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Gilead interference in Ukraine's access to generic sofosbuvir

Gilead forces Ukraine to cancel marketing approval of generic sofosbuvir, a life-saving hepatitis C drug

Médecins Sans Frontières/Doctors Without Borders (MSF) is planning a hepatitis C virus (HCV) treatment programme for people in Ukraine, home to the region's highest HCV prevalence – among the highest HCV rates in the world – with 5% of adults with HCV.[1] The availability of multiple sources for new DAAs, especially sofosbuvir, is critical for treatment providers, including MSF, to manage a sustainable and affordable supply for medical operations.

Ukraine has been making efforts to increase availability of new direct-acting antivirals (DAAs) that cure nearly 100% of people with HCV. In November 2015, the Ukrainian National Drug Regulatory Authority (NDRA) registered a generic version of sofosbuvir, a DAA that is an essential part of HCV combination treatment, as per WHO treatment guidelines

Generic sofosbuvir in Ukraine

There are no patent barriers to the introduction of more affordable generic versions of sofosbuvir in Ukraine. Gilead Sciences (Gilead), the US pharmaceutical corporation that is the originator company of sofosbuvir, did not file for the primary patents on the drug in Ukraine. Gilead's weak secondary patents on sofosbuvir have not been granted in Ukraine, because civil society has repeatedly challenged the corporation's ever-greening patent claims.[2]

Despite the absence of patent barriers, Gilead has used several strategies to maintain monopoly control over the Ukrainian market. Since September 2014, Gilead has signed licensing agreements with multiple Indian generic manufacturers on three key HCV medicines, including sofosbuvir. The license excludes Ukraine as a territory, blocking Indian generic manufacturers – some of the most cost-efficient producers of generic sofosbuvir – from marketing the product in Ukraine.

Indian manufacturers who signed the license are blocked from registering and launching generic versions of sofosbuvir in Ukraine. However, a domestic company applied for and obtained registration in 2015 for a generic version of sofosbuvir, produced by an Egyptian manufacturer. Gilead immediately started an effort to rescind the registration of generic sofosbuvir, to re-establish its market monopoly in Ukraine.

Data exclusivity claim rejected

In June 2015, Gilead filed proceedings before a Ukrainian court to force generic sofosbuvir out of the Ukrainian market.[3] Gilead challenged the registration of a potentially more affordable generic version of sofosbuvir by the Ukrainian Ministry of Health and NDRA on the grounds that it was entitled to market exclusivity ('TRIPS-plus' data exclusivity[4]) until October 2020, and asked to have the registration of generic sofosbuvir revoked. However,

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[1] http://aph.org.ua/en/news/over-5-of-ukrainians-are-infected-with-hepatitis-c/

[2] More details of civil society struggle and Gilead's patent status on sofosbuvir in Ukraine can be found from : http//donttradeourlivesaway.files.wordpress.com/2016/08/civil-society-struggle-for-affordable-sofosbuvir-in-ukraine.pdf

[3] The Administrative court of Kyiv considered the case as the court of first instance

[4] In 1995, the World Trade Organization'sTRIPS Agreement imposed minimum IPstandards across the globe for the firsttime, including the obligation to grantpatent monopolies for pharmaceuticalproducts.Importantly, TRIPS includes legal safeguards that givecountries some leeway in overcomingIP barriers when they hinder access tomedicines, and flexibility in balancingcommercial interests and public health.TRIPS-plus provisions serve toextend monopoly

Gilead lost the case in the district court (known as the 'court of first instance' in Ukraine), which dismissed Gilead's claims. The court also upheld the decision of the Health Ministry and its NDRA to register the generic version of sofosbuvir, and not to grant data exclusivity over this pharmaceutical product to Gilead.[5]

Even as the matter was under appeal by Gilead before the courts, in January 2017 Gilead threatened to launch an investor-state dispute settlement (ISDS) under the US-Ukraine Bilateral Investment Treaty (BIT) to remove generic sofosbuvir from the market. The threat of an ISDS case undermines the legitimate court process concerning the regulatory approval of a generic version of sofosbuvir. This recent move is part of the company's attempt to maintain monopoly control of markets in middle-income countries with a high burden of hepatitis C, including Ukraine.

ISDS threat to reverse the availability of generic sofosbuvir

Investment rules in BITs and free-trade agreements (FTAs) problematically link investors' rights with intellectual property (IP) protection. Under the BIT, foreign corporations have the power to challenge any domestic regulation or judicial decision in arbitration proceedings which are mostly secretive. Corporations pursue such proceedings whenever they claim a government regulation or decision, including those that are fully compliant with the TRIPS Agreement, has affected 'enjoyment' of the companies' investments and expectations of potential profits. These types of provisions can and have been used by companies to sue governments in non-transparent, international arbitration tribunals, outside of domestic courts, under the controversial ISDS mechanism. ISDS tribunals typically do not meet standards of transparency, consistency or due process, and do not provide fair, independent or balanced venues for resolving IP disputes. Most importantly, they do not have an obligation to consider the protection of the right to life and health.

Gilead's threat to use investment rules, and specifically the ISDS clause, was an effort by Gilead to link the decision not to enforce data exclusivity on the drug sofosbuvir to the definition of investment and expropriation of its investment and profits under the provisions of the US-Ukraine BIT.[6] Specifically, Gilead threatened to launch a claim for damages of US$820 million against the Ukrainian government. Under pressure, the Ministry of Justice agreed to a settlement with Gilead and agreed to cancel the marketing approval granted to a generic competitor.[7] This despite the fact that the court of first instance had dismissed Gilead's claims and the matter was under appeal before domestic courts. As a result, Ukraine's Health Ministry issued an order on February 22, 2017 to cancel the registration of generic sofosbuvir and exclude it from the State Register of Medicinal Products of Ukraine.[8]

Several such ISDS disputes have already been filed by corporations against governments under existing ISDS provisions, in an effort to reverse pro-public health laws, policies and judicial decisions. For example, in the context of tobacco control and public health warnings and regulations for packaging, the threat of launching expensive ISDS proceedings against a government has been frequently used by tobacco corporations as an effective tactic to discourage stricter regulations and plain packaging to discourage smoking.[9]

Similarly, ISDS cases or threats of cases are now being used by pharmaceutical corporations to pressure governments to give in to demands that put company profits before people's access to affordable medicines. One example involves the pharmaceutical company Eli Lilly, which filed an ISDS case against the Government of

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protection beyondwhat is required by internationalagreements and to create new kindsof monopolies, even after patent-basedmonopolies have expiredor where they never existed.

[5] https://donttradeourlivesaway.files.wordpress.com/2016/08/civil-society-struggle-for-affordable-sofosbuvir-in-ukraine.pdf

[6] Article VI of the US-Ukraine BIT allows ISDS mechanism :http://investmentpolicyhub.unctad.org/Download/TreatyFile/2366

[7] The decision regarding this settlement was published on Ukrainian government website on January 25th, 2017, available at: http://www.kmu.gov.ua/control/uk/cardnpd?docid=249699210 (in Ukrainian language only).

[8] See: http://open4business.com.ua/ukraine-signs-amicable-agreement-u-s-gilead-biopharmaceutical-producer-hepatitis-c-drug/

[9] Letter from Joan-Charles Rouber to Roy Maclaren regarding proposal for plain packaging of tobacco product in Canada. 1994 http://legacy.library.ucsf.edu/tid/kbw24a99; [accessed 1 March 2017]

Canada after the company, under judicial proceedings, failed to fulfill the legal criteria of patentability under Canadian law for secondary patent claims on a number of known medicines.[10] A decision in the case was recently issued wherein a tribunal dismissed Eli Lilly's claims under NAFTA.[11]

Removing harmful policies, decisions and provisions to safeguard access

Through patent evergreening, data exclusivity and voluntary licensing with Indian generic companies, multinational pharmaceutical corporations are maintaining monopoly control of the Ukraine market for essential HIV and now HCV pharmaceutical products. As part of the settlement agreement with Ukraine, Gilead will allow the country to procure sofosbuvir at their 'access price' of $250 per bottle, up to $350 per bottle including distributor mark-up. Comparatively, if Ukraine had access to generics to improve competition, they could procure at prices as low as $70 per bottle, as seen in other markets.

The current challenge in Ukraine reveals the urgent need to take practical steps to remove legal and regulatory barriers in the country, to safeguard access to affordable sources of medicines to meet the high burden of diseases such as hepatitis C.

MSF offers the following recommendations:

- The Ukrainian government should reinstate the generic registration of sofosbuvir in the country, upholding the sovereignty of its judiciary.
- Arrangement and agreement regarding Gilead's supply of sofosbuvir at $250 per bottle for government procurement and $350 per pack for private pharmacies should not interrupt the existing procurement, sale and use of generic sofosbuvir.
- Ukraine should consider studying the impact of court cases by pharmaceutical corporations seeking to remove generic versions of medicines from the domestic market, on the availability of HIV, HCV and other high-priced medicines.
- Ukraine should reform its patentability criteria to ensure evergreening patent claims on derivatives (e.g. pro-drugs, salts, polymorphs), fixed-dose combinations (FDCs) and new dosage forms of known drugs are not granted to prolong patent monopolies. Additionally, formal pre-grant and post-grant patent opposition procedures should be introduced in the patent law of Ukraine. This will increase access to generic versions of medicines.
- Ukraine should review its bilateral investment treaties. Faced with prohibitive costs of secret arbitral hearings and the risk of excessive damages as a result of ISDS proceedings, a number of developing countries including Indonesia,[12] South Africa,[13] India[14] and Brazil[15] have started reviewing, terminating, reforming or renegotiating the previously concluded BITs, seeking a better balance between investor protection and the right to regulate in the public interest.

[10] Ref. http://www.international.gc.ca/trade-agreements-accords-commerciaux/topics-domaines/disp-diff/eli.aspx?lang=eng.
[11] For more details of the decision, please see: http://www.michaelgeist.ca/2017/03/panel-rejects-eli-lilly-claim-canadian-patent-law-orders-company-pay-millions-costs/,.The full text of the decision is available at: http://icsidfiles.worldbank.org/icsid/ICSIDBLOBS/OnlineAwards/C3544/DC10133_En.pdf .
[12] https://www.ft.com/content/3755c1b2-b4e2-11e3-af92-00144feabdc0
[13] https://www.dlapiper.com/en/us/insights/publications/2014/12/international-arbitration-newsletter-q4-2014/challenging-the-status-quo/
[14] http://blogs.ft.com/beyond-brics/2016/07/15/india-overhauls-its-investment-treaty-regime/
[15] http://ccsi.columbia.edu/files/2013/10/No-159-Perrone-and-C%C3%A9sar-FINAL.pdf