

JPMA's Contribution to Global Health from an Intellectual Property Perspective

5th March, 2013

Japan Pharmaceutical Manufacturers Association

The Japan Pharmaceutical Manufacturers Association (JPMA) believes it has a social responsibility to fulfill unmet medical needs and to help improve global health by creating and delivering innovative new medicines. Our approach and activities are based on the following statement: "We will face public health issues sincerely within an international framework, cooperate with various stakeholders such as governments and international organizations, and contribute to improved access to medicine in developing countries"¹

All member companies work day-in and day-out to research and develop new medicines that will benefit patients around the world. It takes a long time, 9-17 years, and huge investment is made in the researching and developing of every medicine. In order for this R&D process to be sustainable, and to ensure access over time to innovative new treatments for patients, there is a need for a system in which patent rights, trademark rights, and other intellectual property such as clinical data are appropriately protected. This protection of intellectual property enables JPMA member companies to deliver effective and safe new medicines to the patients and thus enhances the social infrastructure and economy of each country.

Some recent developments have raised concerns that the international framework for protection of intellectual property rights could be weakened. One such development has been the granting of compulsory licenses in for example India and Indonesia. According to the agreement on trade-related aspects of intellectual property rights (TRIPS) issued by the World Trade Organization (WTO) in 1995, member states can invoke the right to grant a compulsory license for a technology in which a patent right is protected without obtaining prior authorization from the patent holder, under certain conditions. Based on particular conditions set forth in a country, a compulsory license as an emergency measure may be issued in order to protect peoples' lives regardless of patents in duration, not only in developing but also developed countries. However, the issuing of compulsory licenses cannot in itself solve the issue of access to medicines. Where compulsory licenses are issued without rational justification or sufficient transparency, this could cause concern about further investment in R&D of new medicines. JPMA and its members believe that constructive dialogue between government and the pharmaceutical industry is the most fruitful approach for improving sustainable access to medicines.

In addition to the issuances of compulsory licenses, movements toward limitation of enforceability of patent rights, denial of patentability of inventions regarding crystal polymorphism, use etc., invalidation of patents based upon utility issues, court cases and amendments of law and examination guidelines that limit scope of patent rights regarding medicines and so on can also be observed in India, Indonesia and Canada, for example.

JPMA is greatly concerned that such circumstances could damage the business environment that enables the member companies to commit to the sustainable creation and delivery of new medicines. If companies cannot expect protection of new medicines by patent rights, for example if a compulsory license is mandated without good reasoning and transparency, then investment into the new medicine market of the concerned country will be reduced, resulting in delayed access to new medicines in the long run for patients in that country. In order for the R&D process for innovative new medicines to be sustainable, and to ensure access over time to innovative new treatments for patients, JPMA and its member companies consider that it is a must that patent rights, trademark rights and other intellectual property such as clinical data are appropriately protected.

JPMA commits to promote and enhance the member companies' contribution to the improvement of global health. However, this contribution relies on intellectual property systems that are appropriately established and maintained, and the operation of which will protect pharmaceutical business operations.

¹ Basic Principle issued in 2009 for the JPMA's International Cooperative Project