



Establishing Effective Systems for Early Resolution of IP Disputes in Pharmaceuticals

Merck is committed to finding solutions for unmet medical needs by discovering, developing and commercializing innovative medical products. As an innovative pharmaceutical company, Merck obtains patents to protect its novel medicines, and these patents provide Merck with the necessary incentive to assume the tremendous monetary risks associated with drug discovery. Without appropriate patent protection, imitators can copy our innovative medicines and take unfair advantage of Merck's drug discovery investment. While patent protection is crucial to us at Merck, we also respect the role of generic drug companies in providing low cost pharmaceuticals. Merck further recognizes the public health interest in achieving a proper balance between the rights and interests of innovators and the rights and interest of generic pharmaceutical companies. A proper balance maintains the financial incentive for innovators to research and develop new drugs, while fostering the growth of the generic drug industry.

Obtaining a patent is not always sufficient to ensure that an innovator's intellectual property rights will be respected and that copy products are not introduced prior to when a valid patent expires. This is because innovators rely on a country's judicial and administrative institutions to enforce patent rights. As recognized by TRIPS in Article 41, member countries "shall ensure that enforcement procedures... are available under their laws so as to permit effective action against any act of infringement of intellectual property rights."

Absent a reliable enforcement system, patents are not effective in protecting Merck's intellectual property. Merck believes that the appropriate balance between the needs of innovator and generic pharmaceutical companies, and what will enable the greatest access to new medicines throughout the world, includes an effective mechanism for judicial and administrative adjudication of patent rights for pharmaceuticals prior to market entry

As an innovator, Merck depends on the protection of its intellectual property in order to further invest in the lengthy and costly drug discovery process. Merck believes that the

most effective way to ensure fairness is to establish a mechanism by which countries establish judicial or administrative procedures for the early adjudication of patent rights in a medicine, prior to market entry.