nccr trade regulation
swiss national centre of competence in research

# *Future Challenges Regarding the International Regulation of IPRs and Biotechnology*

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# Human Rights, Graduation and the Research Exemption

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# Introduction/Agenda

- The Role of Human Rights in Biotechnology
- Research Exemptions in Patent Law and Ceilings
- S&D and Graduation in IPRs

# IPRs & Human Rights

- IPRs are utilitarian in nature and do not have a human rights character (exception moral rights in copyright)
- Human Rights influence the shaping and scope of intellectual property rights (e.g. right to health and access to essential drugs)

# Biotechnology Regulation & Human Rights

- Human rights appear to cut both ways in substantive terms, with the exception of a clear ban on biological warfare
- Human rights shape the process of balancing interests and values but do not offer clear guidance in the field
- Human rights are, however, of prime importance in procedural terms. They help in shaping appropriate legal avenues and participation in assessing biotechnology in research and commercial use
- E.g.: PIC, disclosure of origin (TK), due process in patent examination and litigation.

# Research Exemption in Patent Law

- Risk of patent thickening particularly in biotechnology – anti-competitive effects adverse to innovation
- The right to use a protected invention (product or process) for purposes of research (use)
- Broad recourse to research exemption in many countries, but differences ins scope
- TRIPs compliance (fair use exemption Art. 30; Canada – Patents)?

# Factual Evidence

- "In total, the inquiry reveals at least 1,100 instances where the patents held by an originator company potentially overlap with the medicines, R&D programs and/or patents held by another originator company for their medicine. In these cases originator companies might find their research activities blocked, with detrimental effects on the innovation process. In many cases originator companies managed to settle potential disputes, for instance through licensing arrangements. However, in approximately 20% of the 99 cases where a license was requested, the requesting companies did not obtain a license. Reportedly, in several cases this led to the discontinuation of the. R&D project or required additional efforts to go around the obstacles."

- Final Report on Competition Inquiry into the Pharmaceutical Sector, Commission Communication, European Commission, DG Competition, 8 July 2009, available at http://ec.europa.eu/competition/sectors/pharmaceuticals/inquiry/

# Impact of Divergence

- Practical problems in enforcing right to ban research (processes and product patents)
- Legal Insecurity in terms of WTO compatibility (Art. 30 fair use; *Canada – Patent*)
- Trade distortions and complications due to diverging rules

# Harmonization of Research Exemption Rules: Ceilings

- Widely shared interest in research exemption as a tool for innovation, in particular in biotechnology, but also beyond
- Protection of research tools (process patents)
- Harmonization and obligation to introduce research exemption in domestic law
- Ceiling provision: mandatorily limiting protection in research

# Graduation in TRIPS

- Unequal treatment of unequal facts required by law
- Equal treatment of unequal countries remains an unresolved problem and challenge: Special and Differential Treatment of DC (S&D) does not work (e.g. Transfer of technology, Art. 66:2 TRIPs)
- New approaches required

# Graduation

- From progressive liberalization to progressive regulation
- Recourse to threshold legislation, using economic indicators relating to competitiveness of sectors and economy
- Obligations to protect biotechnology inventions dependent upon levels of competitiveness
- Recourse to extraterritorial protection for MNE's in sub-threshold countries

# Thank you for your attention!