

Gilead's patent for 'Hepatitis C' faces legal challenges

18 December 2017 | Regulatory

MSF challenges Gilead's patent application for hepatitis C combination treatment in China, to bring down prices



Medecins Sans Frontieres (MSF) is an international, independent medical humanitarian organization,

MSF has filed a legal challenge in China against Gilead's patent application for the combination of two crucial oral hepatitis C medicines, sofosbuvir and velpatasvir.

This combination is the first direct-acting antiviral (DAA) treatment to be registered for use against all genotypes of the disease.

Rejection of patents for this combination would pave the way towards the availability of affordable generic versions of this treatment that millions of people in China and around the world need.

The legal challenge, filed at the China State Intellectual Property Office (SIPO), offers technical grounds to show that the drug combination does not merit patenting under China's Patents Law.

If granted, the unjustified patent on the combination of these two medicines would give Gilead the monopoly over production and sales of the treatment in China.

It would block Chinese generic companies from producing affordable versions, for use in China and globally.

71 million people have chronic hepatitis C infection is noted worldwide and without access to treatment, nearly 400,000 people die each year.

Though these medicines have proven to be a revolutionary treatment of hepatitis C remains limited in China and many other middle-income countries due to high pricing.

In China, Gilead recently announced the market launch of sofosbuvir at a prohibitive price of US\$8,937 per treatment course, or around \$100 per pill.

The price of the sofosbuvir and velpatasvir combination is still not known in China, as the treatment is not yet registered or available in the country.

By using sofosbuvir at Gilead's price, in combination with another DAA, daclatasvir, would cost about \$12,000 for the 12-week treatment.

Generic competition has driven the price of this same treatment combination to as low as \$120 per 12-week treatment in countries where patent barriers no longer exist.

"With this patent challenge, MSF hopes to prevent Gilead from getting unmerited patent rights on the combination of sofosbuvir and velpatasvir, which would allow them to charge unreasonably high prices," said Yuanqiong Hu, Legal Advisor for MSF's Access Campaign.

According to him, to achieve the affordable source we should focus on the development of generic medicine.

Gilead has applied for multiple patents in China for its hepatitis C medicines, and some of these are being opposed by other pharmaceutical companies and nonprofit organisations based on similar grounds of being unmerited under China's Patents Law.

Since 2015, SIPO rejected two key patent applications for sofosbuvir in China.

Along with China, Gilead's patent applications on sofosbuvir and its combinations have also been challenged in many other countries.