WIPO
WORLD
INTELLECTUAL PROPERTY
ORGANIZATION

WIPO Sub-Regional Workshop on Patent Policy and its Legislative Implementation

Topic 12: Patent-related provisions in the framework of preferential trade agreements

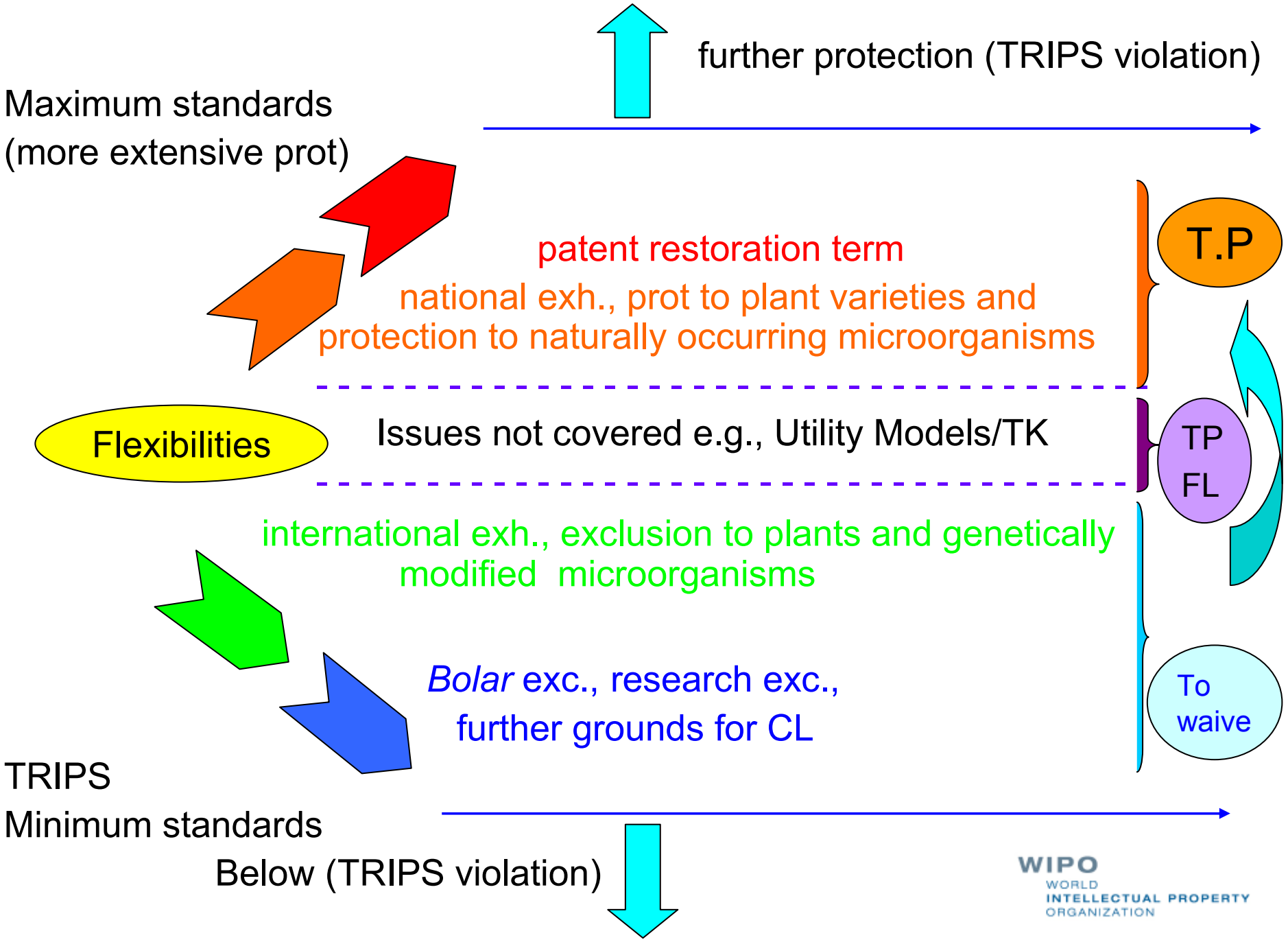
Marco M. ALEMAN
Deputy Director, Patent Law Division, and Head
Legislative and Policy Advice Section, WIPO

Basseterre, Saint Kitts and Nevis
April 10 and 11, 2013

OUTLINE

- Delimiting the concept of TRIPS Plus
- Regional Trade Agreements (EPAs/FTAs and Interim Agreements). Stepping or stumbling blocks
- Interaction between WTO law and RTAs TRIPS Plus provisions
- Delimit, clarify, modify and/or narrow down a TRIPS flexibility (or they go beyond the minimum of TRIPS
- Develop new matters not covered by the TRIPS Agreement
- Repeat the text of TRIPS provisions
- Obligation to “apply” or “accede” to WIPO administered treaties or to respect international commitments in force (Doha Declaration on Public Health)

4. Most common provisions on PTAs concerning patents


further protection (TRIPS violation)
Maximum standards
(more extensive prot)
patent restoration term
national exh., prot to plant varieties and
protection to naturally occurring microorganisms
T.P
Flexibilities
Issues not covered e.g., Utility Models/TK
TP
FL
international exh., exclusion to plants and genetically
modified microorganisms
Bolar exc., research exc.,
further grounds for CL
To
waive
TRIPS
Minimum standards
Below (TRIPS violation)
WIPO
WORLD
INTELLECTUAL PROPERTY
ORGANIZATION

Regional Trade Agreements (EPAs/FTAs and Interim Agreements)

- Regional trade agreements RTAs – be they free trade agreements (FTAs) or customs unions (CUs) is a way to promote liberalization.
- Trade agreements are in principle regional but FTAs are increasingly cross-regional.
- In order to pursue liberalization, countries play simultaneously at three levels, bilateral, regional and multilateral, producing a special synergy among the different process, the so called: competitive liberalization

Legal analyses of the creation of RTAs. The regional integration exception

- GATT Article XXIV, GATS Article V and the Enabling Clause. These provisions allow Members to adopt measures otherwise WTO-inconsistent
- EU (2006) a shift in the trade policy strategy included a new generation of bilateral free trade agreements). Commissioner Mandelson: ”his new FTAs will be addressed to key partners” with the purpose to built “on WTO rules by tackling issues which are not ready for multilateral discussions and for preparing the ground for the next level of multilateral liberalization”.

TRIPS MFN

- TRIPS MFN (article 4 and 5) does not included the exception of “the regional integration”, but “international agreements related to the protection of intellectual property which entered into force prior to the entry into force of the TRIPS Agreement”.
- The MFN clause negotiation process:

  several delegations expressed doubts about the positive contribution of this principle on the IP field

  EU expressed interest to exclude from the MFN Customs Unions and Free Trade Areas

  US delegation proposed a text in which MFN shall no apply in the case of “any advantage, favor, privilege or immunity which *exceeds* the requirements of this agreement and which is provided for in an international agreement to which the contracting party belongs…”.
- TRIPS MFN is concerned it is clear that TRIPS Plus provisions in RTAs are global in nature, thus no distinction is made between a TRIPS obligation and a TRIPS Plus obligation.
- Pauwelyn: “regionalism in IP is automatically multilateralizied”

WIPO
WORLD
INTELLECTUAL PROPERTY
ORGANIZATION

Interaction between WTO law and RTAs TRIPS Plus provisions

- The RTA provisions aims to add clarify, interpretation, to narrow down a TRIPS flexibility; or they go beyond the minimum standard protection of TRIPS.
- Develop new matters not covered by the TRIPS Agreement (i.e., utility models and TK)
- Repeat the text of TRIPS provisions
- Obligation to “apply” or “accede” to WIPO administered treaties (i.e., PLT, Budapest and PCT) or to respect international commitments in force (Doha Declaration on Public Health)

The RTA provisions aims to add clarify, interpretation, to narrow down a TRIPS flexibility; or they go beyond the minimum standard protection of TRIPS.

- Clarity or interpretation: regulatory review exception . RTA provision aims to add clarity on the compatibility of this specific exception with article 30 of TRIPS.
- Narrow dawn a TRIPS flexibility. Any commitments in a bilateral agreement restricting the freedom to choice of a Members is TRIPS Plus, independent of what the restriction consist (national exhaustion is a TRIP Plus provisions, as well as international exhaustion)
- What characterize a TRIP Plus provision is no the fact that it aims for a more extensive protection.
- More extensive protection that the one expressly provided in TRIPS. TRIPS Plus provisions goes above a level of protection expressly stated in the TRIPS Agreement, e.g., patent term extension, data exclusivity instead of data protection, criminal sanction in patents infringements, borders measures covering custom operation beyond importation, e.g., exports and transit.

WIPO
WORLD
INTELLECTUAL PROPERTY
ORGANIZATION

Cont…

- Systematic integration. The VCLT in its article 31 (3) (c) provide for a treaty interpretation in which the interpreter takes into account together with the context “any relevant rules of international law applicable in the relations between the parties”.
- Contradiction. A contradiction or conflict only exist when two treaties are no possible to be interpreted in coherent manner

- Art. 41 of the VCLT
- Conflicting clauses. See Art. 196 (1) and (2) of the EU and Colombia/Peru, Art. 197 (1) EU and Colombia/Peru, and Art. 139 (2) of EC-Cariforum EPA

Develop new matters not covered by the TRIPS Agreement (i.e., utility models and TK)

- Utility models, the EU provisions although develop something that is not included in TRIPS, at the same time, reduce the policy space countries enjoy under TRIPS. Art 148 of the EU-Cariforum
- EPA Genetic resources and traditional knowledge (disclosure of the source/origin of the biological material).

  Disclosure. Some similarities may be notice between Art. 150.4 of the EU Cariforum EPA and Art. 201.7 and 8 of the EU-Colombia/Peru FTA: acceptance that disclosure of the sources (Cariforum)/origin or source (Colombia/Peru) of the biological material be a requisite of the patent application. In the case of the EU Cariforum it is qualify as an administrative requirement. The EU-Colombia/Peru also covers within the provisions traditional knowledge and provided that in their national laws, parties will regulate the "effects of any such requirement".

Repeat the text of TRIPS provisions

- Treaties are equal from the international law perspective (except hierarchy)
- if a hierarchy has not being establish (which is normally in favor of multilateral treaties), the RTAs is going to prevail due the fact that it's contain more specific provision (*lex specialis*) and/or in the case of post-TRIPS FTAs (e.g., in no the case of NAFTA), because the FTAs is later in time (*lex posterior*)
- Art. 200 on exhaustion EU Cariforum EPA

Patent related provisions in certain PTAs (USA)

	US-Chile	US-Australia	US-Singapore
Plazo de prot de la Patent	Extension given for delays caused by regulatory approval process (pharmaceuticals). In addition, extension given when a delay in the granting of the patent exceeds four years from the filing of the application (five years for US- Chile) or two years after a request for examination (three years for US-Chile). In the case of Singapore when decision is taken on the basis of the examination conducted in another Country, if in the later extension is granted, them it could be also extended up to five years		
Segundos usos	No specific provision	Obligation to provide patens for new uses of known products	No specific provision
Protección de material viva	Best efforts to pass legislation on the protection through patents to plants	Exclusions *only* allowed for *ordre public* or morality and diagnostic, therapeutic and surgical methods.	Each party may exclude only as defined in Art 27. and 27.3.(b)
Licencias Obligatorias	No specific provision	Compulsory licenses limited to cases in which is a remedy to anti-competitive practice or national emergencies or other circumstances of extreme emergency and for public non-commercial use (conditions see Art. 17.9.7.(b)). In particular (iii).	
Importaciones Paralelas	No specific provisions	Patent holders may limit parallel imports through contracts or other means	Cause of action to prevent or redress the procurement of *patented pharma Product* by a person that knows that the product is distributed in a breach of contract (in the territory or outside)
Excepción en caso de tramite sanitario	si	Si, if consistent with paragraph 3 (exceptions)	si

Democrat's wish to incorporate key priorities in FTAs (letter March 12 to USTR)

- “The need for expanded access to affordable drugs is dire, and demands careful attention when international trade policies address IP”.

- They recalled that “Congress directed the Administrative branch to adhere to the Doha Declaration as a principal negotiating objective in US trade negotiations” (TPAA 2002).

Democrat's wish to incorporate key priorities on IP in FTAs (letter March 12 to USTR)

- “Regrettably, recent US FTAs…strip away flexibilities to which countries are entitled under TRIPS”.

- “The FTAs provisions also appear to upset an important balance between innovation and access by elevating intellectual property at the expense of public health”.

WIPO
WORLD
INTELLECTUAL PROPERTY
ORGANIZATION

Democrat's wish to incorporate key priorities on IP in FTAs (letter March 12 to USTR)

THE PROPOSAL.

- Data protection. The inclusion of caps in the periods available; measures to facilitate the approval of generics to stimulate competition.
- Patent extension. To limit the total duration permitted.
- Linkage. To mitigate the burden on the regulatory authorities, like the obligation to withhold the approval if a patent could be violated.

Democrat's wish to incorporate key priorities on IP in FTAs (letter March 12 to USTR)

THE PROPOSAL (Cont…)

- Compulsory licensing. Recalled each country freedom to determine the grounds upon which such licenses are granted. Avoid the use of side letters which are “non binding to the parties”.
- Consumer safeguards. Bolar provision; the applicant indications of the best mode to reproduce the invention and measures to avoid evergreening patents.

SHIFT IN THE US TRADE POLICY

- The May 10, 2007, bipartisan agreement on seven points (basic labor standards, environment and global warming, patents and IPR access to medicines, government procurement, port security, investment, workers assistance and training).
- "For decades now, trade has been a polarizing issue in Congress, but today's agreement signals a new direction and renewed spirit of bipartisanship" Charles Rangel (Chairman, Committee on Ways and Means).

SHIFT IN THE US TRADE POLICY. Some reactions…..

- “We applaud your leadership in promoting a trade policy that places public health over private profits and recognizes that developing countries need more flexibility to ensure their populations access to affordable medicines” Oxfam America (May 31 letter to Ms. Pelosi).
- The new trade policy “is proof that a balance between fostering drug innovation and ensuring access to affordable medicines can be achieved”. GPhA (May 31 press Release)

The Agreement (just for pharmaceutical products).

- DATA EXCLUSIVITY. Five years of data exclusivity for NCEs, considering the nature of the data and efforts and expenditure. If the parties grants the approval within six months when relying in FDA approval, the terms will count from them (concurrent period).
- PATENT EXTENSIONS. The obligation “shall” would be changed to “May”. Cooperation and assistance to avoid “unreasonable delays” is envisaged.

The Agreement (just for pharmaceutical products). Cont…

- THE LINKAGE ISSUE.

  There is no obligation to establish a linkage between drug regulatory agencies and patent issues, particularly, no requirement that the agency withhold approval of the generic until it can certify that no patent would be violated.

The Agreement (just for pharmaceutical products). Cont…

- THE CREATION OF A NEW KING OF LINKAGE

  The party would be required:

1. to provide procedures and remedies (judicial or administrative) and preliminary injunctions (equivalent) do dealt with patent infringement and validity disputes;
2. A transparent system to give patent holders sufficient time and opportunity to enforce their rights (notifications, website info, etc).

The Agreement (just for pharmaceutical products). Cont…

- LINKAGE OPTION. A party can be free to chose to fulfill this obligations (procedures and remedies) through a linkage system, if, at the same time:

1. adopt an expeditious system to challenge the validity or the infringement of a patent, and
2. a system to reward to those who successfully challenge a patent.

The Agreement (just for pharmaceutical products). Cont…

- SIDE LETTER. They should be part of the FTAs text.
- The Parties:

1. Would affirm their commitments to the DD;
2. The IP chapter does not prevent Parties from taking measures to protect public health or from utilizing TRIPS/health solutions;
3. Included an exception to data exclusivity to protect public health

Understanding the amendments. Patent term (1)

- Best efforts to process expeditiously MA and PA to avoid unreasonable delays (5 years from the application or 3 from the request of examination). Each party shall provide the means to compensate.
- In the case of pharmaceutical there is no obligation to compensate for the delay regarding the issuance of the patent. But may if the party wish, as well as regarding the restoration for the curtailment of the effective patent term.

Understanding the amendments. Data exclusivity on pharma (1)

- Data regarding products that utilizes NCEs shall be protected against disclosure, if its origination involves considerable effort.
- Each party shall provide that this data (presented after the FTAs entry into force), no other person would rely on it (without permission) within a reasonable period.
- Reasonable period normally means 5 years from the date of the approval, taking into account the nature of the data and the person's efforts and expenditures.

Understanding the amendments. Data exclusivity on pharma (2)

- Party can rely on MA granted by the other Party. In this case the is no clear information about the protection, neither about the exclusivity period.
- Even tough, if the party grant MA in a period of six months, the period of protection starts in date of the first MA in the other party (concurrent period).
- If the decision is not taken during the six months, what is the consequence?.

Understanding the amendments. Data exclusivity on pharma (3)

- Party may takes measures to protect public health in accordance to:

  i) declaration on the Trips Agreement and Public Health;

  ii) any waiver of TRIPS obligations and

  iii) any amendment of TRIPS.

Understanding the amendments. Data exclusivity on pharma (4)

- Party shall provide:

1. procedures (judicial or administrative proceedings) and remedies (preliminary injunctions) for the expeditious adjudication of disputes (infringement and validity)
2. transparent system to provide notice
3. Sufficient time and opportunity to the patent holder to see remedies before the marketed of the allegedly infringing product

Understanding the amendments. Data exclusivity on pharma (5)

- **Party can permit that other person different that the one that submit the information rely on evidence of safety and efficacy (such evidence of prior MA in the party or abroad). Needless to say that this is after the exclusivity period.**
- **If this is the case the party may implement the obligations (16.10.3 a, b, c) by implementing measures in the marketing approval process to prevent that a product covered by a patent by subject of a MA, and to inform the patent owner of any request of MA. In this case the Party also provides effectives rewards for successful challenges of the patent concern.**

Thank you

marco.aleman@wipo.int

WIPO
WORLD
INTELLECTUAL PROPERTY
ORGANIZATION