Briefing on the government use license in Russia, remdesivir

ITPCru

International Treatment Preparedness Coalition

Eastern Europe and Central Asia

Once upon a time…

Extensive Research

- Report published in September 2019 and disseminated widely:
  - Legal Background
  - Extensive overview of the existing practice
  - Debunking myths
  - Recommendations for better use

Summary of the Decision

- What Decision No 3718
- When? December 31, 2020
- Who? Government of Russia (signed by the Prime Minister M. Mishustin)
- Which drug? Remdesivir (patents EA 025252, 025311, 028742, 029712, 020659, 032239)
- To whom? JSC Pharmasyntez
- Period? 1 year
- For what? To provide citizens of Russia with remdesivir
- Legal grounds? Art. 1360 of the Civil Code of Russia (in the interests of security)

Legal Background

- Art.1360 of the Civil Code says the government can use an invention without the consent of the owner in the interests of defense and security, notifying the owner asap and proving an adequate compensation
- A process started several years ago, strongly backed by some CSO (including ITPCru), to amend this article, adding public health to the list of grounds
- In May 2021, this law finally came into force (so the remdesivir CL decision was made in accordance with the previous version of the law)
- In June 2021, another CL law came into force, enabling Russia to use CL for export

Link to a publication in English

Background and Timeline

- Russia **excluded** from the VL on remdesivir
- Push from the civil society for a CL
- Pharmasyntez asked Gilead for a **VL** and made it public in the media
- Pharmasyntez officially asked for a CL (and made it public in the media); Pharmasynez is known for their CLs requests (SOF/DAC in 2016)
- Disappointing data from WHO regarding the efficacy of remdesivir
- Clinical trials of remdesivir, fast-track registration at the end of 2020 (under the newly approved fast-track registration procedure) – not a patent violation under the Russian law
- Registration of the ceiling price (approx. 100 USD per vial without 10% VAT)

Background and Timeline - 2

- Decision!
- Gilead calling this measure “excessive and counterproductive”
- Plans announced to produce 45,000 - 50,000 packs weekly starting from February
- Gilead sues the Russian Government, but loses
- Pharmasyntez reveals their clinical trial costs, allegedly 200 mln RUR (~USD 2.7 mln)
- The total regional sales by September 2021 amounted to ~ USD10 mln, with an average price per vial ~ USD110;
- Large gvt tender announced in November – around 55 mln USD, 75USD per vial;
- By the end of 2021 ITPCru plans to publish a full analysis about the CL, including the sales figures

Further considerations

Among other IP-related measures to facilitate and accelerate access to medicines, Russia (as well as other Eurasian Economic Union states) should:

- Avoid adopting a patent linkage regime (which is an ongoing process)
- Consider adopting an international exhaustion of rights regime
- Continue developing an enabling and transparent environment for further use of inventions without the consent of the patent holder (especially related to Am, By, Kz)
- Support the TRIPS waiver in response to COVID-19