



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

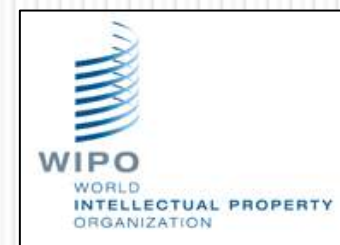
Topic 3: The Patent System and its relationship with other public policies. The case of health related policies

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

PATENT SYSTEM AND ITS RELATIONSHIP WITH OTHER POLICIES: THE CASE OF HRP

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PRESENTATION GOALS

- DEMONSTRATE HOW “TRIPS” AND “DOHA” ALLOW HEALTH RELATED FLEXIBILITIES IN IMPLEMENTING PATENT LEGISLATION.
- CATEGORIZE AND REVIEW IPR HEALTH RELATED FLEXIBILITIES.
- STATE SOME EXAMPLES OF FLEXIBILITIES THAT CAN BE IMPLEMENTED IN DIFFERENT AREAS OF PP.

IPR PROTECTION NOT A “WATERTIGHT COMPARTMENT”

- ADEQUATE AND EFFECTIVE IPR PROTECTION DECLARED A “NEED” IN “TRIPS AGREEMENT” (PREAMBLE, 1ST PARAGRAPH).
- TRIPS’ MAJOR GOAL ON PATENTS → ARTICLE 27.1.
- HOWEVER, IPR PROTECTION POLICIES **MUST BE CONSIDERED AS INTERACTING WITH OTHER POLICIES TO ACHIEVE MAJOR SOCIETY GOALS, E.G.:**
 - EQUAL PROTECTION CLAUSE;
 - DUE PROCESS OF LAW (INCL. TRANSPARENCY);
 - COMPETITION POLICY;
 - **OF COURSE, RIGHT TO HEALTH.**

RIGHT TO HEALTH: A GOVERNMENTAL MANDATE

- RIGHT TO HEALTH → FUNDAMENTAL RIGHT → INDUCES PUBLIC ACTION.
- WHO: “...GOVERNMENTS **MUST** GENERATE CONDITIONS IN WHICH EVERYONE CAN BE AS HEALTHY AS POSSIBLE.”
- THUS, GOVERNMENTAL POLICIES SHOULD ALWAYS BE FORMULATED AND IMPLEMENTED CONSIDERING THE RIGHT TO HEALTH.
- IN ADDITION, TRIPS AUTHORIZES MEASURES NECESSARY TO PROTECT PUBLIC HEALTH AND NUTRITION. (ARTICLE 8.1.).
- DOHA DECLARATION (2001) RECOGNIZES “GRAVITY OF PUBLIC HEALTH PROBLEMS” AND STATES THAT TRIPS:
 - DOES NOT AND SHOULD NOT PREVENT MEASURES TO PROTECT PUBLIC HEALTH.
 - ALLOW MEMBERS TO USE FLEXIBILITIES TO THE FULL FOR SUCH PURPOSES.

BASED ON THE ABOVE:

- IPR PROTECTION MUST BE ADAPTED, IN ORDER TO BE CONSISTENT WITH THE RIGHT TO HEALTH.
- HEALTH MEASURES SHOULD ALSO TAKE INTO ACCOUNT IPR COMMITMENTS.
- RECIPROCAL CONVERGENCE BETWEEN IPR PROTECTION AND THE RIGHT TO HEALTH MANDATES, GIVE RISE TO IPR “FLEXIBILITIES.”

MEANING OF FLEXIBILITIES

- NUNO PIRES DE CARVALHO, “WTO MEMBER COUNTRIES WERE GIVEN SOME *ROOM TO MANEUVER* AND TO CUSTOMIZE THEIR PATENT LAWS IN ACCORDANCE WITH THEIR UNIQUE LEGAL SYSTEMS, **PUBLIC-HEALTH SITUATIONS AND DEVELOPMENT NEEDS**. IN PARTICULAR, MEMBERS WERE GIVEN THE ABILITY TO ADOPT CERTAIN MEASURES THAT NEUTRALIZE THE IMPACT OF EXCLUSIVE RIGHTS, PROMOTE COMPETITION AND FACILITATE ACCESS TO MEDICINES....”

MAJOR FEATURES OF HEALTH FLEXIBILITIES IN TRIPS (ACCORDING TO WIPO)

- COUNTRIES HAVE DIFFERENT POLICY IMPLEMENTATION OPTIONS.
 - FLEXIBILITIES RELATE TO LEGISLATIVE PROCESS OF IMPLEMENTATION.
 - MUST TAKE INTO ACCOUNT NATIONAL INTERESTS.
 - FLEXIIBLITIES HIGHLIGHT THE IDEA OF COMPATIBILITY WITH TRIPS PROVISIONS AND PRINCIPLES.
- (WIPO CDIP 5/4, P. 12).

MOST USEFUL CLASSIFICATION OF FLEXIBILITIES (WIPO CDIP/5/4, P. 12)

- RELATED TO PROCESS FOR ACQUISITION OF RIGHT: (ON THE EXTENT OF SUFFICIENT DISCLOSURE).
- DEFINING THE SCOPE OF RIGHT:
 - E.G., USE OF PATENT INFORMATION FOR EXPERIMENTAL PURPOSES ONLY AND/OR FOR MARKETING APPROVAL.
 - COMPULSORY LICENSING.
- RELATED TO ENFORCEMENT OF RIGHT: E.G., PREVENTING ABUSIVE PRACTICES BY HOLDER (CASE OF EXCESSIVE PRICING, ARGENTINE PATENT LAW, ART. 44).

FLEXIBILITIES IN ACQUISITION PROCESS

- DISCLOSURE REQUIREMENTS CAN MAKE PRECISIONS ON EXTENT OF ARTICLE 29.1.
- THIS FLEXIBILITY CAN BE IMPLEMENTED IN DIFFERENT FORMS (TRIPS 29.1):
 - NOT DEFINING THE EXTENT OF “CLEARNESS AND COMPLETENESS REQUIREMENT”
 - REQUIRING INVENTOR TO SPECIFY PREFERRED EMBODIMENTS (BEST MODE). → E.G., COLOMBIAN DECREE 329/2012.

SCOPE OF PATENT RIGHTS – RESEARCH EXEMPTION POSSIBILITIES

- NOT FOR PROFIT USE OF INVENTION FOR SCIENTIFIC AND OR EXPERIMENTAL USES IN A PRIVATE CIRCLE (ARTICLE 22.1., MEXICAN IP LAW).
- UNDETERMINED EXPERIMENTAL USE (ANCOM, DEC. 486, ART. 53, b.)
- USE OF PATENT INVENTIONS FOR OBTAINING DATA NECESSARY FOR ANTICIPATING MARKETING APPROVAL (BOLAR EXEMPTION), E.G., COLOMBIAN DECREE 729/2012, ARTICLE 3.

SCOPE OF PATENT RIGHTS – COMPULSORY LICENSES AND GOVERNMENT USE

- REINFORCED BY THE DOHA DECLARATION (PAR. 5., b. and c.).
- FREQUENT GROUNDS FOR CL:
 - PUBLIC INTEREST, EMERGENCY (E.G., HEALTH RELATED) OR NATIONAL SECURITY CONSIDERATIONS. (E.G., ANCOM, 486, ART. 65).
 - NON WORKING /INSUFFICIENT WORKING OF PATENT. (E.G., ANCOM, 486, ART. 64)
 - ANTICOMPETITIVE PRACTICES. (ARGENTINEAN LAW 24.481, AS AMENDED, ART. 44).

EXHAUSTION OF RIGHTS

- TRIPS ARTICLE 28, STATES THAT PATENT OWNER, HAS THE RIGHT TO PREVENT THIRD PARTIES TO “IMPORT” PATENTED PRODUCT OR PROCESS.
- HOWEVER, PREVENTING IMPORTATION OF PRODUCTS PUT ON THE MARKET BY PATENTEE, IS SUBJECT TO THE PROVISIONS OF ARTICLE 6, (*Ibid.*) RELATED TO EXHAUSTION OF IPR RIGHTS.
- IN CASE LEGISLATION IMPLEMENTS INTERNATIONAL EXHAUSTION SCHEME, PARALLEL IMPORTATION CAN TAKE PLACE AND SHOULD NOT BE CONSIDERED INFRINGEMENT.