

Seeking to safeguard treatment access:

IP interventions related to SOF in Russia and EECA



ITPCru

International Treatment Preparedness Coalition
Eastern Europe and Central Asia

HCV Community Summit
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WHY OPPOSING

- Understanding the link between IP barriers and access to treatment
- Knowing that patents can be challenged legally
- Believing that civil society can and must do it



WHY SOFOSBUVIR IN RUSSIA

- Very high clinical importance
- Lack of access (no registration at the time of the first submission – May 2015)
- Bad history with access to Gilead's drugs in Russia (TDF, TDF/FTC, TDF/FTC/EFV) – patient community stuck without drugs between the government and the industry
- “Weak” patent – does not quite meet the patentability criteria, i.e. chances for success



Current access to SOF in Russia

- Registered in March 2016
- Not on the market, despite the official answer from the company that it will be available in the 1st quarter of 2017
- “Expected” price – around USD10,000 based on the starting prices of tenders
- The only way to access SOF is to purchase generics from other countries for personal use
- Access to DAA-based regimens in 2016 – around 3200 patients, including regimens with PEG-IFN (total estimations – up to 6 million people)
- First-line WHO regimens NOT available (SOF/LED n/a)



What has been done so far?

- 2 hearings in the Patent Chamber
 - Opposition submitted against the patent for the base compound
 - Civil society organizations
 - The chamber left the patent in force
 - Obvious conflict of interest, as the chairman of the panel represented the department which issued the patent
- 2 hearings in the Court on Intellectual Property
 - The key issue so far in the process was to identify the address of the patent holder to inform them about the
 - The name of the holder is Gilead Pharmasset LLC – the company that has not led any financial activity since 2012
- Another company (Pharmasyntez) has filed an opposition
 - 3 hearings so far, the most recent one is today



Gilead Pharmasset LLC?

Entity Name: GILEAD PHARMASSET LLC

Entity Kind: Limited Liability Company

Residency: Domestic

Status: Good Standing

Entity Type: General

State: DELAWARE

Status Date: 1/13/2011

Registered Agent Information

Name: THE CORPORATION TRUST COMPANY

Address: CORPORATION TRUST CENTER

City: WILMINGTON

State: DE

Phone: 302-658-7581

Country:

Postal Code: 19801

Tax Information

Last Annual Report Filed: 2012

SOF oppositions elsewhere in EECA

- **Ukraine** – pre-grant opposition successful (All-Ukrainian Network of PLWH)
- **Moldova** – pre-grant opposition ongoing (League of People Living with HIV)
 - 3 000 patients to receive DAA-based therapy with Egyptian generics
 - If the patents are granted, the government programme can be put at risk
- **Kazakhstan** (and other EAPO countries) – getting ready for post-grant opposition

Kg – license – 11

Наименование	MHN	Лекарственная форма	Дозировка	Фасовка	Предприятие-производитель	Страна производства	Держатель свидетельства
Валдис	Софосбувир	таблетки, покрытые пленочной оболочкой	400 мг	№28	SHROOQ PHARMACEUTICALS (PVT) LTD	Пакистан	Ис Групп
Софген	Софосбувир	таблетки, покрытые пленочной оболочкой	400 мг	№28	Хетеро Лабс Лимитед	Индия	Хетеро Лабс Лимитед
Гратезиано	Софосбувир	таблетки, покрытые пленочной оболочкой	400 мг	№28	EUROPEAN EGYPTIAN PHARMACEUTICAL INDUSTRIES	Египет	EUROPEAN EGYPTIAN PHARMACEUTICAL INDUSTRIES
Гепцинат	Софосбувир	таблетки, покрытые пленочной оболочкой	400 мг	№28	Натко Фарма Лимитед	Индия	Натко Фарма Лимитед
МайХеп™	Софосбувир	таблетки, покрытые пленочной оболочкой	400 мг	№28	Майлэн Лабораторис Лимитед	Индия	Майлэн Лабораторис Лимитед
Вирсо	Софосбувир	таблетки, покрытые пленочной оболочкой	400 мг	№28	Strides Arcolab Limited	Индия	Strides Arcolab Limited
Ледвир	Ледипасвир + Софосбувир	таблетки, покрытые пленочной оболочкой	90 мг/400 мг	№28	Mylan Laboratories Limited	Индия	Mylan Laboratories Limited
Лисоф	Ледипасвир + Софосбувир	таблетки, покрытые пленочной оболочкой	90 мг/400 мг	№28	Hetero Labs Limited	Индия	Hetero Labs Limited
Харвони	Ледипасвир + Софосбувир	таблетки, покрытые пленочной оболочкой	90 мг/400 мг	№28	Патеон Инк.	Канада	Гилеад Сай Инк.
Гепцинат-ЛП	Ледипасвир + Софосбувир	таблетки, покрытые пленочной оболочкой	90 мг/400 мг	№28	Натко Фарма Лимитед	Индия	Натко Фарма Лимитед

Md – no license – no patents – 4

Denumirea comercială	Forma farmaceutică	Doza	Volum	Divizarea	DCI	ATC	Temen de valabilitate, luni	Nr. de înregistrare
					sofosbuvir			
Grateziano	comprimate filmate	400 mg		N28	Sofosbuvirum	J05AX15	24	22888
Hopetavir® 400 mg	comprimate filmate	400 mg		N6	Sofosbuvirum	J05AX15	24	23122
Nucleobuvir	comprimate filmate	400 mg		N7x4	Sofosbuvirum	J05AX15	24	22503
Twinvir™ 90 mg + 400 mg	comprimate filmate	90 mg + 400 mg		N28	Ledipasvirum + Sofosbuvirum	J05AX	24	23384

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Linkuri utile : [Baza de date EudraPharm](#) [Baza de date EudraGMP](#)

RU – patents – no license - 1

№ п/п	Торговое наименование	Международное непатентованное или группировочное (химическое) наименование	Форма выпуска	Наименование держателя или владельца регистрационного удостоверения лекарственного препарата	Страна держателя или владельца регистрационного удостоверения лекарственного препарата	Регистрационный номер	Дата государственной регистрации
1	Совальди	Софосбувир	таблетки, покрытые пленочной оболочкой	Гилеад Сайенсиз Интернешнл Лимитед	Великобритания	ЛП-003527	25.03.2016

Conclusion

- Civil society in EECA will do its best to protect access to HCV therapy and make sure patents do not hinder access to life-saving treatment
- Generic HCV drugs continue to save lives in EECA

