Challenging patent system in High Income Countries

Sofosbuvir Patent Oppositions at European Patent Office

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Remember us…

- HIV/AIDS Durban international conference
  - « Patients are in the South »
  - « Treatments are in the North »
- Global advocacy on access to ART in the South
  - Financial barriers associated to patentees’ positions
  - TRIPS flexibilities
- Outcomes:
  - WTO Doha Declaration 2001
  - South Africa trial
  - Brazil and Thaïland: compulsory licenses and government-use licenses

⇒ Acess to generic ART

But…

⇒ A Southern problem with Southern-oriented solutions
Fifteen years later…

• The Southern problem has become a Northern problem

DAAs Prices at introduction on the French market

- Gilead sof (Nov 2014) 41,000 €
- BMS dac (May 2015) 25,500 €
- Gilead sof/led (June 2014) 46,000 €
- MSD elb/grazo (Jan 2017) 28,700 €

Jan 2017 OECD report on New Health Technologies

« The immediate budget impact of treating the entire population affected proved to be unaffordable for OECD countries and all payers decided to limit access to the most severely affected patients. »
Demyth price reduction in OECD countries (1)

Current DAAs prices in France

- **Gilead sof at market entry**: 41,000 €
- **Gilead sof today**: 28,700 €
- **MSD elb/grazo**: 28,700 €
Demyth price reduction in OECD countries (2)

Current DAAs prices in France

- Gilead sof: 28,700 €
- Generic sof: 60 €
Demyth price reduction in OECD countries (3)

Current DAAs prices in France

<table>
<thead>
<tr>
<th>Product</th>
<th>Price</th>
</tr>
</thead>
<tbody>
<tr>
<td>Gilead sof</td>
<td>28,700 €</td>
</tr>
<tr>
<td>Generic sof</td>
<td>60 €</td>
</tr>
<tr>
<td>Gilead sof/velpatasir</td>
<td>43,000 €</td>
</tr>
</tbody>
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First line treatment since April 2017
Need to address the IP challenge

- « Magical hand of the free market » has failed to achieve sustainable prices for DAAs
- Major concern on new cancer drugs:
  - Breast cancer: 70,000 euros/patient/year (Kadcyla®)
  - Melanoma: 135,000 euros/patient/year (Mekinist® + Tafinlar®)
- Europe setting offers a comparative advantage regarding advocacy:
  - 100% of DAAs purchases are paid by public funds (reimbursement policies)
  - 18% of Gilead global DAAs revenue = Europe (8.8 billion USD)
- Concern in public opinion (= patients + tax payers)
- Advocacy on universal access + price reduction has partially failed
  - Compulsory license = « atomic bomb »

- A new frontier for Europe advocacy: challenging patents on drugs
European Patent Office

- International organization (≠ European Union institutions)
- Set up in 1973 within European Patent Convention (EPC).
- EPC establishes a common procedure for granting European patents for the contracting states;
  - Requirements for the invention (patentability criteria)
  - Requirements for the patent application
- To date: 38 member States
Sofosbuvir Pro drug patent opposition

- Filed in February 2015 (EP 2203462, granted in June 2014)
- Grounds for opposition: requirements for the invention and the patent application are not met
- Public hearings in October 2016. Outcomes:
  - Requirements for the invention are met
  - Requirements for the patent application are not met
  - Patent maintained under amended form

- European countries have accepted high prices on behalf on a flaved patent...

Stereochemical formula defining sofosbuvir as a drug is not protected by EP 2203462)
Sofosbuvir Base compound patent opposition

- Filed in March 2017 (EP 2604620, granted in June 2016)
- Main grounds for opposition:
  - The subject-matter of the European patent extends beyond the content of the application as filed:
  - Insufficient disclosure of the invention:
  - The subject-matter of the claims does not involve an inventive step:

**Strong CSO commitment in this second patent opposition:**

- MdM network (11 MdM national chapters in Europe)
- MSF network (13 MSF national chapters in Europe)
- A consortium of 5 national NGOs + 1 European network

18 European countries
Patent system in Northern countries

- EPO (Europe): about **70%** of patents opposed are either revoked or maintained in an amended form. Comparable artes in USPTO.
- October 25, 2017: I-MAK files 6 sofosbuvir Gilead’s patents oppositions
  - Base compound (1 patent), Pro drug (2 patents), Crystalline structures (2 patents)
- **86%** Gilead DAAs revenues = USA + Europe
- I-MAK white paper: « unmerited patents and over-patenting by the pharmaceutical industry will cause more than $55 billion in excess costs to Americans »
  - **Revlimid**® (lenalidomide): patents prevent competition to 2028 → $45 billion in excess costs
  - **Sovaldi**® (sofosbuvir): patents prevent competition to 2034 → $10 billion in excess costs
  - **Gleevec** ® (imatinib): In the one-year period from 2015-16, approximately $700 million in excess costs were passed onto payers as a result of a pay-for-delay payment from Novartis to a generic company
Lessons learned

• Civil society organizations may successfully invite themselves in patent system in Northern countries
• CSOs may provide objective evidence on IP system principles diversion by pharmaceutical companies
• Need to set up a cultural fight alongside the advocacy work: IP regulation tools have also to be used in the North
  • France: government-use license established in 1959 when pharmaceutical patent has been set up as the social arrangement for incentivizing R&D
• Outcome for global advocacy: while shaking 80% of the global market, Northern CSOs play a new role (not only supporting LMICs CSOs and global advocacy Southern-oriented)

• The way forward: challenge anti-trust laws and regulation (cf. Sen Kefauver, USA, 1959)
DECLARATION OF THE HEPATITIS COMMUNITY

NO ELIMINATION WITHOUT DECRIMINALIZATION!

We, members and representatives of the viral hepatitis community—a community that includes people living with viral hepatitis, doctors, nurses, social workers, researchers, public health experts, and people who use drugs—are concerned over the growing gap between the enormous impact of hepatitis B and hepatitis C over people who use drugs and those who have access to prevention, diagnosis, and treatment services around the world.

Sharing unsterile drug injection equipment puts people at high risk of hepatitis B and hepatitis C infections. Globally, it is estimated that among the 156 million people who currently inject drugs, 62% are hepatitis C antibody positive, and 9% are living with chronic hepatitis B infection. From a public health and human rights perspective, improving access to prevention and treatment for people who use drugs is crucial to reducing hepatitis C incidence and eliminating the epidemic, as sharing of needles, syringes, and other injecting equipment is estimated to account for 23% of new infections.

Ensuring access to interventions such as low-threshold needle and syringe programs, opioid substitution therapy, hepatitis C treatment and other harm reduction interventions are essential to reduce hepatitis C incidence and prevalence among people who inject drugs, and these interventions are cost-effective. In 2016, the Member States of the World Health Organization (WHO) adopted the first ever Global Health Sector Strategy (GHS) on viral hepatitis. It identified harm reduction as one of the core interventions needed to reach the goal of viral hepatitis elimination by 2030.

Despite the evidence and WHO recommendations, comprehensive harm reduction services are inaccessible for most people who use drugs worldwide. In 2017, among the 179 countries and territories where injecting drug use has been reported, just 86 (46%) have implemented opioid substitution therapy and 92 (62%) have needle and syringe programs.

Furthermore, the regional and national coverage varies substantially and is most often below WHO indicators, with less than 1% of people who inject drugs living in countries with high coverage of both services. Even where services do exist, people who use drugs face more difficulties in accessing hepatitis C prevention and treatment due to poor access to health services, their exclusion through treatment criteria, threats of violence and abuse when disclosing status as drug users, and universal stigmatization. As a result, the hepatitis C epidemic continues to grow among people who use drugs.

This lack of access to hepaticare for people who use drugs is deeply rooted in and driven by our laws and policies which criminalize drug use, drug possession and, ultimately, people who use drugs themselves. Punitive drug law enforcement is a direct barrier to harm reduction services in many ways:

- The prohibition of drug paraphernalia possession impedes harm reduction service delivery and uptake
- many national laws impose severe and disproportionate custodial sentences for minor, non-violent drug offenses (such as drug use, possession and low-level supply)
- people who use drugs are frequently incarcerated or sentenced to judicial drug treatment, often leading to interruption of medical treatments, without access to treatment and other harm reduction services, and at heightened risk of hepatitis infection
- policies criminalizing drug use fuel stereotypes and negative assumptions of people who use drugs, ultimately reinforcing stigmatization and discrimination.

Even in countries that have integrated harm reduction into domestic public health policies, criminalization remains a glass ceiling on the fear of arrest continues to drive people away from prevention and care services.

A number of countries, such as Portugal and the Czech Republic, decriminalized minor drug offenses years ago with significant public health benefits. These policy changes have proven very successful and have led to an increase of access to harm reduction and health services by people who use drugs—contributing to decreased new HIV infections, and reduced harms associated with drug use and drug dependence. While our laws and policies that prohibit drug use are portrayed and described as necessary to preserve public health and safety, the evidence overwhelmingly demonstrates that they have driven unnecessary and disproportionate human rights violations including violence, abuse, discrimination, and the undermining of people’s right to health.

Growing recognition of the need for evidence-based drug policy reform has led several world leaders, public health experts, the WHO and other United Nations agencies and their closest allies and leading advocates of human rights, to challenge the decriminalization of minor, non-violent drug offenses, and to strengthening on health-oriented alternatives to criminal sanctions.

We, the viral hepatitis community, wholeheartedly support Member States’ commitment to the goal of eliminating viral hepatitis by 2030. In order to achieve that goal, we call on world political leaders to remove all barriers to the uptake of the full range of prevention services by people who use drugs by reforming laws, law enforcement procedures and discrimination that hinder access, including the criminalization of minor, non-violent drug offenses and to adopt an approach based overwhelmingly on public health promotion, respect for human rights and evidence.