



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

Topic 6: Patent protection in Latin America. The evolution of legal frameworks at the national and regional legal and main tendencies

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

PATENT PROTECTION IN LATIN AMERICA. THE EVOLUTION OF LEGAL FRAMEWORKS AT THE NATIONAL AND REGIONAL LEVELS AND MAIN TENDENCIES: THE EXAMPLE OF COLOMBIA



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PRESENTATION OBJECTIVES

- REVIEW DEVELOPMENTS IN PATENT PROTECTION IN THE ANDEAN REGION – EMPHASIS IN COLOMBIA.
- SHOW HOW PUBLIC HEALTH-RELATED ISSUES INFLUENCE IPRs LEGISLATION ON A PERMANENT AND SUBSTANTIAL MANNER.
- CATEGORIZE ANDEAN LEGISLATION AND LOCAL IMPLEMENTATION IN COLOMBIA, COMPARED TO OTHER COUNTRIES.

ANDEAN START OF IPR REGIONAL PROTECTION

- FIRST COMMON IPR REGIME ISSUED IN 1974 → DECISION 85 OF ANDEAN PACT.
- DESPITE INTERNATIONAL ORIGIN OF ANDEAN LEGISLATION ON PATENTS, ITS ORIGINAL AIM WAS TO FOSTER IMPORT SUBSTITUTION POLICY.
- ANDEAN COUNTRIES (CHILE INCLUDED) WERE NOT MEMBERS OF OF PARIS CONVENTION (UNTIL 1990s).

BASIC FEATURES OF DECISION 85 PATENT POLICY

- NON PATENTABILITY OF ACTIVE PHARMACEUTICAL PRINCIPLES, MEDICINES, FOOD AND BEVERAGES.
- FOREIGN INVENTIONS WHOSE APPLICATIONS WERE FILED ONE YEAR AFTER THE FIRST FOREIGN APPLICATION, BECAME NOT PATENTABLE (CONFUSION BETWEEN NOVELTY AND PRIORITY REQS. LATTER, ONLY APPLICABLE FOR ANDEAN APPLICATIONS).
- PRODUCTS OR PROCESSES AFFECTING LOCAL DEVELOPMENT, AS DECLARED BY LOCAL GOVERNMENTS, COULD BE EXCLUDED FROM PATENTABILITY.

ECONOMIC OPENING IN THE EARLY 90s AND PATENT PROTECTION

- ANDEAN COUNTRIES ISSUED THREE DIFFERENT IPR REGIMES BETWEEN 1991 AND 1993 (DECISIONS 311, 313 AND 344).
- ALL THESE THREE REGIMES, ISSUED BEFORE APPROVAL OF MARRAKESH FINAL ACT (1994) ACCEPTED PATENTABILITY OF PHARMACEUTICAL PRODUCTS.
- EXCEPT THOSE LISTED AS “ESSENTIAL MEDICINES” BY THE “WHO”.

DECISION 486 - ANCOM

- ISSUED IN 2000: COMPLIANCE WITH TERMS STATED IN TRIPS ARTICLE 65, PARAGRAPHS 1. AND 2.
- PATENTABILITY REQUIREMENTS, CONSISTENT WITH TRIPS 27.1 (THUS, ELIMINATED LIST OF “WHO” ESSENTIAL MEDICINES OF NON PATENTABILITY).
- BIOTECH PATENTS WERE ALSO ACCEPTED.
- PATENT PROTECTION EXTENDED FOR 20 YEARS (FOLLOWING D. 344 COMMITMENT AND CONSISTENT WITH TRIPS ART. 33).
- HEALTH RELATED FLEXIBILITIES WERE REPLICATED FROM TRIPS WITHOUT MUCH VALUE ADDED.

TRIPS / DOHA - EMERGENCY COMPULSORY LICENSING REGULATION

- COL. GOVT. ISSUED DECREE 4302 OF 2008.
- BEFORE GRANTING A C.L., EMERGENCY AND/OR PUBLIC INTEREST GROUNDS **MUST BE DECLARED** BY MINISTRY WITH JURISDICTION ON ISSUE.
- AFTER DECLARATION HAS BEEN MADE, PATENT OFFICE CAN GRANT NON EXCLUSIVE LICENSES.
- ONE ONLY CASE HAS BEEN FILED (LOPINAVIR + RITONAVIR CASE).
- COLOMBIAN GOVERNMENT DECIDED NOT TO ISSUE SUCH EMERGENCY DECLARATION.

TRIPS / DOHA - PARALLEL IMPORTATION

- ANCOM DECISION 486 (Art. 54) SELECTED INTERNATIONAL EXHAUSTION SYSTEM, IN ACCORDANCE WITH TRIPS ARTICLES 6 and 28(a), Footnote 6.
- CONSEQUENTLY, PARALLEL IMPORTATION ACCEPTED IN ANCOM MEMBER COUNTRIES LEGISLATION.
- REGARDING MEDICINES, MARKETING APPROVAL IS REQUIRED PRIOR TO IMPORTATION.
- COLOMBIAN DECREE 1313 OF 2010 STATED THAT MEDICINES LISTED BY THE MoH, CAN BE IMPORTED BY AUTHORIZED INSTITUTIONS, IF ADMINISTRATIVE REQUIREMENTS ARE MET AND LABELING SPECS ARE FULLFILLED.

TRIPS / DOHA - MARKETING APPROVAL EXEMPTION

- ARTICLE 52, DECISION 486, DOES NOT CONSIDER “MARKETING APPROVAL APPLICATIONS” PATENT INFRINGEMENTS.
- HOWEVER, PATENTEES HAVE BEEN SUCCESSFUL REQUESTING INJUNCTIONS (PRELIMINARY AND PERMANENT) CLAIMING “MARK. APPR.” FILINGS CONSTITUTE IMMINENT INFRINGEMENT BEHAVIORS.
- DECREE 729 OF 2012 HAS MADE CLEAR:
 - PATENT HOLDER CANNOT IMPEDE THIRD PARTIES TO USE IT FOR OBTAINING “MARK. APPR.”.
 - THIRD PARTIES CAN MANUFACTURE, OFFER SELL, USE OR IMPORT PATENT PRODUCT FOR SUCH PURPOSES.
 - THIS, IN ORDER FOR PRODUCTS TO ENTER RELEVANT MARKET AFTER PATENT EXPIRATION.

MORE PATENT FLEXIBILIZATION REYES & REYES BEING CONSIDERED – NEW HEALTH A B O G A D O S DRAFT

- MINISTRY OF PUBLIC HEALTH INTERESTED IN STRENGTHENING SURVEILLANCE OF LOCAL HEALTH SYSTEM.
- NEW DRAFT STATES (AMONG OTHER MEASURES) THAT PATENT OFFICE WILL REQUEST MoH ASSESSMENT, REGARDING PATENTABILITY OF HEALTH RELATED PATENT APPLICATIONS (BR. “ANUNENCIA PREVIA”).
- JUSTIFICATION OF DRAFT STATES THAT MoH WOULD EXPECT TO REVIEW PATENT APPLICATIONS ON AN “INVENTIVE STEP” BASIS ONLY.
- THE DRAFT DOES NOT MENTION TRIPS /DOHA FLEXIBILITIES, ESPECIALLY ARTICLE 8, REGARDING “PUBLIC HEALTH PROTECTION” MEASURES THAT CAN BE TAKEN BY MEMBERS IN FORMULATING OR AMENDING IPR LEGISLATION.

HOW ABOUT OUR ANDEAN NEIGHBOORS?

- VENEZUELA WITHDREW FROM ANCOM AND REISSUED 1955 LAW (NON PATENTABILITY OF PHARMACEUTICALS).
- ECUADOR: HAS BEEN ONLY GRANTING PATENTS FOR PHARMACEUTICAL PROCESSES.
- PERU, DESPITE ANDEAN MEMBERSHIP AND COMMITMENTS, SIGNED FTA WITH THE US AND IS CURRENTLY NEGOTIATING TPP MEMBERSHIP.
- CHILE ORIGINAL NEGOTIATOR OF TPP: STRONG PATENT PROTECTION (TRIPS PLUS).