

**C. REVIEW OF THE PROVISIONS OF ARTICLE 27.3(B)**

**D. RELATIONSHIP BETWEEN THE TRIPS AGREEMENT AND THE CONVENTION ON BIOLOGICAL DIVERSITY**

**E. PROTECTION OF TRADITIONAL KNOWLEDGE AND FOLKLORE**

- We join other members in recalling the WIPO General Assembly agreement to continue intensive negotiations on traditional knowledge, traditional cultural expressions and genetic resources in the IGC, with 18 days of meetings planned for work in 2013. Our position on these issues is well known and continues, including with respect to patent disclosure requirements, which we continue to oppose.
- Significant work remains to be done in the IGC to better understand the policy objectives and principles that would support proposals regarding the protection of traditional knowledge, traditional cultural expressions and genetic resources.
- Finally, we would need to reflect further on any proposal for the Secretariat to work on this issue.

**F. REVIEW UNDER PARAGRAPH 8 OF THE DECISION ON THE IMPLEMENTATION OF PARAGRAPH 6 OF THE DOHA DECLARATION ON THE TRIPS AGREEMENT AND PUBLIC HEALTH**

- Thank you, Mr. Chairman, and the Secretariat, for the report on the status of notifications of acceptance of the 2005 Protocol Amending the TRIPS Agreement.
- The United States strongly supports the paragraph 6 system as established under the 2003 waiver decision and the 2005 Protocol.
- We encourage other Members to notify their acceptance of the amendment so that it can enter into force.
- We want to take this opportunity as part of today's review of the implementation of paragraph 6 on the Doha Declaration on the TRIPS Agreement and Public Health to provide some context.
- As we have noted previously (such as in paragraph 202 of IP/C/M/67, February 15, 2012), the paragraph 6 system is one of many tools to address the issue of access to medicines.

- There are also other tools of course to address this important issue as well, which also merit discussion, including tariff reduction and voluntary licensing.
- As we have noted previously, such as in paragraph 203 of the same document, tariffs are applied to medicines, to the components of those medicines, such as active ingredients, and medical products. Tariffs imposed by governments are, however, borne by consumers, by patients.
- In recognition of this reality, during the Uruguay Round, the United States joined several other Members (Canada, the European Union, Japan, Norway, Switzerland, and Macao) in eliminating tariffs on medicines and active ingredients in order to liberalize trade, lower costs, and increase access to these essential products.
- Since then, the participants in the pharmaceutical zero-for-zero agreement have updated it four times in order to include additional inputs for medicines, thereby reducing costs of production for medicines.
- However, some countries continue to impose relatively high tariffs on medicines, inputs to medicines and medical products. According to an October 18, 2012 paper by the WTO Economic Research and Statistics Division entitled “More Trade for Better Health, International Trade and Tariffs on Health Products”, several countries continue to maintain relatively high tariff rates on these products, despite a general trend toward tariff reduction on these goods.
- The report concludes, “the question to ask is why countries even maintain tariffs on health products. Imposing tariffs typically translates into higher product prices, especially in the presence of long supply changes. Maintaining tariffs ultimately means taxing the sick and creating additional costs for the health system.”
- One case exemplifies this point. Last year, the Assistant Minister for Public Health and Sanitation in Kenya reported that his country’s removal of taxes and tariffs for malaria products lead to a 44 percent decline in the rate of infant mortality and disease, and a 50 percent reduction on infant mortality in one region.
- Moreover, the impact of tariffs on medicines extends beyond consumers. Not only do medicines tariffs adversely impact patients, but as a 2005 WHO study demonstrated, tariffs on active ingredients adversely impact local industries, unless they can make the active ingredient (and often they do not).
- Turning from tariffs to licensing, the United States notes that voluntary licensing and policies that promote such licensing also provide important tools to promote access to

medicines.

- I would like to briefly explain some of the activities of the U.S. National Institute of Health that exemplify this trend.
- For example, the NIH was the first contributor to the Medicines Patent Pool (MPP) in the voluntary licensing of U.S. government-owned patents related to the use of HIV-retroviral (ARV) protease inhibitor drugs. The MPP promises to enhance access to ARV treatment for people living with HIV/AIDS in developing countries and facilitate the development of new combinations of ARVs and adapted formulations for developing countries.
- The US NIH is only one owner of intellectual property in the area of public health, but our actions are demonstrative of the partnerships that are occurring internationally, and the significant voluntary licensing that occurs. These practices are helping to enhance access to medicines, and we would urge other members to consider participating in this effort.
- Thank you, Mr. Chairman

## **G. NON-VIOLATION AND SITUATION COMPLAINTS**

- Thank you, Mr. Chair. We welcome your guidance regarding assumptions with respect to any extension of the moratorium.
- The United States has provided several communications regarding concrete examples and modalities. We refer Members to those communications, and will continue to work with you, Mr. Chair, and with Members on this issue.
- We continue to be of the view that the moratorium should and will expire at the next Ministerial conference, unless there is consensus to do otherwise.
- The possibility of non-violation disputes has been a part of the GATT dispute settlement system since the beginning. And the United States maintains that non-violation complaints are fully appropriate in the context of the TRIPS Agreement.
- The TRIPS Agreement was carefully negotiated to accommodate different legal regimes and to accommodate Members' need to achieve policy objectives. The availability of non-violation complaints will merely assist Members in their efforts to preserve the balance of concessions and to protect against measures that frustrate legitimate expectations.

## **J. TENTH ANNUAL REVIEW UNDER PARAGRAPH 2 OF THE DECISION ON THE IMPLEMENTATION OF ARTICLE 66.2 OF THE TRIPS AGREEMENT**

- We have closely reviewed the LDC proposal. We feel that U.S. reporting is constantly being improved and refined, and reflects the priorities raised by LDCs.
- We also have questions about the underlying rationale of several aspects of the proposal, as well as possible unintended consequences of limiting the information reported and ultimately the effectiveness of such reports.
- For these reasons, we think it is best to continue the positive feedback loop to react to specific questions and priorities raised by LDCs, which will continue to inform our report drafting, rather than impose rigid strictures that may hinder rather than facilitate reporting.

## **K. TECHNICAL COOPERATION AND CAPACITY-BUILDING**

- The U.S. government, working independently, as well as other governments and international organizations, offers technical assistance on IPR protection and enforcement to countries around the world, including least-developed countries (LDCs).
- The United States submitted a report to the TRIPS Council describing these programs, pursuant to Article 67.1 of the TRIPS Agreement.
- Regarding U.S. programs, in FY 2011, the U.S. Patent and Trademark Office's Global Intellectual Property Academy (GIPA) conducted more than 140 training, technical assistance, and capacity building programmes for over 4300 participants from 137 different countries. Most participants came from developing and least developed countries.
- We thank the Secretariat, and, in particular, the government of Sweden for its generous support of last week's Priority Needs for Financial and Technical Cooperation Symposium, which was extremely productive. In last week's symposium, several LDCs provided updates on the status of their TRIPS Agreement implementation. Many LDCs participated in this program, and they exhibited appreciation for the value of IP in supporting innovation and development of their economies. LDCs are clearly progressing with their implementation of the TRIPS Agreement.
- One point that was emphasized, however, was that even once laws are in place, and administrative structures are set up, more work needs to be done. For example, educational campaigns need to be organized to increase awareness of intellectual property. Judges need training on intellectual property. New officials at intellectual property office need to be trained.
- The United States has many resources that can help with this work. Our technical assistance is demand driven, and although we appreciate the Needs Assessments that have been filed and will reach out to LDCs to continue to follow up on these reports, we also appreciate LDCs reaching out to us.

- Some important contacts for Intellectual Property technical assistance include:
  - For general training, a training database is available at: <http://www.usipr.gov/>
  - For an educational campaign, to discourage the use of illegal downloads and counterfeit products, the U.S. Embassy in your capital should be of assistance. On the Department of State website: <http://www.state.gov/e/eb/tpp/ipe/index.htm>, select: contact us- and you should find the appropriate contact.
  - For more comprehensive assistance the U.S. Department of Commerce's Commercial Law Development Program provides training to stakeholders responsible for IP enforcement and adjudication of disputes such as government ministries, customs officers, patent examiners and judges. CLDP also conducts programs on IP Protection and Its Impact on the Economy, Technology Transfer, IP Law Curriculum in Law Schools, and Public Awareness Campaigns.
  - Similarly, the USPTO's Global Intellectual Property Academy provides training to government officials responsible for IP acquisition, enforcement and adjudication of disputes such as government ministries, customs officers, patent examiners and judges.
  - And of course, as the designated contact point for technical and financial assistance for implementation of TRIPS, you should feel free to reach out to me.

## **L. INTELLECTUAL PROPERTY AND INNOVATION**

- Thank you, Mr. Chair.
- The United States is pleased to join with Brazil in sponsoring this item on the agenda.
- Innovation is a common objective we all share, whether as inventors or consumers or governments. Innovation offers tremendous potential, not only to build businesses, to generate revenue, and to create jobs, but also to answer critical questions about the world in which we live and to address the challenges we all face. Innovation can actually improve our standards of living.
- Our objective today is to have an exchange of information on national innovation strategies and the role intellectual property protection plays in fostering innovation. Our hope is that by sharing national experiences, we all may contribute to the mutual goal of providing stable and predictable environments to promote and benefit from innovation.
- In the United States, our innovation policy focuses on investing in the building blocks of innovation and promoting market-based innovation.
- Each of these aspects recognizes that the private sector is the engine for innovation and that the government plays an important role in supporting such innovation.

- Turning to the building blocks of our innovation architecture, U.S. resources are directed to educating our students with 21<sup>st</sup>-century skills, strengthening and broadening fundamental research, building and maintaining physical infrastructure, and developing an advanced information technology ecosystem.
- Turning to R&D, for example, investments help to encourage basic research – research that may at some point have a commercial potential, but may take decades to realize. For example, the first fully electronic digital computer was funded in the 1940s by the United States government. The first commercially successful computer – with modest sales of 1,800 units– was sold in the 1950s. Of course, the rewards of the investments in the 1940s and 1950s are still being enjoyed today.
- The development and commercialization of intellectual property in connection with government-funded R&D has been significantly enabled by U.S. federal legislation, known as “Bayh-Dole Act” that has been studied and emulated in many other jurisdictions.
- Regarding the promotion of market-based innovation, the United States employs a variety of mechanisms to reduce the risk inherent to the inventive process. These mechanisms include: tax credits for research and experimentation; lending support and tax incentives for entrepreneurs; regulatory review and streamlining; innovation incentives, such as prize funding and challenges; and, of course, stable, predictable, and transparent systems for the protection of intellectual property rights.
- These and other policies are designed to mobilize inventors, whether working in government laboratories, office parks or home garages.
- The U.S. National Aeronautics and Space Agency’s (NASA) experience on fostering invention to address specific challenges is instructive. NASA launched its Innovation Pavilion to develop a forecasting algorithm to protect astronauts from radiation exposure in space. Over 500 participants from 53 countries entered the competition. NASA received a solution that exceeded its requirements from a retired radio-frequency engineer in New Hampshire. The winner had never worked for NASA, nor responded to a past government request for proposals. His winning approach forecast solar proton events with 85 percent accuracy.
- Fostering market-based innovation is not only about advancing innovation through promoting capitalization and a supportive regulatory environment, but also about driving commercialization. Having a great idea is only the first of many steps. Without a market place of ideas that catalyzes commercialization, the social benefit of innovation to consumers will not be fully realized.
- Stable and predictable intellectual property protection provides another indispensable incentive to innovate by rewarding the risk inventors take. Too many ideas fall prey to inadequate funding, theft, and failed commercialization and diffusion. IP provides a

critical safeguard, particularly to economies like all of ours that rely on innovation.

- Take the case of a farmer and businessman working in Kampala, Uganda. For this entrepreneur, IP promotes “innovation” through capturing the value chain of roast coffee, so that his community could benefit from selling high value roast coffee, rather than unprocessed raw beans.
- To advance up this value chain and provide this product – a new product from his community – he also introduced many new services and practices, include banking services, terracing to conserve water, pulping machines to clean the beans, and a new organizational structure of purchasing beans from farmers.
- These improved business processes alone would have yielded additional returns for the coffee growers, but this entrepreneur took another step – he marketed the coffee with a brand, a brand that would develop a reputation that consumers would appreciate and thus seek out the brand for future coffee purchases.
- The protection of this individual’s innovations and those of his community by intellectual property rights such as trademark laws and unfair competition protections help to ensure that the community can continue to benefit from these innovations.
- To maximize such innovation, IP systems also benefit from refinement and improvement, including through promoting recognized best practices. The recent U.S. enactment of the America Invents Act (AIA) exemplifies several best practices. Under the AIA, the U.S. government has taken steps to significantly reduce patent application backlogs and otherwise streamline the patent application process.
- Other important best practices include promoting patent quality and licensing to enable IP systems to optimize innovation. By ensuring the registration of high-quality patents, IP authorities preserve the integrity of the public domain and promote well-defined patents to foster continued innovation. Disclosure of innovations through high-quality patents, combined with patent licensing, allows inventors to lawfully borrow and cross-fertilize knowledge in order to advance additional innovation.
- To ensure that the benefits of a modern system of high-quality patents are broadly available, the AIA also includes a pro bono program designed to assist financially under-resourced independent inventors and small businesses. Through the program, the USPTO works with and supports intellectual property law associations around the country to provide advice on patent applications; to inventors and small businesses that do not exceed a certain income threshold.
- Additional “best practices” for pro-innovation patent systems include a “first inventor to file” system, which has long existed in major jurisdictions around the world. With the adoption of the AIA, the United States has now joined the international consensus.
- Patent grace periods represent another innovation best practice. After invention often

comes the critical step of securing funding to actually grow a business, which means showing investors what has been developed and putting out information while also preparing a patent application. In the United States, we have found that intellectual property is often a core asset of these innovative startup companies. So a grace period is one example of an innovation-friendly patent system feature that is critical to 21<sup>st</sup> century innovation.

- An additional U.S. Government initiative I would like to highlight is the “Patents for Humanity” program. This initiative is part of the President’s global development agenda and provides business incentives to spur increased participation by the patent community in confronting global challenges by rewarding those who apply their patented technology to address humanitarian issues among impoverished people around the world, including medical technology, food & nutrition, clean technology, and information technology.
- Finally, while governments can significantly enhance national innovation, including through IP awareness and an emphasis on quality, it is necessary to also stress the importance of avoiding the temptation of policies that degrade national innovation environments or that seek to promote the production of the inventions of others, rather than foster innovation itself. Innovation policies are best when they provide stability and predictability, including in IP systems.
- However, measures such as domestic manufacturing requirements and other industrial policies, whether implemented through or alongside IP systems, can add to the risk inherent in innovation, deter capitalization, imperil the rule of law, and ultimately undermine the goal of promoting innovation.
- Localization barriers to trade can take a variety of forms, including among other things, local content requirements, subsidies contingent upon the use of local goods, mandates to purchase domestically-manufactured goods or domestically-produced services; preferences to domestic intellectual property rights holders; measures to force technology transfer and many others.
- Countries are putting these measures into place in order to meet other domestic objectives, but these requirements have harmful consequences for trade and investment, as well as for economies’ long-term economic growth goals, including innovation.
- And many countries have recognized the negative impact such policies can have on innovation. For example, in November 2011, Leaders of the economies in the Asia Pacific Economic Cooperation (APEC) forum meeting in Honolulu committed to implement policies that promote effective, non-discriminatory, and market-driven innovation policy in the Asia-Pacific region.
- Specifically, APEC members agreed in Honolulu to actively enforce intellectual property rights, refrain from imposing technology transfer mandates, promote adoption of global standards, implement transparent and non-discriminatory government procurement policies; and minimize the trade-distorting impact of information and communication



technology policies, including privacy and security. We commend these principles for study by interested WTO Members; they can be found on the website, [www.apec.org](http://www.apec.org), as Annex A to the 2011 APEC Leaders Declaration.

- In conclusion, we have outlined variety of components of an innovation strategy, including but not limited to IP protection. With the assistance of the IP system, our scientists and researchers can see their important innovations developed into the new medical treatments, plant varieties, energy efficient technologies, and communications equipment that will be needed in the future.
- We look forward to hearing from others as to what measures they are taking to help innovation flourish, and the role of intellectual property in supporting innovation, in the hope that we can learn from each other's experiences, and that we can all benefit from the innovation that results.
- Thank you, Mr. Chairman.

#### **P. OTHER BUSINESS**

- As Members are aware, this matter is currently under discussion in the Dispute Settlement Body.
- We continue to believe that the DSB is the appropriate forum for those discussions and refer Members to our statements provided in that body on this dispute.