

Panel: How would we change the TRIPS Agreement?

# Legal Rules and Political Realities

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Presentation at

Médecins Sans Frontières' Access Campaign

Revising TRIPS for Public Health:

Can TRIPS be reformed to meet public health needs?

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# Variable Geometry in TRIPS

- It is well-recognized that intellectual property protection has different technical, economic and social consequences in different subject matter areas
- TRIPS Agreement design focuses on the “forms” of IP and generally reflects a principle of non-discrimination among subject matter
- An alternative TRIPS Agreement could be divided among subject matter categories, with forms of IP addressed with subject-matter specificity
- Such “variable geometry” could be reflected in reorganized TRIPS Council working groups

# Sustainable Medicines Supply Systems

- A wide range of proposals is being made to improve the efficiency of R&D, production and distribution of medicines
- If adopted, such proposals might well require direct amendment of the TRIPS Agreement or, as an alternative, agreement among states party to the new mechanisms to modify application of the TRIPS Agreement among themselves
- For example, a consensus-based R&D Treaty among all WHO member states could be used to modify rights and obligations under the TRIPS Agreement as a later in time treaty among the same parties (see Article 30(3), VCLT); narrower adherence raises complications (see Article 30(4), VCLT)
  - The WTO Appellate Body has recognized the WTO is not a self-contained legal system, and would recognize later-in-time coincident party treaty modifications
- From a purely legal standpoint, the difficulties of modifying the TRIPS Agreement to accommodate new arrangements should be surmountable, but advance work should be done

# The TRIPS Agreement Applied

- *Canada-Generics* panel at WTO upheld regulatory review exception under Article 30
- A number of the “incidents” raising most serious problems have not involved genuine TRIPS-inconsistencies
  - South Africa Medicines Act notable for lack of plausible TRIPS complaint
  - Legal complaints concerning issuance by Thailand of government use/compulsory licenses “spurious”
  - Novartis proceeding against Section 3(d) of Indian Patent Act very unlikely to succeed in hypothetical WTO dispute (Swiss government declines to pursue)
  - Regarding seizures of generic medicines in transit based on patent, combination of GATT and TRIPS rules serve to restrain mercantile excess

# Controlling *Abuse* of the TRIPS Agreement

- Abusive invocation of the TRIPS Agreement by powerful actors should be subject to greater control
- Abuse by private sector enterprises can be addressed by competition and unfair practices laws, with compulsory licensing, monetary damages, and other penalties applied
  - A few model cases might be sufficient to modify general behavior
- Inter-governmental remedies may be limited to more powerful actors, but cross-retaliation cases at WTO have demonstrated inherent power in threatened suspension of IP protections

# TRIPS Agreement one element in larger picture

- Governments at all levels of development face budgetary constraints, and relatively few treat comprehensive access to medicines as genuine priority
- International mechanisms to finance procurement and distribution of essential medicines are reasonably within reach
- Mechanisms for improving supply of advanced treatments are realistic, including fair compensation royalty arrangements
- Rational prescribing and better attention to quality safety and efficacy are important

# The reality of the TRIPS Agreement

- Eliminating the TRIPS Agreement likely would not result in a dramatic change to the global medicines supply situation
- Many critical scientific challenges remain, which the TRIPS Agreement debatably affect at the margin at this stage
- Alternative to TRIPS Agreement is not “protection vacuum”, but reversion to pre-and mid-Uruguay Round era
  - Bilateral relations, likely increased threats and retaliation
- In pursuing modification of TRIPS Agreement, “Be careful what you wish for”. Negotiations do not always turn out as hoped

# Political leadership needed

- Courageous and pragmatic political leadership is “more necessary” than modification of legal rules
  - Priority-setting, financing and willingness to move forward are critical elements
  - This is not to suggest that changes in legal rules are not desirable or necessary, but rather to stress that governments and policymakers do not take adequate advantage of existing rules
  - It is easier for governments to debate policy in Geneva than to act at home
- A final few words about the Medicines Patent Pool