

# Intellectual Property and Patient Access



## Key points:

- Recognition of intellectual property (IP) is central to ensuring ongoing innovation in biomedical research.
- Gilead believes responsible use of IP can drive medical innovation while at the same time expanding access to treatment for patients in need, including people in developing countries.
- Gilead strongly supports and has taken a leadership role in establishing voluntary licensing and technology transfer partnerships with generic drug manufacturers as a proven and effective approach to expanding use of patented medicines in low-income countries.

The recognition and protection of intellectual property by governments is the foundation of innovation across all industries. This is especially true in the development of new medicines. Without patent protection, pharmaceutical companies could not secure or generate the up-front capital required from their investors to ensure continued research and development (R&D) of new medicines that address unmet patient needs. At Gilead, we believe that the responsible use of IP is the best way to simultaneously drive therapeutic innovation and ensure access to treatment for all patients, regardless of their ability to pay for healthcare or where they live in the world.

## Voluntary Generic Licensing in Resource-limited Countries

In recognition of the unmet need for patented medicines in the world's least-developed countries – especially those in sub-Saharan Africa where the burden of HIV and many other diseases is greatest – Gilead has established voluntary licensing agreements with multiple manufacturers in India, South Africa and China. Gilead grants licenses to these manufacturers to produce high-quality, low-cost generic versions of the company's HIV and hepatitis B medicines for distribution in over 100 low- and lower middle-income countries. Through these partnerships, Gilead works directly with generic manufacturers, transferring all the technology required so that they can manufacture our medicines as quickly and efficiently as possible, and in accordance with internationally-recognized standards of Good Manufacturing Practices (GMP). This process:

- Assists our partners in obtaining key regulatory approvals and product prequalifications from organizations such as the World Health Organization and the U.S. Food and Drug Administration. These certifications are frequently critical in order to enable and encourage the use of new medicines in developing countries.
- Helps our partners rapidly scale up production of our medicines to meet global demand, which in turn achieves economies of scale in drug manufacturing that help to lower drug prices.
- Encourages competition among our generic drug manufacturing partners, which also has the effect of driving down drug prices.

This licensing model respects Gilead's IP while at the same time expanding patient access to Gilead's patented medicines. To date, 19 companies have accepted Gilead's offer to license IP allowing them to produce and sell generic versions of Gilead's HIV and hepatitis B therapies at prices they set. The lowest price of a generic version of Viread® (tenofovir disoproxil fumarate 300 mg) in low-income countries has fallen by 80 percent since 2006 and is currently \$4.00 per patient per month. In the same time period, the number of HIV patients in low- and lower middle-income countries receiving Viread-containing regimens has increased from 30,000 to some 6.7 million, with 99 percent receiving generic versions of these products from our licensing partners.

Gilead's partners are also licensed to produce generic versions of Gilead's most recently approved HIV product, the single tablet regimen Stribild® (elvitegravir 150 mg/cobicistat 150 mg/emtricitabine 200 mg/tenofovir disoproxil fumarate 300 mg), as well as the drug's components, elvitegravir and cobicistat. Partners were granted licenses allowing them to produce this medicine in July 2011, one year ahead of its U.S. regulatory approval, to help reduce the time required for generic production to begin. In addition, we are developing global treatment access initiatives including voluntary generic licensing for Sovaldi®, which was approved in December 2013 for the treatment of chronic hepatitis C.

## Medicines Patent Pool

Gilead was the first innovator pharmaceutical company to join the Medicines Patent Pool (MPP), a United Nations-backed initiative to promote the licensing of drug patents for use in low-income countries. Through the MPP-Gilead agreements,

signed in 2011 and 2014, MPP can sub-license Gilead's IP for its HIV medicines to generic manufacturers to produce generic versions. In July 2014, Gilead expanded its MPP licensing agreements by granting generic manufacturers in India and China future rights to develop its investigational drug, tenofovir alafenamide (TAF), for the treatment of HIV and hepatitis B in 112 resource-limited countries, contingent on the medicine's U.S. regulatory approval. It is Gilead's hope that as more companies join the MPP, the potential impact on patient access will continue to grow.

### **Patent Protection and Access**

In countries where patent protections exist, Gilead and its regional distribution partners work with local governments, medical organizations and other stakeholders to increase access to the company's medicines. For example, Gilead and its partners work with national regulatory authorities to ensure that its medicines are approved for use, support medical education and training activities so that clinicians know how and when to prescribe its drugs, and manage supply chains to ensure that sufficient quantities of medicines are always available for patients in need. In a number of countries, these measures have been shown to help increase uptake of Gilead medications compared to countries where patent protections do not exist.

### **The Importance of Partnerships**

Ongoing cooperation between and within the private and public sectors is essential to ensure that patents do work for the benefit of patients. The access programs of Gilead and the MPP demonstrate that IP and access can not only coexist, but that responsible use of IP can actually drive a significant expansion in access to medicines in developing countries.