European Alliance for
Responsible R&D and Affordable Medicines

REGIONAL ACCESS TO MEDICINES DIALOGUE FOR ACTIVISTS IN THE EU
The Second Global Summit on IP and A2M – Virtual Pre-Summit
Doha Declaration@20: Reimagining Access
14 – 21 November 2021
Hosted by the European Alliance for Responsible R&D and Affordable Medicines
Wednesday 17 November, 09:30-11:30 am

Objectives

The Pre-Summit served as a platform to reflect, discuss, and strategize on two decades of the implementation of the Doha Declaration and the use of TRIPS flexibilities, its impact on health and access to medicines, the lessons from the Covid-19 pandemic and to both imagine and reimagine what the next two decades of TRIPS implementation will or could bring. The recognition, preservation, and sustainability of the work of civil society were central to the theme and sessions at the pre-summit regional dialogues.

Some of the questions discussed included:
- How did you fight patent barriers to access so far?
- Was it possible to use TRIPS flexibilities?
- What would be needed in the future for EU activists to continue this fight?

The dialogue provided a place for EU activists to reflect on the past 20 years since the Doha Declaration and is part of the weeklong **event GSIPA2M-2021Virtual: A Virtual Pre-Summit held from 14-21 November 2021** featuring plenary sessions, special lectures, regional workshops, side events, special sessions and much more.

Summary points

1. Opposition to patents of dubious validity
    - Presented by Médecins du Monde (MdM, Elena Urdaneta)
    - Patents on Sofosbuvir to treat Hepatitis C
    - Burden of disease for some vulnerable groups
    - Patents owned by Gilead patents
    - Post-grant oppositions at the EPO
    - 1st opposition: “2015 opposition was the ever first opposition proceeding against a drug patent carried out by civil society in Europe. We have demonstrated that we could successfully invite ourselves in the patent system in Europe to raise non-compliance with patent regulation”

- 2nd opposition (under examination) by MSF, MdM and others: The second opposition has a much stronger social and associative basis, since more than 30 organizations from 17 European countries have mobilized around a common political initiative.
- While impact on production and prices takes time, oppositions have considerably weaken the claims of initial patents
- Collaborations/coalitions are key for opposition of patents: it is a resource-intensive, technical activity

2. Coalitions at national level
    - Irene Bernal, Salud por Derecho and No es Sano coalition (Spain)
    - Campaign was started to raise the IP and A2M issue in the political agenda
    - It grew over the years; providing evidence-based documents in support to campaigns and actions targeting policymakers and other stakeholders
    - Focus: transparency, accountability and public interest in innovation
    - Alternative innovation mechanisms such as hospital production of CART-T treatments
    - Around 1/3 of initial prices
    - For oncology and other patients, and health systems
    - Hospital production authorized by a hospital exemption in Spain and other countries (Switzerland, the Netherlands)
    - This type of treatment was traditionally done by universities; Novartis started doing this but universities reacted
    - Important opportunity for the movement to advocate a new way that can be transferred elsewhere
    - Key alliances with hospitals and universities
3. Using competition law
    - 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
    - The competition case resulted after 2.5 years in a fine of €19.6m as Leadiant charged an excessive and unfair price, and thus was found making misuse of their economic power position
    - This decision is helpful in stopping the 'pharma piracy' business model making misuse of the EU Orphan drug incentives
    - Replicated in Belgium, Spain, and Italy
    - Competition cases are 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
4. TRIPS flexibilities tool

- 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
- In 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 the scope
- In combination with other tools and resources
- Connecting with European stakeholders, including generic manufacturers

5. Future work
    - Advocacy work on the new EU pharmaceutical strategy with a focus on data and market exclusivities and limits to compulsory licensing (the EU as a TRIPS-plus treaty)
    - Exchanges of information. Sharing of practices, for instance, information for competition cases to be initiated in different European countries or sharing the experiences of national coalitions to replicate good practices in other countries
    - Exploring and learning from stable collaborations for patent oppositions (case of the Coalition of seeds)
    - Interactions between NGOs and the European Patent Office (EPO) to raise awareness about A2M
    - Looking at the broad scope of Moderna patent on mRNA (how the patent affects all mRNA tech)

Resources

- The coalition 'No patents on seeds': https://www.no-patents-on-seeds.org/en
- Patent protection, data exclusivity and compulsory licensing in Switzerland: https://www.publiceye.ch/fileadmin/doc/Medikamente/ValerieJunod_Legal-Analysis-CL_20190129.pdf
- The CAR-T treatment is now also being done in the University Hospital Groningen, supported by an €30m grant of the NL government: https://www.umcg.nl/EN/corporate/News/Paginas/grant-30-mil-promising-new-cancer-treatment.aspx
- Compulsory licensing and opt-out by EU countries: https://medicineslawandpolicy.org/2020/04/never-say-never-why-the-high-income-countries-that-opted-out-from-the-art-31bis-wto-trips-system-must-urgently-reconsider-their-decision-in-the-face-of-the-covid-19-pandemic/, and https://www.keionline.org/32707

Agenda

09:30-09:35 **Welcome**
09:35-10:50 **Fighting patent barriers: the patent opposition for Sofosbuvir,** ***Elena Urdaneta, former Director General, Médecins du Monde (Doctors of the World)***
09:50-10:10 **Discussion**
10:10-10:15 **The experience of A2M and IP in Spain,** ***Irene Bernal, Salud por Derecho and No es Sano***
10:15-10:30 **Discussion**
10:30-10:40 **Using competition law: the experience of the CDCA Leadiant case in the Netherlands,** ***Wilbert Bannenberg, Pharmaceutical Accountabiliy Foundation***
10:40-11:00 **Discussion**
11:00-11:05 **TRIPS Flexibilities navigator: a tool to educate, empower and build community,** ***Jaume Vidal, Health Action International***
11:05-11:20 **Discussion: what do EU activists need to continue this fight?** ***Everyone***
11:25-11:30 **Final remarks**