Intellectual Property and Public Health - International Framework and Recent Developments in WIPO: SCP and CDIP

WTO-ESCAP-IIUM REGIONAL WORKSHOP ON IP AND PUBLIC HEALTH AND ENVIRONMENT PLOICY FOR THE ASIAN AND PACIFIC REGION

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Medical innovation and patents

- Some issues around patents and medical innovation
  - Scope of protection and scope of exceptions
  - Morality and ordre public issues
  - Interaction with other forms of IP and non-IP law (including the regulation of pharmaceuticals)
  - Breadth of claims (research tools)
  - IP management in the public interest
  - Compulsory licensing and government use provisions

Areas of flexibility

Pre-grant:

- choice of what is patentable, and what is not
  (e.g. higher life forms, morality exceptions, medical treatments)
- decision whether or not to seek a patent, and who applies
  (e.g. role of public sector institutions – Bayh-Dole)

Post-grant:

- choice of how to exercise the patent
  (working the patent, what obligation to license?)
- choice of scope or reach of patent rights
  (what kind of research exception, what reach of claims?)
- choice of how to regulate the patent, once granted
  (compulsory licensing, government use)

Some specific legal issues

- Additional protection
  - Some legal systems offer protection to types of inventions that loose part of effective patent term due to marketing approval procedures. Examples:
    - Europe:
      - Special title of protection called Supplementary Protection Certificates (SPC). Conditions: medicinal product covered by a patent in force; valid marketing authorization which is the first one, and not already obtained an SPC. Maximum of 5 years
    - Other administrative protection (US)
      - US grant an extension to any patented product (and process) which has been subject to a regulatory review period before its commercial marketing or use
- Linkage with other forms of regulation: regulatory approval of pharmaceuticals

Standing Committee on the Law of Patents (SCP)

WIPO work before 1995

- Paris Convention (1883)
- PCT (1970)
- Negotiations 1985 to 1991 for a Treaty Supplementing the Paris Convention as far as Patents are Concerned; Diplomatic Conference resulted in no treaty, mainly due to differences concerning first-to-file and the grace period
- Patent Law Treaty (PLT, 2000): Harmonizes and simplifies formal requirements for national and regional patent applications and patents. Excludes expressly substantive requirements of patentability

Draft Substantive Patent Law Treaty (SPLT)

- Draft SPLT discussed since 2001 in WIPO/SCP
- Objective: bringing closer together some operational concepts relevant for examination of patent applications. Quality; avoid duplication of work.
- Covers main substantive requirements relevant for the grant of patents, i.e. prior art, novelty, inventive step, industrial applicability, sufficiency of disclosure and drafting/interpretation of claims
- Does not cover after-grant (exploitation) phase; left to national laws
- Certain issues not yet addressed (first-to-file; grace period)

allenges

among industrialized countries

le subject matter/technical character

ile; grace period

effect of earlier applications

f developing countries

does not fit all; fear of “TRIPS-plus”

ns and grounds for refusal/invalidation of an
on (e.g. public health, protection of genetic
s, environment)

certain policy issues (origin of genetic
s)