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W A S H I N G T O N , D C

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Thank you to the subcommittee for allowing this opportunity to submit post-hearing comments for the 2011 Special 301 Report.

First, I would like to follow up on the panel's question about a comment we made in our written report about enforcement measures for patents in the 2010 Special 301 Report. I believe the specific question was whether we thought the USTR was pushing countries to adopt criminal standards for patent violations. I have gone back to the passage in our written report and am having trouble locating the specific language the question was directed to. Our general concern is that in several places in past reports there are vaguely worded pressures for countries to adopt various civil, criminal and border measures to combat "counterfeiting" or, sometimes more generally, intellectual property violations. As we discuss in our comments, the Special 301 reports do a poor job of clearly defining what is meant by counterfeiting or carefully restricting comments about enforcement measures to their specific subjects (be they trademark counterfeiting, copyright piracy, more general IP violations, etc.). Future reports should be careful to define "counterfeiting," using the trademark specific TRIPS definition rather than a looser definition of "unauthorized generic" which sometimes creeps into industry discourse. To the extent that USTR wishes to clarify its stance that it does not pursue criminal penalties for patent violations, that would be helpful and we will be careful to remove this concern from future comments.

Second, I would like to guide the committee to further information it should consider in its efforts to create a new section of the Special 301 report documenting global best practices on intellectual property policy. The inclusion of a new best practices section of the report will be a welcome addition if it defines "best" in reference to policies that promote a full range of interests, including consumer interests, human rights, and the legal enabling environment needs of industries that rely on intellectual property limitations and flexibilities.

In the patent filed, considerations should include adherence to the U.S. endorsement of the Doha Declaration, including its recognition of the right of all countries to use "to the full" all TRIPS flexibilities that promote access to medicines for all. As we discussed in our written comments, the Special 301 report specifically, and USTR policy more generally, has never endorsed the specific language of the Doha Declaration that countries should remain free to use all TRIPS flexibilities "to the full."

In the copyright field, consideration of best practices should include promoting the global legal conditions necessary for all people to enjoy affordable access to knowledge and its products.

As I testified at the oral hearing, the independent research on the impact of maximalist intellectual property norms and enforcement practices on access to the subjects of patents and copyrights in middle income countries (such as India, Brazil and Thailand) is coalescing. We now know more certainly than perhaps we did in the past that in the medicines, media and software markets alike, intellectual property monopolies in middle income countries with high wealth inequality produce an economic incentive for, and a routine practice of, pricing products to be affordable to only a sliver (e.g. 5-10%) of the domestic population. In such countries the income difference between the wealthiest tenth or so of the population and the remaining segments is so extreme that monopolies will make less money by serving more of the population at a lower price. It is a different dynamic than exists in wealthier countries like the U.S. where even a monopoly makes the most profit by serving a large portion of the population. In a middle income and highly unequal country like Brazil, Thailand and India, rigid enforcement of intellectual property monopolies without countervailing price restraining policies will predictably lead to the great majority of the population having no access to the protected products. Where the products in question are needed medical or educational products, the access problem causes dire developmental disabilities. Where the good in question is a highly desired cultural product – like movies and music – the access problem often fuels rampant piracy.

The pricing problem has been long recognized with respect to the case of medicines, ultimately through the Doha Declaration. The newly released report on Media Piracy in Emerging Economies (<http://piracy.ssrc.org>) shows that the same dynamics plague global media markets:

Media piracy . . . is probably better described as a global pricing problem. High prices for media goods, low incomes, and cheap digital technologies are the main ingredients of global media piracy. If piracy is ubiquitous in most parts of the world, it is because these conditions are ubiquitous. Relative to local incomes in Brazil, Russia, or South Africa, the price of a CD, DVD, or copy of Microsoft Office is five to ten times higher than in the United States or Europe. Licit media goods are luxury items in most parts of the world, and licit media markets are correspondingly tiny. Industry estimates of high rates of piracy in emerging markets—68% for software in Russia, 82% for music in Mexico, 90% for movies in India—reflect this disparity and may even understate the prevalence of pirated goods.

As long as IP protected goods – whether they be medicines or media products – are priced in middle income countries as luxury goods affordable only to the rich, there will be a strong pull of the majority of consumers toward competitively produced products. Those competitive products can either be sold legally (e.g. generic medicines) or illegally (e.g.

pirated CDs). The more the legal regime makes it impossible to sell legal competing products, the more illegal suppliers will fill the void. In this sense, an IP maximalist agenda and the goal of eradicating all forms of IP “piracy” in middle income countries are at odds. If the USTR is going to press for the globalization of intellectual property standards and enforcement, it also needs to globalize a set of policy tools to effectively respond to the problems in the markets being created to ensure that the goal of the US is not, explicitly or implicitly, to create highly stratified global markets of knowledge goods in which only the top 10 percent or less of the world’s consumers can afford access to knowledge, culture and their products.

Instead of embracing the content industry calls for maximally constructed one-size-fits-all intellectual norms and enforcement standards for the world, American policy should recognize the value of diversity. Middle income countries need different IP laws that we do because their economies, particularly income distribution, are radically different than ours.

An effort to document a set of best practices that meet the legitimate interests of intellectual property holders and of the consumers and citizens they must ultimately serve would be a truly valuable exercise. An effort to define best practices that only listens to one side of a multi-faceted debate will be a travesty to global public interests.

Here are is an incomplete set of best practices toward the goal of ensuring access to medicines and knowledge for all in middle income developing countries like Brazil, Thailand and India:

- Maximize the use of patent and copyright limitations and flexibilities toward the goal of fostering an environment of broad competition between legally authorized (e.g. licensed on reasonable terms) competitors;
- Maximize the use of scope restrictions for intellectual property protections, e.g. section 3(d) of India’s Patent Act limiting patent monopolies on new forms of existing substances and other inventions with more limited innovative contribution;
- Maximize the use of competition law restrictions on the market power of IP-holding firms, e.g. with strong duties to license on reasonable commercial terms and against licensing terms that restrict competition;
- Maximize use of pooled purchasing, single-payer and other means of coordinated purchasing to exert downward pressure on prices, particularly for essential goods like medicines and text books;
- Maximize use of price controls and other consumer protections to restrain excessive prices where competitive markets cannot be promoted and sustained;
- Recognize and encourage the use of diverse mechanisms that separate and de-link research and development (R&D) incentives from prices, for example through the use of innovation inducement prizes that reward innovations that improve health outcomes and permit open competition for products;
- Promote licensing of all publicly funded R&D to the developing world, for example by licensing to the UNITAID patent pool publicly-funded IP held by NIH and Universities, and by supporting similar initiatives addressing other health needs, to ensure affordable upstream and downstream access to medical technologies relevant to health needs of developing countries;

- Encourage governments to provide open access to government funded research, such as is now required by the NIH Public Access Policy.

The following resources support these points and include other principles for establishing best practices.

GENERAL ECONOMIC LITERATURE

Sean Flynn, Aidan Hollis & Mike Palmedo, *An Economic Justification for Open Access to Essential Medicine Patents in Developing Countries*, 37 J.L. Med. & Ethics 184 (2009).

<http://www.wcl.american.edu/pijip/go/fhp2009>

Explains the economic incentives that monopolies in middle income countries have to price to the top sliver of income earners.

Sean Flynn, *Using Competition Law to Promote Access to Knowledge. From Intellectual Property to Access to Knowledge*. 2010.

http://www.wcl.american.edu/pijip_static/documents/flynn08122008.pdf?rd=1

Joseph Stiglitz, Intellectual-Property Rights and Wrongs, Project Syndicate (2005).

<http://www.project-syndicate.org/commentary/stiglitz61/English>

Carsten Fink and Keith E.Maskus (eds.), Report of the Commission on Intellectual Property Rights Intellectual Property and Development, Lessons from Recent Economic Research, p. 215 (World Bank and Oxford University 2005).

ACCESS TO MEDICINE

WHO, Report of the Commission on Intellectual Property Rights, Integrating Intellectual Property Rights and Development Policy

United States House of Representatives, Committee On Government Reform – Minority Staff, Special Investigations Division, Trade Agreements and Access To Medications Under The Bush Administration, Prepared For Rep. Henry A. Waxman (June 2005)

Report of the Special Rapporteur on the Right of Everyone to the Enjoyment of the Highest Attainable Standard of Physical and Mental Health, U.N. doc. A/HRC/11/12 (Mar. 31, 2009)

U.S. Civil Society Platform on Trade-Related Intellectual Property and Access to Medicines Issues (2009). <http://www.essentialaction.org/access/uploads/IP-MedsPlatformMay2009.pdf>

Sisule Musungu & Cecilia Oh, The use of flexibilities in TRIPS by developing countries: can they promote access to medicines?

http://www.who.int/intellectualproperty/studies/TRIPS_flexibilities/en/index.html

Carlos Correa, *Protection of Data Submitted for the Registration of Pharmaceuticals: Implementing the Standards of the Trips Agreement*, South Centre/WHO (2002) at 5.
<http://apps.who.int/medicinedocs/pdf/h3009ae/h3009ae.pdf>:

Judit Rius-Sanjuan, James Love and Robert Weissman, *Protection of Pharmaceutical Test Data: A Policy Proposal*, Consumer Project on Technology, (Nov. 2006).
<http://www.cptech.org/ip/health/data/CPTech-Test-Data.pdf>

COPYRIGHT AND ACCESS TO KNOWLEDGE

Joe Karaganis (ed.), *Media Piracy in Emerging Economies* (2011)
<http://piracy.ssrc.org>

Shows that in media and software markets, intellectual property monopolies in middle income countries with high wealth inequality promote exclusionary pricing that public policies must respond to if we are to maximize global social welfare. Includes overview and case studies in various markets.

Access to Knowledge for Consumers: Reports of Campaigns and Research 2008–2010.
http://www.consumersinternational.org/media/453199/a2k-reports2010_b.pdf

This report includes profiles of copyright flexibilities in different countries, as well as data from consumer surveys in 23 countries on copyright and access. It also contains information on advocacy efforts to expand access to knowledge.

Consumers International. *IP Watchlist*. 2010.
<http://a2knetwork.org/sites/default/files/IPWatchList-2010-ENG.pdf>

Often-cited report that grades countries and lists the best and worst for access to information policies. Also includes a brief section on best practices.

Global Information Society Watch. *Access to Online Information and Knowledge*. 2009.
<http://www.giswatch.org/sites/default/files/GISW2009.pdf>

Contains brief thematic reports on IPRs, Information & Democracy, Information & Livelihoods, Knowledge Rights, Access to Libraries, Access to Educational Materials, Open Standards, and Open Culture. These are followed by country overviews.

Global Information Society Watch. *Access to Infrastructure*. 2008.
<http://www.giswatch.org/en/2008>

Includes thematic reports on Net Neutrality, Open Standards, Spectrum Management, Trends in Technology, and Accessing Content. These are followed by country overviews.

WIPO Director General Francis Gurry. "The Future of Copyright." Address to the Blue Sky Conference: Future Directions in Copyright Law. Queensland University of Technology, Sydney, Australia. February 25, 2011.

Short speech in which DG Gurry gives three principles for copyright in the 21st century: 1) "neutrality to technology and to the business models developed in response to technology," 2) "comprehensiveness and coherence in the policy response," and 3) designing "better business models."

WIPO . Secretariat of the Standing Committee on Copyright and Related Rights, 21st Session. Standing Committee on Copyright and Related Rights. Updated Report on the Questionnaire on Limitations and Exceptions November 2010.

http://www.wipo.int/edocs/mdocs/copyright/en/sccr_21/sccr_21_7.pdf

This is a report based on a survey of Member countries on Limitations and Exceptions for educational activities; for libraries and archives; for persons with disabilities; for religious, social and cultural needs; and for other questions on digital technology.

Also of interest is the US response to the WIPO questionnaire:

<http://www.wipo.int/export/sites/www/copyright/en/limitations/pdf/us.pdf>

WIPO. Draft WIPO Treaty on Exceptions and Limitations for the Disabled, Educational and Research Institutions, Libraries and Archive Centers. Twentieth Session. Geneva, June 21-24, 2010.

The draft treaty proposals contain examples of language under debate at WIPO to expand access to knowledge goods (including language related to the price of goods). This language could be used to guide other types of limitations and exceptions.

Africa Group Proposal:

http://www.wipo.int/edocs/mdocs/copyright/en/sccr_20/sccr_20_11.pdf

US Draft Consensus Instrument:

http://www.wipo.int/meetings/en/doc_details.jsp?doc_id=133815