

Our 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 choose our medicines (trademarks). Our company group intends to create superior medicines through the appropriate protection and use of these types of intellectual property, contributing to the improvement of global health^{*1}.

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 also respect the intellectual property rights owned by such partners.

We also further respect the valid intellectual property rights owned by any third parties.

In terms of global health, pharmaceutical systems, medical insurance systems, patent systems, and economic situations, for example, differ among countries, and each country therefore has their own individual problems. Thus, we need to flexibly address the problems of each country categorically and for each type of therapy.

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

Some countries and areas have difficulty accessing medicine because of their inadequate medical infrastructure, which is due to economic and/or geographical reasons. In reality, medicine is not sufficiently delivered to the patients in need of them. In these countries and areas, we are flexibly dealing with this situation under the policy of placing top priority on improving access to medicine and minimizing patent filing, the enforcement of rights or other procedures so as not to block access to medicine. We do not intend to file patent applications or enforce rights in Sub-Saharan African^{*2} countries with the exception of South Africa, Least Developed Countries (LDCs)^{*3} defined by the United Nations or Low Income Countries (LICs)^{*4} defined by the World Bank. For Lower Middle Income Countries (LMICs)^{*5} and Upper Middle Income Countries (UMICs)^{*6} defined by the World Bank, we file patent applications only in some 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^{*7} 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^{*9}) should be flexibly exercised in accordance with the content of paragraph 6 of the Doha Declaration^{*8}.



- *1 Transnational problems related to health and healthcare
- *2 Sub-Saharan Africa: the region of the African continent that lies south of the Sahara desert
- *3 Least Developed Countries defined by the United Nations:
http://www.mofa.go.jp/mofaj/gaiko/ohrlls/ldc_teigi.html
- *4 Low Income Countries defined by the World Bank:
<http://data.worldbank.org/income-level/low-income>
- *5 Lower Middle Income Countries (LMICs) defined by the World Bank:
<http://data.worldbank.org/income-level/lower-middle-income>
- *6 Upper Middle Income Countries (UMICs) defined by the World Bank:
<http://data.worldbank.org/income-level/upper-middle-income>
- *7 Agreement on Trade-Related Aspects of Intellectual Property Rights
- *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
- *9 TRIPS Agreement Article 31bis:
https://www.wto.org/english/tratop_e/trips_e/wtl641_e.htm