

Daiichi Sankyo Group Policy on Intellectual Property Rights and Access to Medicines in Developing Countries

Various types of intellectual property are used throughout the process of bringing medicines from the R&D phase to their eventual commercialization, as well as their use by a large number of patients. These types of intellectual property include the ideas needed to overcome scientific and technical issues (patents and utility models), designs that make products easy to use (designs), and branding to ensure that customers can properly identify our medicines (trademarks). The Daiichi Sankyo Group intends to create innovative pharmaceuticals addressing diverse medical needs through the appropriate protection and use of these types of intellectual property, contributing to the enrichment of quality of life around the world.

To continuously create innovative medicines through, for example, open innovation and open development, we are also building cooperative relationships with external partners that possess cutting-edge scientific and technological capabilities. We respect the intellectual property rights owned by such partners, as we do with regard to all valid third party intellectual property rights.

In terms of transnational challenges related to health and healthcare, pharmaceutical systems, medical insurance systems, patent systems, and economic situations differ among countries, and each country has its own specific challenges. Thus, we need to flexibly address the challenges of each country categorically and for each type of therapy.

1. Handling Patents in Countries and Areas That Have Difficulty Accessing Medicine

In some countries and areas, doctors and patients have difficulty accessing medicine due to an inadequate medical infrastructure as a result of their economic and/or geographical situations. In these countries and areas, we are flexibly dealing with this situation under our policy of placing top priority on improving access to medicine and minimizing patent filing, enforcement of rights or other procedures. We do not intend to file patent applications or enforce rights in Sub-Saharan African*¹ countries with the exception of South Africa, Least Developed Countries (LDCs)*² defined by the United Nations or Low Income Countries (LICs)*³ defined by the World Bank. For Lower Middle Income Countries (LMICs)*⁴ and Upper Middle Income Countries (UMICs)*⁵ defined by the World Bank, we file patent applications only in some more developed countries. In the countries where we are filing patent applications, we flexibly enforce intellectual property rights on a per-country basis, with consideration given to improving access to medicine.

2. The Flexibilities under the TRIPS Agreement

In our opinion, the compulsory license provided for in Article 31 of the TRIPS agreement*⁶ should be carefully exercised in situations like public health-related national emergencies. On the treatment of crises regarding access to medicine in Sub-Saharan African countries, LDCs and LICs, the compulsory license giving permission to export to those areas (TRIPS Article 31bis*⁷

should be flexibly exercised in accordance with the content of paragraph 6 of the Doha Declaration*⁸.

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1 Sub-Saharan Africa: the region of the African continent that lies south of the Sahara desert

2 Least Developed Countries defined by the United Nations:

<https://unctad.org/topic/least-developed-countries/list>

3 Low Income Countries defined by the World Bank:

<http://data.worldbank.org/income-level/low-income>

4 Lower Middle Income Countries (LMICs) defined by the World Bank:

<http://data.worldbank.org/income-level/lower-middle-income>

5 Upper Middle Income Countries (UMICs) defined by the World Bank:

<http://data.worldbank.org/income-level/upper-middle-income>

6 Agreement on Trade-Related Aspects of Intellectual Property Rights

7 TRIPS Agreement Article 31bis:

https://www.wto.org/english/tratop_e/trips_e/wtl641_e.htm

8 Doha Declaration on the TRIPS agreement and public health; 2001:

https://www.wto.org/english/thewto_e/minist_e/min01_e/mindecl_trips_e.htm