

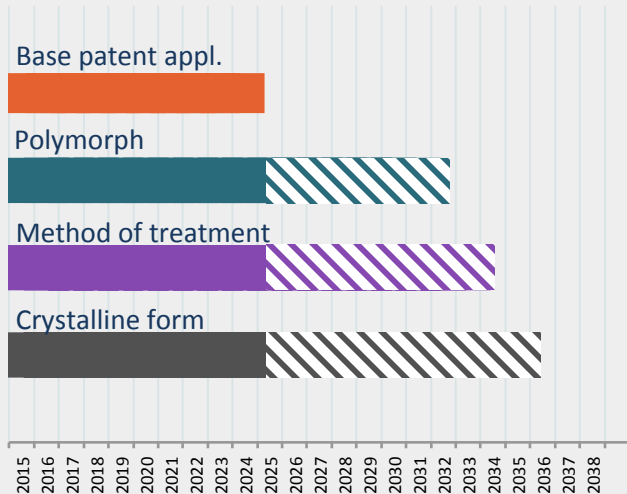


## Pre-grant Patent Oppositions on SOF in Ukraine

Sergiy Kondratyuk

All-Ukrainian Network of People Living with HIV/AIDS

# Patent applications on SOF in Ukraine



# SOF pre-grant oppositions in Ukraine

WO2012012465

(method of manufacturing)

- Opposed, REJECTED by the Ukrainian Patent Office

WO2011123645

(polymorph)

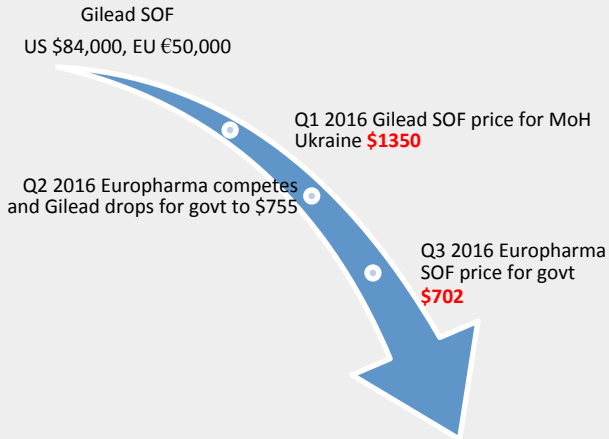
- Opposed, PRELIMINARY REFUSAL

WO2013040492

(method of treatment)

- Opposed, PRELIMINARY REFUSAL

# NO PATENTS: Temporary duopoly competition in 2016 for SOF in Ukraine



## Data exclusivity in Ukraine: article 222 EU Association Agreement

- 2. “...the Party **shall not, for a period of at least five years from the date of the first approval in that Party, permit other applicants to market the same or a similar product**, on the basis of the marketing approval granted to the applicant which had provided the test data or studies...”
- “**During such period, the test data or studies ...will not be used for the benefit of any subsequent applicant** aiming to obtain a marketing approval for a medicinal product...”

# Data exclusivity enforcement

Gilead lawsuit against MoH Ukraine to cancel market authorization of generic sofosbuvir

- dismissed by Administrative court as no reliance on data from registered in Ukraine Sovaldi was made according to DRA;  
<http://www.revestr.court.gov.ua/Review/62499794>

Gilead had filed an notification on potential investment case with Ministry of Justice for 820 mln USD

- US and Ukraine bilateral agreement on investments defines confidential information as investment

Settlement between MoH, MoJ Ukraine and Gilead

- DE until 2020
- 750 USD 12-weeks SOF hospitals
- 1050 USD 12 weeks SOF pharmacies

# Patentability criteria

Upon introduction of Patentability Guidelines in Argentina patenting of medicines dropped 5-7 times

According to evergreening study in Thailand about 70% of patents on medicines were result of evergreening practice

Patents on medicines granted in 2012

