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CONSTRAINTS FACED BY DEVELOPING COUNTRIES AND LEAST DEVELOPED COUNTRIES (LDCs) IN MAKING FULL USE OF PATENT FLEXIBILITIES AND THEIR IMPACTS ON ACCESS TO AFFORDABLE ESPECIALLY ESSENTIAL MEDICINES FOR PUBLIC HEALTH PURPOSES IN THOSE COUNTRIES

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The Scope of the Study

- TERMINOLOGIES
- CONSTRAINTS TO THE FULL USE OF PATENT FLEXIBILITIES BY DEVELOPING COUNTRIES AND LDCs
- IMPACT OF CONSTRAINTS ON THE ACCESS TO AFFORDABLE ESPECIALLY ESSENTIAL MEDICINES FOR PUBLIC HEALTH PURPOSES IN DEVELOPING COUNTRIES AND LDCs
- PRELIMINARY CONCLUSIONS

TERMINOLOGIES – Patent flexibilities

The term “flexibility” in TRIPS (paragraph 6 of the preamble and Article 66.1)

The Doha Declaration. The expression “flexibilities” had gained widespread use in the broader sense. Paragraph 4.“Members reaffirmed their right to use…, the provisions in the TRIPS Agreement, which provide flexibility for this purpose”

The Doha Declaration, in paragraph 5, clarifies that these flexibilities include the right to Members to: applying the customary rules of interpretation of public international law when interpreting the TRIPS Agreement; the right to grant compulsory licenses and the freedom to determine the grounds; to determine what constitutes a national emergency or other circumstances of extreme urgency; to leave each Member free to establish its own regime of exhaustion.

The term “TRIPS flexibilities” means that there are different options through which treaty commitments can be transposed into national law, thus, national interests are accommodated and yet TRIPS provisions and principles are complied with.

“Flexibilities” as a mechanism to consider national policies

Flexibilities go beyond health issues, since this concept is not technology-oriented

- i.e., CLs

Some examples of flexibilities that play a role in promoting access to medicines

- Transition period
- Exhaustion
- Patent term of protection
- Exclusions from patent protection
- Exceptions and limitations

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TERMINOLOGIES – Full use of patent flexibilities

Countries exercise their right to choose options made available in international treaties to meet their domestic policy objectives

- a government makes choices from the various options and
- implements those choices under the national legislation

Once the government transposes options in the international agreements to the national level, various individual stakeholders use the national legal framework

- there is public expectation that adequate use of the national legal framework by each stakeholder would lead to the attainment of the public policy goals, such as public health and access to medicines

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CONSTRAINTS TO THE FULL USE OF PATENT FLEXIBILITIES BY DEVELOPING COUNTRIES AND LDCs

- Constraints encountered by governments at the stage of national implementation of flexibilities
  - *Constructive ambiguity of international treaties*
  - *Complexity of practical implementation*
  - *Operation of law and administrative framework*
  - *Institutional capacity*
  - *National governance and internal coordination*
  - *Extrinsic influences*
- Constraints faced by various stakeholders in using a national legal framework that has implemented policy options
  - *Ambiguity and uncertainty of national law*
  - *Technical and technological capacity*
  - *Identifying relevant patents and their status*
  - *Other aspects that affect the use of compulsory licenses*
  - *Other challenges where use of flexibilities has not led to intended policy outcomes*

TRIPS Agreement implementation
Art. 27 and some of its flexibilities

Explicit obligation to give protection

- Inventions – whether products or processes – in all fields of technology
- Micro-organisms

Explicit permission to exclude from patent protection

- Plants and animals
- Diagnostic, therapeutic and surgical methods

Implicit permission not to give protection

- Discoveries
- Substances existing in nature
- Incremental innovation

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Ambiguity and uncertainty of national law – One example…(one example taken from a national patent law)

"The following is not recognized as an infringement of the exclusive right of the patent owner:

4) Application of means containing objects of industrial property protected by patents if these means are introduced into an economic turnover in a legal way in compliance with the rights granted by a patent owner. In this case the person who under the permission of the patent owner acquires a mean containing patented object of an industrial property or manufactured with the use of the patented method, shall have the right to use or dispose this mean without additional permission, unless otherwise is provided by the agreement."

IMPACT OF CONSTRAINTS ON THE ACCESS TO AFFORDABLE ESPECIALLY ESSENTIAL MEDICINES FOR PUBLIC HEALTH PURPOSES IN DEVELOPING COUNTRIES AND LDCs

- The literature review has shown that no meaningful empirical studies have been published to date that would allow credible conclusions about the impact of constraints to the full use of patent flexibilities on access to medicines in developing countries and LDCs.
- Empirical studies have examined the relationship between patent protection and pharmaceutical product launch in developing countries, between patent systems and the pharmaceutical trade value, or between patent protection and general availability of medicines in developing countries and LDCs (SCP/21/8, pages 21 and 22).

Several countries' experiences regarding the impact of the use of certain patent law provisions on access to medicines reported during the SCP sessions

- The Delegation of Brazil (compulsory license that the government had issued to local producers on antiretroviral drug efavirenz in 2007).
- The government of Thailand (CL regarding a cancer drug imatinib).
- Empirical work on parallel trade on the case of the European Union (EU).
- European Commission report on the pharmaceutical sector (2009).
- The Commission on Intellectual Property Rights, Innovation and Public Health' Report (2006).
- Member States during the SCP discussions, stressing the multifaceted nature of the problem (Delegation of Slovakia, speaking on behalf of the European Union and its Member States and the proposal of the Delegation of the United States of America).

The access to medicines discussion – Two dimensions…

- From the health policies point of view
- From the patent policies point of view

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From the health policies point of view

- It would be dificult to ignore the challenges that humanity face on the issue of access to medicines:

  “the WHO estimates that one third of the world population has no access to essential medicines” The world Medicines Situation 2011, Vogerzeil and Mirza, WHO, Geneva 2011

- Access to essential medicines has become an indicator of the Governments commitments to the right to health

  The UN High Commissioner Sets of Indicators, namely, 12 indicators for human rights, including the right to health and access to medicines as a indicator of the later

From the health policies point of view, cont'd…

However caution has to be shown when addressing the impact of patents as the "cause" or "solution" to this problem.

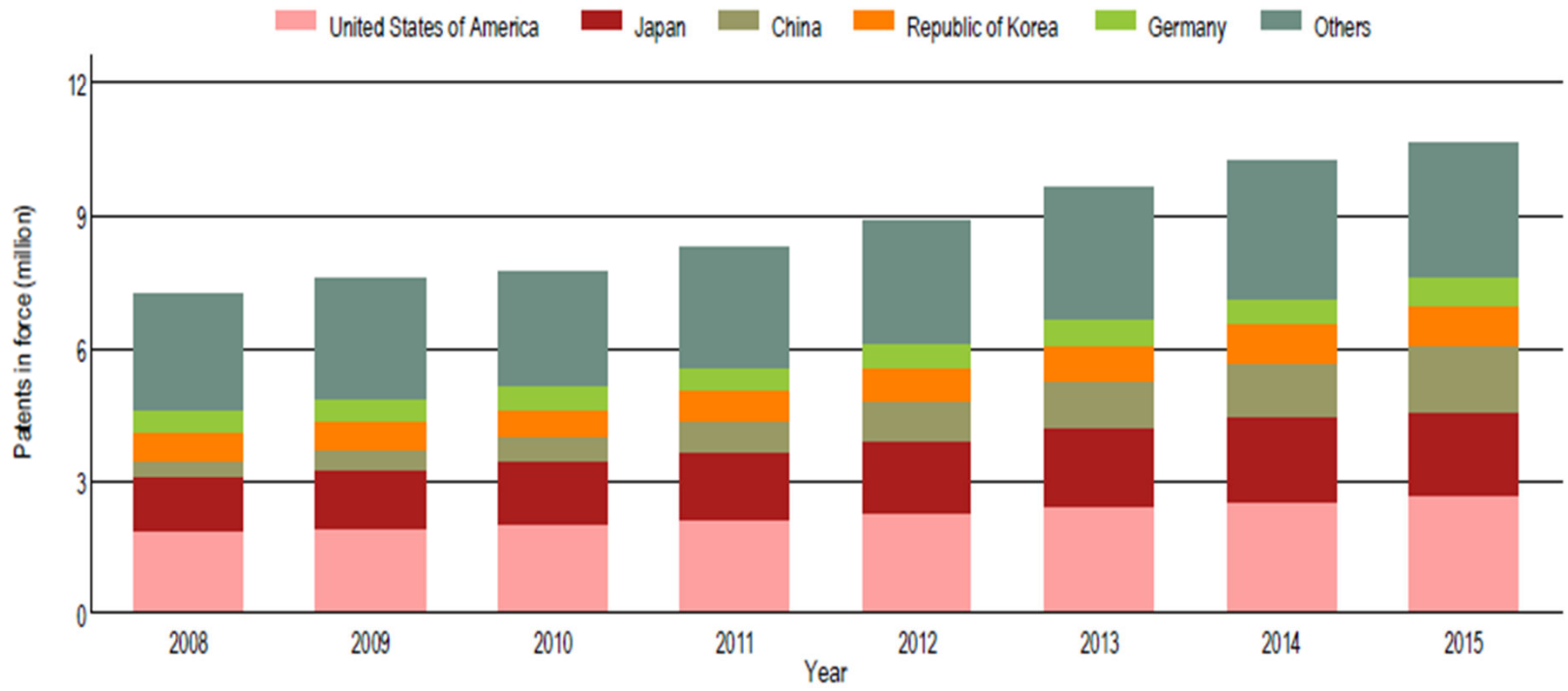
A syllogism like (**lack of any logic**)

- there is an access to medicines problem
- Patents rights exclude the access
- Thus, patents cause the problem

To properly address to patent impact, there is need to answer the following question: How many essential medicines are under patent in a given country?

Patents in force

A40 Trend in patents in force worldwide



Note: World totals are WIPO estimates using data covering 108 patent offices.

Source: WIPO Statistics Database, October 2016.

PATENTS AND ACCESS TO ESSENTIAL MEDICINES

- It is only when patents in a given medicine exist locally (consuming or importing country) and/or in the manufacturer's country (supplying or exporting country), that patents can *lawfully* impede access.
- For those life saving/sustaining medicines considered by WHO, a Model List of essential Medicines (MLEM) is provided to guide countries and other global health actors.
- The study of Beall & Amir Attaran (2016) regarding the 18th edition of the WHO MLEM shows the following data:

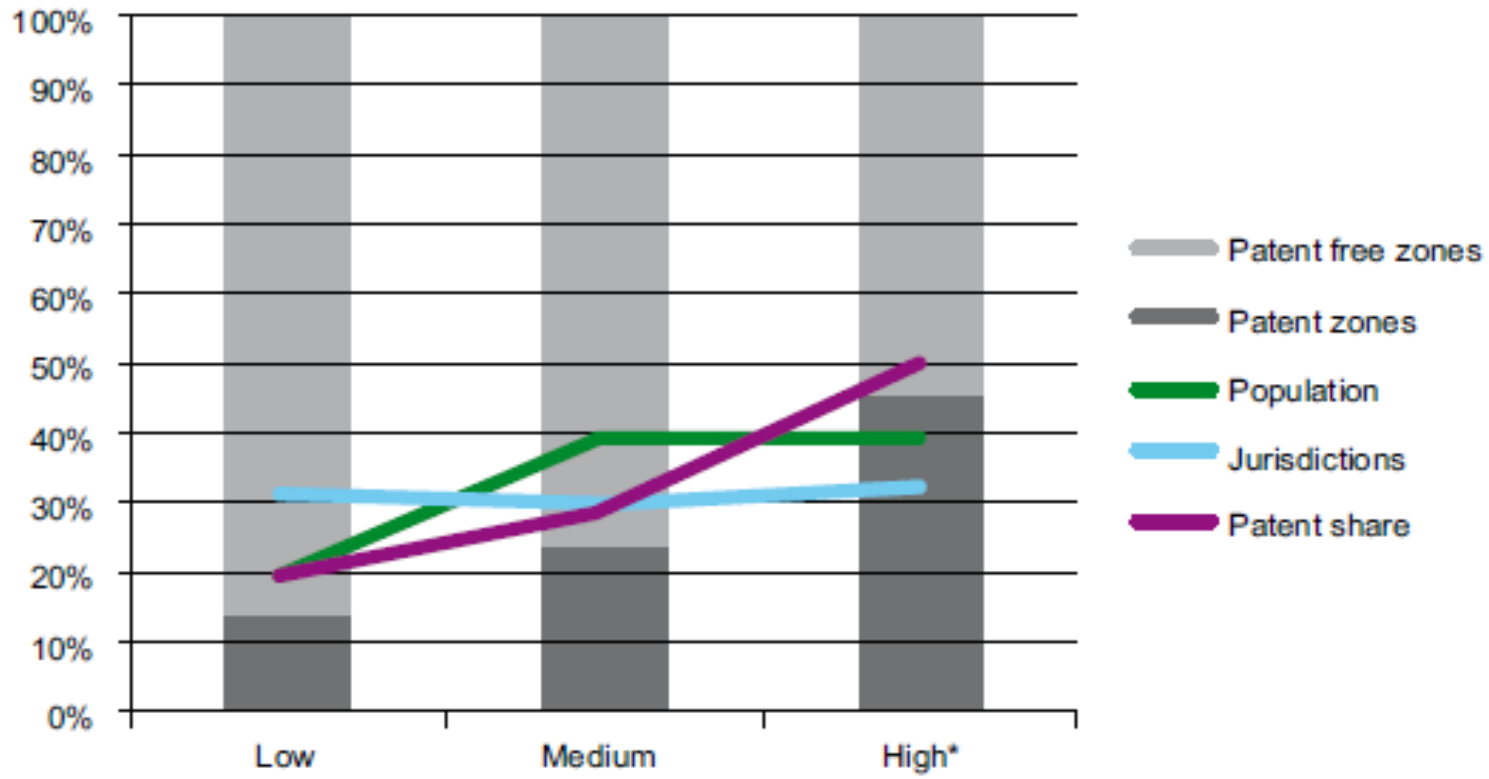
  - 20 of the 375 items listed in the WHO MLEM are under patent (5%).
  - 13 out of those 20 items are for HIV and the other 7 are antibiotics or for non communicable disease.
  - Regarding 137 countries covered, for those 20 products (patented in USA and Canada), the patent situation in developing countries is as follows: no patents filings in 44 countries, 11 countries received 1 single filing, 16 countries just 2 filings.

NUMBER OF PATENTS AND JURISDICTIONAL COVERAGE BY MEDICINE WITH EXPIRATION RANGES

Medicine	Jurisdictions with active filings	Active filings	First expiration	Last expiration
Abacavir	53	152	2018	2023
Artemether + lumefantrine	1	1	2018	2018
Atazanavir	20	67	2017	2031
Azithromycin	8	28	2018	2022
Bevacizumab	9	16	2017	2019
Didanosine	20	44	2015	2024
Efavirenz	23	69	2015	2024
Efavirenz + Emtricitabine + Tenofovir	42	173	2015	2029
Emtricitabine	11	21	2015	2022
Emtricitabine + Tenofovir	41	95	2017	2024
Lamivudine + Nevirapine + Stavudine	22	65	2021	2028
Lamivudine + Nevirapine + Zidovudine	34	34	2017	2018
Lopinavir + ritonavir	38	135	2016	2028
Omeprazole	6	8	2015	2022
Oseltamivir	7	19	2016	2018
Pegylated interferon alfa 2a	60	60	2017	2019
Pegylated interferon alfa 2b	14	29	2016	2022
Ritonavir	38	153	2016	2028
Saquinavir	28	28	2024	2024
Tenofovir	11	52	2015	2029

Beall & Amir Attaran (2016)

PATENT PERVASIVENESS BY HUMAN DEVELOPMENT INDEX GROUP



* An HDI category of "high" is mostly upper-middle income countries, according to the World Bank.
This study did not include countries in the "very high" HDI category.

Beall & Amir Attaran (2016)

TOP 20 COUNTRIES FOR PATENT FILINGS OF MEDICINES APPEARING ON THE MLEM

Country	Region	Filings	# of MLEM drugs patented	HDI	Population in 1000s	Health spending per capita (rank relative to other 137 nations in study)
China	East Asia & Pacific	134	16	High	1401586.60	$373 (49th)
Mexico	Latin America & Caribbean	111	18	High	125235.58	$962 (9th)
Romania	Europe & Central Asia	79	16	High	21579.20	$881 (12th)
Philippines	East Asia & Pacific	71	13	Medium	101802.70	$164 (79th)
Bulgaria	Europe & Central Asia	67	14	High	7112.64	$1,057 (6th)
Brazil	Latin America & Caribbean	62	13	High	203657.21	$1,009 (8th)
Turkey	Europe & Central Asia	61	12	High	76690.51	$1,039 (7th)
India	South Asia	60	11	Medium	1282390.30	$126 (88th)
South Africa	Sub-Saharan Africa	50	15	Medium	53491.33	$915 (10th)
Indonesia	East Asia & Pacific	38	12	Medium	255708.79	$123 (89th)
Serbia	Europe & Central Asia	37	9	High	9424.03	$1,176 (4th)
Albania	Europe & Central Asia	37	10	High	3196.98	$515 (34th)
Macedonia, FYR	Europe & Central Asia	37	10	High	2109.25	$758 (18th)
Malaysia	East Asia & Pacific	32	10	High	30651.18	$645 (22nd)
Ukraine	Europe & Central Asia	28	11	High	44646.13	$527 (31st)
Belarus	Europe & Central Asia	24	7	High	9259.67	$762 (17th)
Colombia	Latin America & Caribbean	24	8	High	49529.21	$614 (26th)
Thailand	East Asia & Pacific	24	8	High	67400.75	$331 (54th)
Azerbaijan	Europe & Central Asia	23	7	High	9612.58	$520 (33rd)
Kyrgyz Republic	Europe & Central Asia	23	7	Medium	5707.53	$152 (82nd)

Beall & Amir Attaran (2016)

PRELIMINARY CONCLUSIONS

- In implementing flexibilities into their national laws with a view to access to medicines, governments seek to strike a right balance among diverse interests, with a view to ensure access to both existing and future medicines
- The debates related to “full use of flexibilities” takes place at two levels: (i) Government choice and transposition of international law and (ii) use of national provisions by individual stakeholders
- No credible conclusion can be drawn on the impact of full use of patent flexibilities on access to medicines, let alone the impact of constraints to such use, due to lack of data sufficient to permit empirical impact analysis
- One way to help inform policy dialogue on these issues could be through reporting by the Member States on implementation and use of patent flexibilities in their territories. Questionnaires? Sharing Sessions? Other ideas?

MANY THANKS !!!

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