

Public Policy Statement: 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.

Patent Linkage

Patent linkage systems provide for adjudication of patent rights prior to marketing approval for a generic drug. In general, linkage requires that patents protecting an innovative pharmaceutical are listed with a government registry, to provide notice to potential generics manufacturers. Generics manufacturers must provide notice to the innovator of its submission of an application, thereby allowing the innovator the opportunity to seek enforcement of its patent rights. The health agency refrains from approving the generics drug for a reasonable period of time to allow for resolution of any patent dispute.

In the United States, the early adjudication of innovator patent rights is triggered upon submitting an application to market a generic pharmaceutical product to the U.S. Food and Drug Administration (FDA). The patent linkage system links patent rights with the marketing approval process. Patent linkage was introduced into U.S. law with the passage of the "Drug Price Competition and Patent Term Restoration Act of 1984" (commonly called the Hatch-Waxman Act). Legislators envisioned the Hatch-Waxman law as a compromise between the interests of innovators, who wanted to obtain early

adjudication of their patent rights, and the interests of generic manufacturers, who wanted a predictable pathway for gaining marketing approval of generic drugs.

Under the Hatch-Waxman scheme, the FDA maintains a list of qualified patents which innovators have obtained to protect a marketed product. When a generic company applies to the FDA for regulatory approval of a copy product, the generic company must notify the innovator that it will respect the innovator's patent rights and delay market entry until patent expiration, or explain that it either does not infringe any listed patents or the listed patents are invalid. If an innovator believes that their patents would be infringed by the copy product prior to patent expiration, it may introduce a patent infringement lawsuit. The FDA refrains from granting marketing approval to the generic applicant for up to 30 months if the patent holder initiates an infringement lawsuit against the applicant based on a listed patent. FDA approval is suspended until the patent has expired or is judged to be invalid or not infringed by the court. The patent linkage process has been credited with helping accelerate generic entry in the US market by providing greater clarity and predictability over the patent status of pharmaceutical products.

A similar patent linkage system is in place in Canada, linking the approval by Health Canada with an administrative determination of patent rights. Not all developed countries, however, have introduced linkage. For example, Japan and the member states of the European Union do not provide for patent linkage and do not verify patent status when registering generic products. However, these countries have well-established patent laws and legal institutions which have resulted in the development of a reliable process for adjudicating patent rights either prior to or upon generic entry. Innovative pharmaceutical companies can generally rely on the courts in developed countries (like Japan and the European Union member states) to quickly assess an innovator's patent rights that would be eroded by generic entry.

While the patent dispute system in Europe has generally worked well, we believe that there is room for improvement in terms of resolving, at an early stage, any dispute before a generic pharmaceutical enters the market. Merck supports further dialogue with the EU Commission, member states and other stakeholders, on resolution of patent issues prior to generic entry.

The need for patent linkage is particularly important in developing countries that lack a reliable judicial enforcement system. In the developing world, there is often a dearth of legal precedent, particularly in patent law, and limited administrative resources. As a result, both innovators and generic manufacturers lack a predictable pathway for the entry of generic drugs.

In addition, linkage systems encourage the rule of law, since linkage presumes the validity of a government-issued patent. Linkage may also help conserve judicial resources, by obviating the need for resolution of damages issues, which may occur if a generics manufacturer enters the market and is later found to have infringed the innovator's patent rights.

Merck maintains that a patent linkage system or a similar system that enables the validity of patents on products to be determined in the courts before generic versions of the product are introduced in the market place is the most effective way to properly balance the rights of innovators and generic companies, and advocates for the adoption of such systems in all countries.

Conclusion

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.