous innovation and the diffusion of life-saving technologies across the globe. However, there are serious barriers to access to medicines in LDCs and LICs for complex, multifaceted reasons which can only be addressed through public-private cooperation and commitment. Takeda believes its access to medicine and intellectual property initiatives will bring us one step closer to improving people's lives worldwide.

June 20th, 2017

This position will be reviewed on an annual basis.

 $\underline{\text{http://www.un.org/en/development/desa/policy/cdp/ldc/ldc_criteria.shtml}}$

 $\underline{\text{https://datahelpdesk.worldbank.org/knowledgebase/articles/906519-world-bank-country-and-lending-groups}}$

ⁱ Least Developed Country (LDC) as defined by the United Nations, in 2015

ii Low Income Countries (LICs) as defined by the World Bank FY2016: