

Intellectual Property Issues in Geneva, Focus on Public Health

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Key Issues:

- Health
- Environment / Climate Change
- Biodiversity / Genetic Resources
- Traditional Knowledge
- Food Security
- Access to Knowledge



Paying For The Idea

- Research and development can cost millions



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But...

- Monopoly pricing can leave new innovations out of reach of people who need them



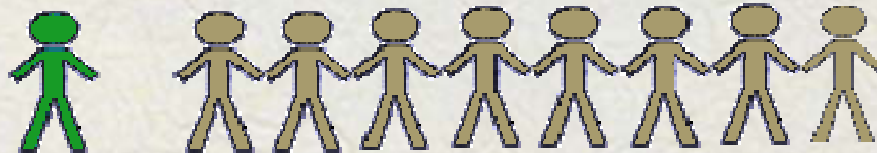
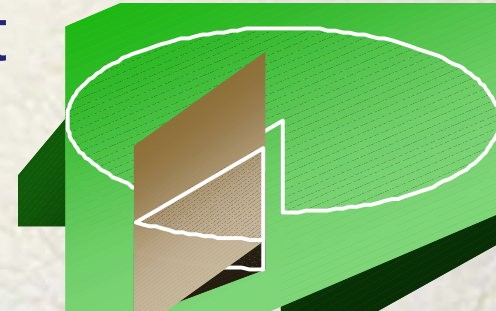
IP And Medicine

- IP helps reward pharmaceutical companies for making drugs
- But:
 - Expensive drugs unavailable to the poor
 - Diseases for the poor don't get treated because there is no market for the resulting drugs



The 10/90 Gap

- Research funding -- only 10 percent is going towards diseases that primarily affect the poorest 90 percent of the population
- These diseases therefore are considered “neglected”



Why does IP matter so much to public health?

- With most common medicines, once the formula is known, making more is relatively trivial cost-wise
- *The idea is everything*
- Therefore the cost of idea licensing is a significant part of overall cost



IP and Other Global Issues

- Similar debate:
 - How to ensure that the right technologies are developed
 - How to ensure that those technologies get in the hands of people who need them
- Also:
 - How to use the patent system to protect against misappropriation



Key Geneva Players

- World Health Organization
 - Global Strategy and Plan of Action
 - Pandemic Influenza Preparedness
 - Counterfeit Medicines
- World Trade Organization
 - Trade-Related Aspects of Intellectual Property Rights (TRIPS)
- World Intellectual Property Organization



WHO and Innovation

What incentive mechanisms are needed to encourage public health innovation – in vaccines and medicines – relevant to developing countries?



WHO: The Global Strategy

- Commission On Intellectual Property Rights, Innovation, and Public Health (2004 - 2006)
- Intergovernmental Working Group on Public Health, Innovation and Intellectual Property (2006 - 2008)
- Global Strategy and Plan of Action on Public Health, Innovation and Intellectual Property (2008 - present)



WHO: CIPIH, mandate

- Summarise disease evidence
- Summarise research to date
- Consider IP as a factor, as well as other funding mechanisms
- Analyse potential solutions
- Make proposals



WHO: CIPIH, outcomes

- Intellectual property rights are a “general incentive” but need to be seen as “part of a bigger picture”
- Markets often small, and different incentives may be needed
 - Foundations
 - PPPs
 - TRIPS flexibilities



But...

- 5/10 commission members file reservations
- 2 say it outpaces mandate, doesn't elaborate enough on patent distortions preventing generic access
- 2 say it falsely links patents -> price -> access (where is really lack of infrastructure / procurement schemes, poverty)
- 1 says there should have been more evidence-based analysis



WHO: Intergovernmental Working Group, mandate

- Tasked with creating the Global Strategy and Plan of Action
- Member-state driven (rather than expert driven)
- Yields “most important document since Doha on IP and public health.”



WHO: IGWG, key outcomes

- Priority needs assessment
- Implementation of new incentive schemes for R&D
- Improving developing country R&D capacity and access to health products
- Boosting technology transfer
- Securing sustainable financing



May 2008, Global Strategy Adopted

“Public health leaps ahead in addressing two fundamental and long-standing needs: to improve access to existing interventions, and to include diseases of the poor in the drive to develop new products.” - Margaret Chan



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Case study: Chagas



- Affects 8-11 million people in Central and South America and Mexico
- Potentially life-threatening if left untreated
- Serious complications in about 30 percent of infected people
- No vaccine, and treatments for acute stage limited to symptoms



Case Study: schistosomiasis

- Most devastating parasitic disease after malaria*
- Transmits via fresh water
- ~200 million infected in Africa, Asia and South America
- Not deadly but can damage CNS, cause fever, fatigue



- Bayer, Merck and WHO collaborate
- Praziquantel medication
- Shin Poong Co., South Korea
- Egyptian International Pharmaceutical Industries Company
- However...



But: Where do things stand now at WHO?

- In May 2008, two “urgent” actions
- Delay in adopting outstanding parts of plan of action; not much accomplished in remainder of 2008
- Expert Working Group on R&D financing -- the key outcome for many -- didn't meet until January 2009, and then talked “process”



Expert Working Group, At Issue

- How to create sustainable financing mechanisms (either through the creative use of intellectual property or via other means) for neglected disease research
- Concerns:
 - that it won't be truly innovative
 - transparency of process



“Counterfeit” And Sub-Standard Drugs

- Mislabeled, misleading, or poor quality medicines are a real danger to public health

However...

counterfeit \neq sub-standard \neq generic



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Counterfeit

- “Counterfeit” has a legal meaning under the WTO TRIPS agreement, explicitly linking it with trademark violation
- At the WHO, protest against term because:
 - Association could “open door” to IP enforcement in a health agency
 - IMPACT group not representative

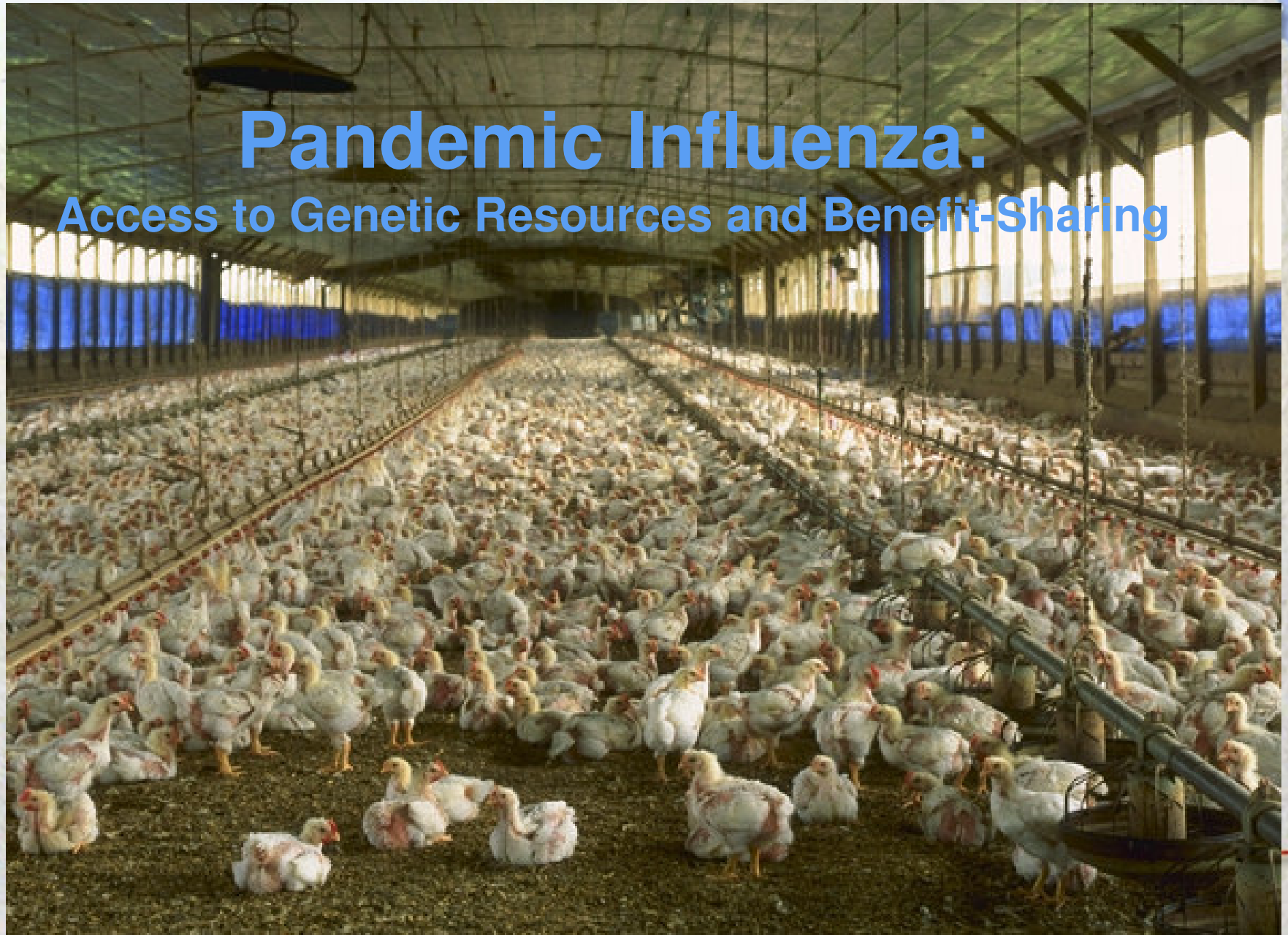


Related problems: borders

- Non-traditional IP enforcement, under “protecting public health”
- The World Customs Organization
- EU border delays and potential threats to South-south trade
 - EU regulation changes in 2003, widening scope of applicability
 - Customs agents not equipped to determine patent violation



Pandemic Influenza: Access to Genetic Resources and Benefit-Sharing



Preparing For A Pandemic

- H1N1 may not be the disease, but it is likely at some point there will be one
- Pandemic flu is a problem because it will affect parts of the world not normally equipped to manufacture flu vaccines
- Vaccine manufacture, especially on influenza, is quite complicated



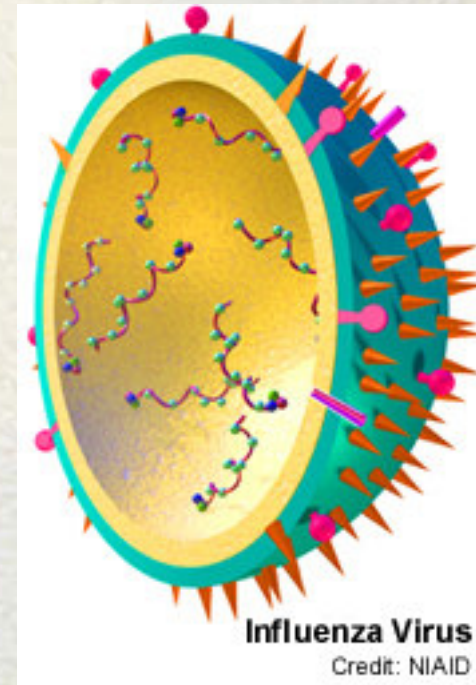
Key Question:

- How to create enough vaccines fast enough
- How to ensure they get to the people who need them
 - Priority: health workers, electricity, water, fire, roadwork, police
 - Vulnerable: old, young, people with immune deficiency
- *How to ensure they get to people who can't afford them*



Who Owns Viruses?

- Seasonal flu mutates and each year different strains are considered a problem
- Each year, the challenge is to match prepared vaccines to expected virus strains
- There is an influenza virus sharing network through WHO that helps find these strains



Avian Flu

- Outbreak is in developing countries in the tropics -- mainly Indonesia
- Little seasonal flu experience
- Concern:
 - If viruses given away
 - How to guarantee vaccine access?



Pandemic Influenza Framework

- Critical parts of the influenza framework-- in particular a legally-binding Standard Material Transfer Agreement detailing obligations of laboratories receiving pandemic-related materials (viruses, parts of viruses) -- not yet finished
- DG Chan is meant to finalise for January



WTO: TRIPS and Public Health



Doha Declaration

- 2001: public health declaration affirms TRIPS flexibilities
 - Right to grant compulsory license
 - Freedom to determine grounds for CL
 - Freedom to define “national emergency” or other urgent circumstances
 - Freedom to determine exhaustion of IP rights



“Paragraph 6 Solution”

- The ability to export all drugs produced under compulsory license to those who need it
- But... “a decision gone wrong... diplomatic compromise with little practicality. The mechanism put in place is difficult to operate, because it is based on a case-by-case, drug-by-drug, country-by-country process. You cannot maintain a generic drug industry based on an order-by-order supply decision making process.” Ellen ‘t Hoen, MSF

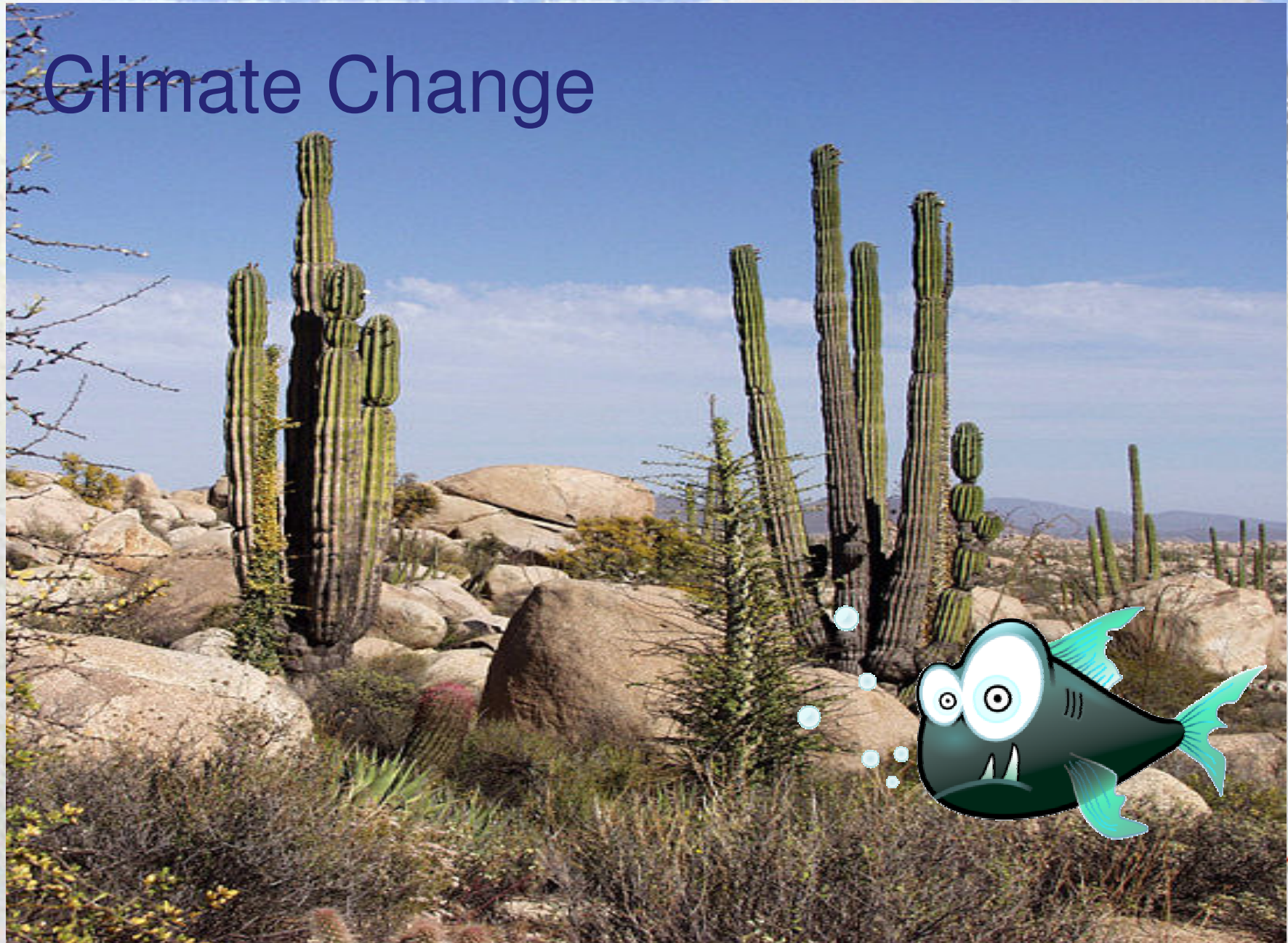


Patentability of Drugs

- Countries have right to decide patentability criteria
- Three-step test: novelty, inventive step, industrial applicability
- Eg. A pharmaceutical chemical compound is patented, but different forms (such as cream versus ointment) are not.
- Pre- and post-grant opposition



Climate Change



No More Business As Usual

- Climate change is a threat to the future of civilization
- Technology transfer being recast as a matter of global public good
- IP, as a source of incentive to innovate and as a potential barrier to access, will also be critical



United Nations Framework Convention on Climate Change

- Currently trying to update the Kyoto agreement in an attempt to create a framework to combat danger of climate change
- The IP section contains 4 options, all “bracketed” (or, not agreed), and very far apart



- “We know that IP is an incentive, no one denies that. The people who pay for R&D have the right to keep the rights on their technology. At the same time, how are we going to balance the incentive for an innovator with need to diffuse? This is not an issue of morality or charity, it’s a commitment issue, under the article of the convention. ”
Wanna Tanunchaiwatana (technology sub-programme, UNFCCC)



Is IP A Barrier To Diffusion?

- Environmental technology is not pharmaceuticals
- *It's not just the idea*
- Base technology is often off-patent
- Other issues add to the cost -- engineering, building materials



For example, wind turbines



However...

- Technology needs to be diffused as quickly as possible, and as cheaply as possible to combat climate change
- Martin Khor, South Centre: business as usual cannot continue, than neither can IP as usual.



Case: UNFCCC options

1. Use the IP system to promote technology development, diffusion and transfer
2. Remove barriers to tech development, diffusion and transfer arising from IP protection, including exclusions from patenting
3. Exempt LDCs and vulnerable countries from IP on climate-related adaptation and mitigation technology
4. Establish an expert group to create a framework for evaluating when IP is a barrier, and to make recommendations

Option 1:

“Technology development, diffusion and transfer [shall] be promoted by operating the intellectual property regime. [This process shall also make use of the flexibilities in the IPR regime to][in a manner that encourages development of climate-friendly technologies and simultaneously] [such as compulsory licensing to] facilitates [the][their] demonstration, diffusion and transfer to developing countries.

Option 1, continued:

Buy down the cost of technologies to provide the: (a) Full cost for LDCs; and (b) Partial cost for other developing countries taking into account the ability to pay]

Alternative to paragraph 33: [Parties shall cooperate to develop and deploy patent sharing and/or intellectual property free renewable energy and energy efficiency technologies.]



Option 2:

Specific and urgent measures [shall] [should] be [instituted in [a] relevant forum[s]][established] [and mechanisms developed] to remove barriers to development and transfer of technologies from [developed][the developed Parties that have commitments under the Convention and the other developed Parties in a position to transfer environmentally sound technologies] to developing country Parties arising from the intellectual property rights (IPR) protection, [including][in particular]:

Option 2, continued:

(a) [All necessary steps shall be immediately taken in all relevant fora to [mandatorily exclude from patenting] [revoke all existing patents on essential/urgent] [implement compulsory licensing for] [specific] [climate-friendly] [environmentally safe and sound] technologies [in developing countries] [held by Annex II Parties which can be used to adapt to or mitigate climate change][, including those developed through funding by governments or international agencies];]

Option 2, continued:

(b) [[Pooling and sharing publicly funded technologies and making the technologies available in the public domain at an affordable price] [[Creation of a “Global Technology Pool for Climate Change” [that promotes] [sharing] [of] [and ensures access to] technologies that can be used to adapt to or mitigate climate change and associated know-how [and trade secrets] to developing countries [including on non- exclusive royalty-free terms] [at an affordable price] [and on terms and conditions that promotes access for developing countries] in order to provide better information service and reduce transaction costs;]]

Option 2, continued:

(c) [Use to the full flexibilities contained in the Trade Related Aspects of Intellectual Property Rights (TRIPS) including Compulsory licensing to access intellectual property protected technologies, taking into account the example set by decisions in other relevant international forums relating to IPRs, such as the Doha Declaration on the TRIPs Agreement and Public Health;]



Option 2, continued:

(d) [Parties agree that nothing in any international agreement on intellectual property shall be interpreted or implemented in a manner that limits or prevents any Party from taking any measures to address adaptation or mitigation of climate change, in particular the development and transfer of, and access to technologies;]



Option 2, continued:

- (e) Adoption of a Declaration on IPRs and Environmentally Sound Technologies in relevant fora to, inter alia, reaffirm the flexibilities in the TRIPS Agreement and enhance the enabling environment for implementing these flexibilities.
- (f) [Preferential pricing] [Differential pricing between developed and developing countries].



Option 2, continued:

- (g) Reviewing all existing relevant IPR regulations in order to provide certain information to remove the barriers and constraints that GHG mitigation technologies are subject to.
- (h) Promoting innovative IPR sharing arrangements for joint development of environmentally sound technologies.
- (i) Limited/reduced time patents on climate friendly technologies.



Option 2, continued:

- (j) [Genetic resources, including germplasms of plant and animal species and varieties that are essential for adaptation in agriculture, shall not be patented by multinational or any other corporations.] [Biological resources including microorganisms, plant and animal species and varieties, and parts thereof that are used for adaptation and mitigation of climate change shall not be patented.]



Option 3:

[LDCs][Countries vulnerable to the adverse effects of climate change] should be exempted from patent protection of climate-related technologies for adaptation and mitigation, as required for capacity-building and development needs.]



Option 4:

The Executive Body on Technology (EBT) should establish a committee, an advisory panel, or designate some other body, to proactively address patents and related intellectual property issues to ensure both increased innovation and increased access both for mitigation and adaptation technologies. Such a committee/panel should:



Option 4, continued:

- (a) Actively engage enterprises and institutions in both developed and developing countries;
- (b) Develop a clear framework for evaluating and determining when intellectual property becomes a barrier to international technology research, development, deployment, diffusion and transfer and provide options for corrective action;
- (c) Make recommendations back to the UNFCCC COP or COP/MOP on barriers that may require further actions.]

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- Thank you!
 - William New, wnew@ip-watch.ch
 - Slide show by Kaitlin Mara, kmara@ip-watch.ch



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