

## Outcomes of A2M session at the Global Congress on IP

### Items for a research agenda:

1. **API Market** – Better understanding is needed of the costs and functioning of the API markets and both the IP and the cost factors that result in higher costs for local manufacture. API is a major determinant of drug prices and, esp in Brazil, is area of low transparency of the market.
2. **Voluntary Licenses** – causes and impacts. VLs are a growing trend and their terms can negatively impact unrestrained competition and price drops globally.
3. **Savings from a new R&D model** – We need data showing how a reform in the R&D system would translate into huge savings, even if there is a binding contribution commitment by countries. This evidence would be helpful to advocate for the R&D convention
4. **Patent Opposition Systems** – overview of where oppositions are allowed and whether the national law provisions make them feasible and accessible for civil society or not. Oppositions are a good strategy because allow for collaboration and don't rely on political will, but very few discussions on oppositions systems are out there.
5. **Competition Mechanisms** – overview of where oppositions are allowed and whether the national law provisions make them feasible and accessible for civil society or not. Oppositions are a good strategy because allow for collaboration and don't rely on political will, but very few discussions on oppositions systems are out there.
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7. **Competition mechanisms** – overview of provisions that can be used to fight abuses from pharma companies. Drug companies are increasingly creating clusters to control the market (through acquisitions, licenses)
8. **Manufacturing capacity** – analysis is needed on the manufacturing capacity of various countries. Where does this exist? Various countries are working to expand manufacturing capacity, but mapping of this would be helpful since it is a precondition to the use of many TRIPS flexibilities.
9. **Clinical trials** – how to strengthen the public health perspective at this level and how to make the data become a public good. Clinical trials are in the heart of the current expensive innovation system. Also is a stage of the research dominated by the logic of the market
10. **Training of patent examiners by industry and developed countries & poor outcomes** – There used to be a robust program of trainings for developing country patent examiners by WHO, but that has stopped under current leadership. This needs to be documented and the program revived. PLUS we need research showing poor *use* of existing laws limiting patentability—are they being applied? This is a major area where, de facto, TRIPS flexibilities are lost.
11. **Biotech drugs** – robust, detailed exploration of how the biologics markets currently function and how the problems of access will be different for biologics. (Include current and projected prices.) In the near future these drugs will invade the market for several diseases and the a2m movement has a lack of knowledge to discuss biogenerics, including the process of biosimilar/biobetters.
12. **Regional Procurement strategies** – There is increasing interest in pooled procurement. But how will IP impact ability to use these strategies? Can this argument be used to halt FTAs because of single country's affect on regional procurement? Conversations ongoing about pooled procurement at AU level, GFATM level, etc. but without IP conversation.
13. **Drugs pipeline** – set priority targets, are there X number of key drugs we should all focus attention on? Discuss possibilities of price reductions/prevent patenting of beforehand
14. **TRANSPARENCY & "Information Deficit"** – What are the ways that are/are not working to make the patent system more transparent and eliminate information deficits that activists and companies face? Are there countries or examples where all patents must be declared (on packaging?) in order

for them to be enforced? (Gopa) Major barrier to campaigning on key drugs and to oppositions work.

## **ACTION & COMMITMENT AGENDA**

1. Commitment to be actively engaged in the process toward 2013 Global Congress and to select members of A2M who will work on developing that track and making it a central opportunity for our colleagues who are not here.
2. Connect ongoing IP law reform initiatives and keep the GC network updated and ready to provide support when needed. (countries involved: Brazil, South Africa, Argentina, Uganda, Malawi)
3. Development of a list of priority flexibilities and orientations to make them more efficient (Gopa, GTPI, Peter and Chicosa)
  - Compulsory licenses (Issues: freedom to set the grounds, limit to compensation, simplified procedures)
  - Patent Oppositions (Issues: pre and post, feasible deadlines, low costs, anyone allowed to present)
  - Patentability Criteria (Issues: Strict criteria, exclusions from patentability. Argentinean Guidelines. Anvisa's prior consent)
  - Parallel importation
  - Bolar Exception
  - General challenges for the use of flexibilities: Manufacturing capacity / information deficit
4. Letter supporting the participation of the Health authority on the review of patents in Brazil to be submitted to the ongoing public consultation. (Draft: Marcela)
5. Letter in defence of the new patent examination guidelines approved in Argentina (Draft: Marcela)
6. Support to the actions in Guatemala to contest data exclusivity on Kaletra (Focal Point: Francisco Rossi)
7. Open letter to WHO board to annul the meeting where the discussion on a R&D convention was postponed (Draft: Gopa) BEFORE JANUARY 20<sup>th</sup> meeting
8. Develop a positive message in Europe about the need of an R&D convention (Juliana)
9. Build support to deadline extension of LDC in Developed and developing countries (Celine, Matt, Gopa and Pedro) – Civil society letter
10. IDEA: call for applicants to be obliged to provide the non-proprietary names (INNs) in the patent applications and to disclose the full list of countries where the application was filled.
11. Call for public databases on patents to be more updated and transparent, showing patents covering each drug and pointing out which patents effectively block competition. Major barrier = "information deficit" & Transparency. But solution??
12. Keep commitment with the fight against TPP, EU-India FTA and other FTAs that can have a negative impact on access to medicines

## **Opportunities + demands**

1. National patent-reform efforts: Brazil, South Africa, India (?), Argentina, Uganda, Malawi, ARIPO
2. UNAIDS meeting on MICs (Marcela)
3. BRICS health Ministers meeting (10 & 11 January) (Support to the R&D convention)
4. TRIPS Council Meetings (5,6 March / 10, 11 June / November)

- LDCs deadline extension likely considered in March
  - Problems in the use of flexibilities needs to be tabled
5. Ministerial Meeting in Bali – Doha developing round (December 3-6, 2013)
  6. Global Commission on HIV and the Law Report - Pressure on UN agencies to do something with it, Opportunities for scholars to amplify important findings
  7. Document produced by ARIPO on local manufacture

## **Common messages and coalition building**

*Key messages we are hoping all groups can embrace:*

- Rights language (individual, sovereign)
- Costs vs. Benefits for people and countries

*Opportunities for joint action*

- R&D Agenda... how will it be funded? Can medical + technological come together?
- TRIPS? 2013 Ministerial—opportunity for reevaluation of the model?

*Request for Help*

- A2M groups are facing a resource crisis—the funder exit has hit A2M groups especially hard since both government and foundation funding has been slashed and there is no segment of industry (e.g. Google) willing to support.

## **Narrative**

Fundamental rights of people, like Health and Freedom of expression are increasingly under threat, as well as Sovereign rights of states. In addition, the extraordinary costs of closing the knowledge economy negatively impacts lives, budgets, Innovation. More than ever is important that movements resist together to violations and reform together the current system.

Our fights in the field of flexibilities should be re-framed in the perspective of a fight for “sovereignty rights”. In this sense, we believe other movements could join forces with A2M to fight in the level of “sovereignty rights”.

In the case of Trade agreements for example, Basic rights like the right to health and the right to expression are under threat, so the movements should definitely keep working together to resist.

The conflict corporate rights vs citizens rights is being more and more expressed not only in trade agreements but also in the private power influence over multilateral agencies. The A2M movement will work in order to push WHO to recover its neutrality and independence, and may this effort can be connected to similar actions by other movements concerned with the role of multilateral agencies.

The A2M movement is increasingly interested in showing the huge cost of the IP based model and how countries simply cannot afford it anymore. Alternative models are urgently needed. Any moves in the discussion of the cost of the system by other movements can offer a possibility for collaboration.

Biomedical research is an essential area of cross-over—it is access to knowledge, produced with public support, and yet increasingly privatized. Opportunities to translate knowledge into medical innovation through open access is an essential shared goal across A2K & A2M movements.

The A2M movement is now facing an amazing opportunity to change the way medical innovation is conducted. For years A2M activists have pointed out how the patents based model failed to deliver the medicines that most of the population needs, and how this system is unaffordable. After years of discussion at multilateral levels, a report came out proposing an R&D convention based on the principles of de-linkage, open innovation, public goods. The negotiation of such a convention would be a landmark not only for A2M, but for all those trying to build an “Open Society”. However, we are losing the battle. Because of lack of political will and financial crisis, countries are not following this important recommendation. We urgently need support to push governments to negotiate this convention, which certainly will be a powerful precedent for all movements defending open access to knowledge goods.