



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

Topic 10: Patentability subject matter. Multilateral commitments and available flexibilities

Basseterre, Saint Kitts and Nevis
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SCOPE OF PATENT RIGHTS: MINIMUM STANDARDS AND FLEXIBILITIES

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ARTICLE 27.1

- Subject to the provisions of paragraphs 2 and 3, patents shall be available for any inventions, whether products or processes, in all fields of technology, provided that they are new, **involve an inventive step** and are **capable of industrial application**. Subject to paragraph 4 of Article 65, paragraph 8 of Article 70 and paragraph 3 of this Article, patents shall be available and patent rights enjoyable without discrimination as to the place of invention, the field of technology and whether products are imported or locally produced.
- For the purposes of this Article, the terms "inventive step" and "capable of industrial application" may be deemed by a Member to be synonymous with the terms "non-obvious" and "useful" respectively.

TRIPS SUBJECT MATTER STANDARD

- ✓ ARTICLE 27.1 WAS AIMED AT CREATING SUBJECT MATTER HOMOGENEITY WITH RESPECT TO PATENT PROTECTION IN WTO MEMBERS.
- ✓ THIS, AS ART. 27.1 STATES THAT PATENTS:
- ✓ SHOULD BE AVAILABLE FOR ALL SORTS OF INVENTIONS.
- ✓ WHETHER RELATED TO PRODUCTS OR PROCESSES.
- ✓ IN ALL FIELDS OF TECHNOLOGY.
- ✓ PROVIDED THAT THEY COMPLY WITH THE FOLLOWING REQUIREMENTS:
 - NOVELTY.
 - INVENTIVE STEP (NON OBVIOUSNESS).
 - CAPABLE OF INDUSTRIAL APPLICATION (UTILITY).

HOWEVER, ARTICLE 27.1, IS PER-SE FLEXIBLE

- TRIPS DOES NOT DEFINE WHAT AN INVENTION IS.
- BASED ON THAT FLEXIBILITY, COUNTRIES ARE ENTITLED TO:
 - DEFINE INVENTION IS: (e.g., MEXICAN LAW OF 1991, ART. 15→ INVENTION IS CONSIDERED ANY HUMAN CREATION THAT ALLOWS TRANSFORMATION OF MATTER OR ENERGY EXISTING IN NATURE, TO BE USED BY MEN FOR THE SATISFACTION OF HIS SPECIFIC NEEDS.)
 - SPECIFY WHAT AN INVENTION IS NOT (E.G., ANCOM, DEC. 486, ART. 15).
 - LEAVE THE DECISION ON WHAT AN INVENTION IS (AND WHAT IT IS NOT) TO THE PATENT EXAMINER AND/OR THE COURTS (IN ACCORDANCE WITH MUNICIPAL LAW).

ARTICLE 27.1, ALLOWS FLEXIBILITIES (II)

- ✓ ARTICLE 27 DOES NOT DIFFERENTIATE, REGARDING SUBJECT MATTER, BETWEEN INVENTIONS AND DISCOVERIES. THUS, "NON PATENTABILITY OF DISCOVERIES" CAN BE IMPLEMENTED AS ONE OF THE SEVERAL POLICY OPTIONS.
- ✓ NOR IT MAKES SPECIFICATIONS REGARDING THE EXTENT OF A "PROCESS INVENTION" TO "USES" (OR SECOND USES, LIKE SWISS TYPE CLAIMS).→ THIS CAN BE, IF SO DESIRED, EXCLUDED FROM PATENTABILITY TOO.

PATENTABILITY REQUIREMENTS - NOVELTY

- REGARDING NOVELTY, IT HAS BEEN USUALLY STATED THAT SUCH REQUIREMENT IS FULFILLED, IF CLAIMED INVENTION DIFFERS IN ANY RESPECT FROM EACH AND EVERY ELEMENT ANALYZED AS PRIOR ART.
- IF ANY ELEMENTS OF THE CLAIMED INVENTION ARE NOT INCLUDED IN A SPECIFIC ITEM CONTAINED IN PRIOR ART, INVENTION IS SAID TO BE NOVEL.
- NOVELTY REQUIREMENT ANALYSIS IS PERFORMED IN AN INDIVIDUAL FASHION, THAT IS, COMPARING EACH AND EVERY ELEMENT OF CLAIMED INVENTION WITH EACH AND EVERY ELEMENT OF PRIOR ART.

PATENTABILITY REQUIREMENTS – INVENTIVE STEP (NON OBVIOUSNESS)

- WITH REGARD TO INVENTIVE STEP, THE DISCUSSION HAS BEEN VERY ACTIVE AND IS STILL GOING ON:
- INCLUDES (AMONG OTHER ISSUES) THE FOLLOWING:
 - IS IT POSSIBLE TO DEFINE EX-ANTE WHAT COMPRISES INVENTIVE STEP?
 - WHO IS ACTUALLY THE PERSON HAVING ORDINARY SKILL IN THE ART “PHOSITA”?
 - HOW TO CONSTRUE INVENTIVE STEP IN DEVELOPING COUNTRIES AND LDCs?
 - HOW TO MATCH “INVENTIVE STEP” REQUIREMENTS WITH “RIGHT TO HEALTH” AND ADEQUATE ACCESS TO MEDICINES?

EXAMPLES OF SOME INVENTIVE STEP DEBATES (OPEN AND CONTINUOUS) IN PHARMACEUTICAL PRODUCTS

- POLYMORPHISM.
- SUSTAINED RELEASE SCHEMA.
- PARTICLE SIZE.
- COMBINATION OF KNOWN COMPOUNDS.

PATENTABILITY REQUIREMENTS – INDUSTRIAL APPLICATION

- IT HAS BEEN USUALLY STATED THAT AN INVENTION IS “INDUSTRIALLY APPLICABLE”, IF IT CAN BE MADE IN ANY KIND OF INDUSTRY.
- HOWEVER, TRIPS ARTICLE 27.1 DOES NOT DEFINE THE REQUIREMENT OF “INDUSTRIAL APPLICATION”.
- SUCH DEFINITION SHOULD BE IMPLEMENTED IN COORDINATION WITH OTHER POLICY GOALS AND OBJECTIVES.
- IN ADDITION, EACH COUNTRY CAN BE MORE OR LESS DEMANDING WITH RESPECT TO THE PROOF OF INDUSTRIAL APPLICATION (E.G., COULD REQUEST APPLICANT TO PROVIDE INFORMATION RELATED TO “BEST MODE” OF CARRYING OUT THE INVENTION).

FINAL COMMENTS

- IN THE AREA OF SUBJECT MATTER, TRIPS ARTICLE 27.1. STATES THAT INVENTIONS SHALL BE PATENTABLE IF NOVEL, COMPRISING AN INVENTIVE STEP AND INDUSTRIALLY APPLICABLE.
- HOWEVER, ARTICLE 27.1 IBID. DOES NOT DEFINE ANY OF THOSE REQUIREMENTS. THIS MEANS THAT THE ACTUAL EXTENT OF SUBJECT MATTER PROTECTION AND EXTENT, SHOULD BE ESTABLISHED BY EACH LEGISLATURE.
- FOR SUCH PURPOSES, AN IN-DEPTH POLICY ANALYSIS BASED ON RELEVANT GOALS, OBJECTIVES AND VALUES MUST BE PERFORMED BY EACH DEVELOPING COUNTRY, BEFORE FORMULATING THE EXTENT OF SUBJECT MATTER PROTECTION.
