Report from the EU regional dialogue on patents & other IP barriers to Access to Medicines

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Rosa Castro, European Alliance for Responsible R&D and Affordable Medicines

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Opposition to patents of dubious validity

Médecins du Monde (MdM, Elena Urdaneta)

- Patents on Sofosbuvir to treat Hep C
- Burden on vulnerable groups
- Post-grant oppositions at the EPO to patents owned by Gilead
- 1st opposition: 2015, first opposition proceeding against a drug patent by civil society in Europe. It demonstrated we can successfully challenge non-compliance with patent regulation in Europe
- 2nd opposition (under examination) by MSF, MdM & others: much stronger collaboration, + than 30 orgs from 17 European countries
- Impact on prices takes time, but oppositions have considerably weakened initial patents
- Collaborations key for patent oppositions: resource-intensive, technical activity

National coalitions

Irene Bernal, Salud por Derecho and No es Sano coalition (Spain)

- Coalition stimulated by need to raise the IP and A2M issue in the political agenda
- Evidence-based support to actions targeting policymakers and other stakeholders
- Focus on transparency, accountability & public interest in innovation
- Alternative innovation mechanisms such as hospital production of CART-T treatment led to a 1/3 of initial prices
- Benefits for oncology and other patients, and health systems
- Hospital production based on hospital exemption in Spain (and Switzerland, the Netherlands)
- Treatment traditionally done by universities. Novartis. Backlash
- Opportunity for the movement to advocate alternatives that can be transferred elsewhere
- Key alliances with hospitals and universities

Using competition law to increase access

Wilbert Bannenberg, Pharmaceutical Accountability Foundation (the Netherlands)

- A coalition of NGOs including lawyers, doctors, pharmaceutical experts
- CDCA Leadiant case; exponential price raise after a well-known drug used off-label to treat a rare disease gained orphan status (500x)
- Complaint to Dutch competition authority for excessive pricing
- After 2.5 years, case led to a fine of €19.6m as Leadiant charged an excessive and unfair price (found that it was making misuse of economic power position)
- Replicated in Belgium, Spain and Italy
- Case helpful to stop ‘pharma piracy’ business (misuse of the EU Orphan drug incentives)
- Competition cases relatively affordable, but take a long time and absorb resources from competition law authorities
- Exponential price increase needs to be precluded by legislation, for instance orphan drug

TRIPS flexibilities navigator

Jaume Vidal, Health Action International

- Information for action
- Data resources to track usage across Europe (for instance, how many times has compulsory licensing been used and where)
- Links to resources and tools
- Tool for different stakeholders: advocates but also policymakers
- Beta testing, to be launched in December 2021
- Looking for participants and contributors rather than users
- A living tool for a community with possibilities of scaling up and widening scope
- In combination with other tools and resources
- Connecting with European stakeholders, including generic manufacturers

What next?

- Advocacy work on the new EU pharmaceutical strategy. The EU as a TRIPS-plus treaty: data/market exclusivities and limits to compulsory licensing
- Continuing exchanges of information and practices (e.g., competition cases in different European countries, national coalitions to replicate good practices in other countries)
- Exploring more stable collaborations for patent oppositions (case of the Coalition of seeds)
- More interactions between NGOs and the European Patent Office (EPO)