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Health related flexibilities in the intellectual property system

Kaunas
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Hans Georg Bartels, Global Challenges Division

Concept of flexibility

WIPO Document CDIP/5/4 rev., par.34
http://www.wipo.int/meetings/en/doc_details.jsp?doc_id=142068
(Trilateral Study, page 72)

"The term "flexibilities" means that there are different options through which TRIPS obligations can be transposed into national law so that national interests are accommodated and yet TRIPS provisions and principles are complied with. This definition would effectively delimit the scope of the concept through the following elements:

(i) it highlights the idea of various options for means of implementation;

(ii) it refers to the legislative process of implementation, reflecting that the first step to get advantage of a given flexibility consists in incorporating it into the national law;

(iii) it refers to the reason for flexibilities, which is to accommodate national interest; and

(iv) it reflects that a given flexibility needs to be compatible with the provisions and principles of the treaty."

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Some elements of flexibility

WIPO Document CDIP/5/4 rev., par. 13, 23, 25, 37-40
http://www.wipo.int/meetings/en/doc_details.jsp?doc_id=142068

- Across-cutting issue, not just among the different domains of intellectual property, but among intellectual property policies and other related policies
- International treaties have to be implemented in the national legal system in order to be recognized as source de droit
- Flexibilities in the process of the acquisition of the right
- Flexibilities in defining the scope of the right
- Flexibilities when enforcing the right
- Flexibilities under the TRIPS Agreement
- Method of implementing TRIPS obligations
- Areas not covered by the TRIPS Agreement

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The WTO Agreement on Trade-related Aspects of Intellectual Property Rights

https://www.wto.org/english/docs_e/legal_e/legal_e.htm#TRIPs

- Article 6 Exhaustion
  For the purposes of dispute settlement under this Agreement, subject to the provisions of Articles 3 and 4 nothing in this Agreement shall be used to address the issue of the exhaustion of intellectual property rights.

- Article 7 Objectives
  The protection and enforcement of intellectual property rights should contribute to the promotion of technological innovation and to the transfer and dissemination of technology, to the mutual advantage of producers and users of technological knowledge and in a manner conducive to social and economic welfare, and to a balance of rights and obligations.

- Article 8 Principles
  1. Members may, in formulating or amending their laws and regulations, adopt measures necessary to protect public health and nutrition, and to promote the public interest in sectors of vital importance to their socio-economic and technological development, provided that such measures are consistent with the provisions of this Agreement.
  2. Appropriate measures, provided that they are consistent with the provisions of this Agreement, may be needed to prevent the abuse of intellectual property rights by right holders or the resort to practices which unreasonably restrain trade or adversely affect the international transfer of technology.

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Background to the Doha Ministerial Declarations

https://www.wto.org/english/thewto_e/minist_e/min01_e/mindecl_trips_e.htm

Trilateral Study, pages 71-72

- The TRIPS Agreement expects Members to make patents available for pharmaceuticals while retaining options for public health purposes
- Controversy subsequent to adoption of the TRIPS Agreement
- April 2001: WHO-WTO workshop in Høsbjør, Norway
- Special session of the TRIPS Council on June 20, 2001
  https://www.wto.org/english/tratop_e/trips_e/counciljun01_e.htm
  "Member governments said they are committed to ensure that the TRIPS Agreement is part of the solution for the health crises in the world's poorest nations."
  WTO News item
  https://www.wto.org/english/news_e/news01_e/trips_drugs_010620_e.htm

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The Doha Ministerial Conference

November 9–13, 2001

https://www.wto.org/english/tratop_e/dda_e/texts_contents_e.htm

- The Doha Ministerial Declaration (WT/MIN(01)/DEC/1)
- Ministerial Declaration on the TRIPS Agreement and Public Health (WT/MIN(01)/DEC/2)
- Ministerial Decision on Implementation-Related Issues and Concerns (WT/MIN(01)/17)
- Ministerial Decision on the Waiver for the EU-ACP Partnership Agreement (WT/MIN(01)/15)
- Ministerial Decision on the EU's Transitional Regime for Banana Imports (WT/MIN(01)/16)

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The Doha Ministerial Declaration

https://www.wto.org/english/thewto_e/minist_e/min01_e/mindecl_e.htm

- Paragraph 6.
  - We strongly reaffirm our commitment to the objective of sustainable development, as stated in the Preamble to the Marrakesh Agreement.
  - [...]
  - We recognize that under WTO rules no country should be prevented from taking measures for the protection of human, animal or plant life or health, or of the environment at the levels it considers appropriate, subject to the requirement that they are not applied in a manner which would constitute a means of arbitrary or unjustifiable discrimination between countries where the same conditions prevail, or a disguised restriction on international trade, and are otherwise in accordance with the provisions of the WTO Agreements.
- Paragraph 17. We stress the importance we attach to implementation and interpretation of the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS Agreement) in a manner supportive of public health, by promoting both access to existing medicines and research and development into new medicines and, in this connection, are adopting a separate declaration.

The Ministerial Declaration on the TRIPS Agreement and Public Health

https://www.wto.org/english/thewto_e/minist_e/min01_e/mindecl_trips_e.htm

- Articulates the role of TRIPS Agreement in promoting access to medicines and clarifies specific flexibilities
- Recongnizes the gravity of public health problems, the importance of intellectual property protection for the development of new medicines and the concerns about its effects on prices.
- Four clarifications (paragraph 5)
  - The Agreement shall be read in the light of the object and purpose of the Ageement: expressed in its objectives and principles
  - Each Member has the right to grant compulsory license and the freedom to determine the grounds for grant of compulsory licenses
  - Each member has the right to determine what constitutes a national emergency or other circumstances of extreme urgency
  - Each Member has the right to establish its own regime for exhaustion
- Paragraph 6: commencement of work on special export licenses
- Paragraph 7: committment of developped country Members to technology transfer

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The Paragraph System for Special Export Compuslory Licenses

https://www.wto.org/english/tratop_e/trips_e/public_health_e.htm

- Paragraph 6:
  We recognize that WTO members with insufficient or no manufacturing capacities in the pharmaceutical sector could face difficulties in making effective use of compulsory licensing under the TRIPS Agreement. We instruct the Council for TRIPS to find an expeditious solution to this problem and to report to the General Council before the end of 2002.
- Decision of the General Council of August 30, 2003:
  The obligations of an exporting Member under Article 31(f) of the TRIPS Agreement shall be waived with respect to the grant by it of a compulsory licence to the extent necessary for the purposes of production of a pharmaceutical product(s) and its export to an eligible importing Member(s)
  https://www.wto.org/english/tratop_e/trips_e/implem_para6_e.htm
- Decision of the General Council of December 6, 2015: Protocol of Amendment
  Members and dates of acceptance:
  https://www.wto.org/english/tratop_e/trips_e/amendment_e.htm

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Flexibility referred to in the WHO Global strategy and plan of action on public health, innovation and intellectual property

- Reference to the Doha Declaration on the TRIPS Agreement and Public Health
- Calls WHO Member States i.a.
  - incorporating TRIPS flexibilities into their national laws (Element 5.2a)
  - taking into account the impact on public health when considering the adoption of more extensive IP protection than that required under the TRIPS Agreement (Element 5.2b).
  - considering flexibilities when negotiating other trade agreements (Element 5.2c)
- Highlights a number of flexibilities and public policy options designed to facilitate research and access to medical technologies, e.g.:
  - Research exception (Element 2.4e)
  - Regulatory exception or Bolar-type exemption (Element 6.3a)
  - Voluntary patent pools of upstream and downstream technologies (Element 4.3a)
  - Transition period for LDCs (Element 5.2d)

Health, the patent system and public interest

Public interest embedded in the patent system

- **Conditions of patentability (Art. 27, 29 TRIPS)**
  patentable subject matter, novelty, inventive step, industrial applicability, disclosure

India Patent Act (Patents Amendment Act of 2005)
Section 3(d)

(Trilateral Study, Box 3.16, page 132)

"(*d)* the mere discovery of a new form of a known substance which does not result in the enhancement of the known efficacy of that substance or the mere discovery of any new property or new use for a known substance or of the mere use of a known process, machine or apparatus unless such known process results in a new product or employs at least one new reactant.

Explanation.–*For* the purposes of this clause, salts, esters, ethers, polymorphs, metabolites, pure form, particle size, isomers, mixtures of isomers, complexes, combinations and other derivatives of known substance shall be considered to be the same substance, unless they differ significantly in properties with regard to efficacy".

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Supreme Court of India
Civil Appeal Nos. 2706-2716 of 2013, April 1, 2013

http://supremecourtofindia.nic.in/outtoday/patent.pdf

- Patent application claimed:
  crystal modifications of imatinib, processes for its manufacture and its use
- Patent refusal: lack of the required enhancement in efficacy under Section 3(d) of Indian Patents Amendment Act of 2005
- Supreme Court:
  - Section 3(d) allows patent protection for all incremental inventions of chemical and pharmaceutical substances under the given requirements
  - The patent application
    - did not claim superiority of the beta crystal form over the starting material imatinib, or even over imatinib mesylate in amorphous form or any form other than the alpha crystal form
    - did not demonstrate fulfillment of the requirements for therapeutic efficacy
  - First Supreme Court guidance on the interpretation of Section 3(d).
    - "Efficacy" depends upon the function, utility or purpose of the product under consideration
    - In the case of a medicine that claims to cure a disease "efficacy" can only be "therapeutic efficacy".
- The issues are:
  - National law of India
  - Patentable subject matter: "is not an invention"

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WHO, WIPO, WTO Joint Technical Workshop on Patentability Criteria (October 27, 2015)

https://www.wto.org/english/tratop_e/trips_e/trilat_workshop15_e.htm

27 October 2015

INTELLECTUAL PROPERTY: WHO-WIPO-WTO JOINT WORKSHOP 2015

Workshop on Patentability Criteria

On 27 October 2015, the World Health Organization, the World Intellectual Property Organization and the WTO jointly organized a technical workshop on patentability criteria. It provided participants with practical insights into how the main substantive patentability criteria are applied in practice at country level and how different definitions and interpretations can impact on public health.

See also:

World Health Organization

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WTO OMC

The aim was to support participants to engage in a policy debate that is characterized by its highly technical nature and assist them to appropriately frame and assess national patent systems and practices. To do so, the three collaborating agencies provided a brief overview of the legal framework at multilateral, regional and national level. This was followed by an interactive session led by a practitioner who presented and discussed a number of practical cases. The final discussion provided an opportunity to look at matters of public interest and concerns with respect to the design and application of patentability criteria at country level and potential repercussions on public health.

The Workshop took place back to back with the WHO-WIPO-WTO Symposium on "Public Health, Intellectual Property, and TRIPS at 20: Innovation and Access to Medicines; Learning from the Past, Illuminating the Future" that was held at the WTO on 28 October 2015.

PROGRAMME

14h00 – 14h10 **Welcome and introduction**

Health, the patent system and public interest

Public interest embedded in the patent system

- Conditions of patentability (Art. 27, 29 TRIPS)
  patentable subject matter, novelty, inventive step, industrial applicability, disclosure
- Publication and dissemination of information
  - scope of publication
  - databases
  - legal status information

Availability of information

(Trilateral Study, page 61)

- Despite the standardization of patent documents
  Patent publication differs considerably from country to country. e.g.
  - no publication of patent applications, only granted patents
  - publication of only a short notice of the patent grant
  - supplementary information
- TRIPS Article 29 (disclosure)
- Paris Convention Article 12
  Each country establishes a central office for the communication to the public of patents, etc.: - the names of the proprietors of patents granted with
  - a brief designation of the inventions patented
- On-line availability of information → Patentscope
- Additional documents:
  search reports, corrections, amendments, translations
- Legal status information
- **Challenges**:
  - Availability
  - Updating of databases
  - Reliability

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Availability of Patent Legal Status Data

- WIPO study on availability of legal status data
  (CDIP/4/3 REV./INF 3)
  http://www.wipo.int/patentscope/en/programs/legal_status/index.html
  - 87 patent authorities contributed information
  - Sometimes deficient situation regarding availability of reliable legal status data and their comparability

Statistical Summary of WIPO Questionnaire on Availability of Patent Legal Status Data
http://www.wipo.int/export/sites/www/patentscope/en/programs/legal_status/docs/statistical_summary_questionnaire_ls.pdf

9. Can data (e.g. dates) for the following legal events be recorded in the patent register and retrieved by the public if available for a particular patent application or granted patent?

	Yes	No
9.1 Request for examination	33	35
9.2 Entry into national phase of PCT applications	50	19
9.3 Non-entry into national phase of PCT applications	12	56
9.4 Withdrawal of application	54	17
9.5 Rejection of application	56	14
9.6 Appeal to rejection	40	29
9.7 Grant of patent	73	0
9.8 Opposition to grant	38	32
9.9 Request for invalidation/revocation/nullification	45	25
9.10 Granted patent has been invalidated/revoked/nullified	65	7
9.11 Granted patent has expired, i.e. no further extension possible	59	14
9.12 Granted patent has lapsed, i.e. renewal fee not paid	64	9
9.13 Payment of fees (e.g. renewal)	57	14
9.14 Any events related to examination other than final decisions, e.g. a search report or examination report has been issued	36	34
9.15 Change of ownership	69	3
9.16 Data related to licenses	57	15

Availability of Patent Legal Status Data

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  (CDIP/4/3 REV./INF 3)
  http://www.wipo.int/patentscope/en/programs/legal_status/index.html
  - 87 patent authorities contributed information
  - Sometimes deficient situation regarding availability of reliable legal status data and their comparability
- Committee on WIPO Standards (CWS)
  http://www.wipo.int/cws/en/
  Proposal to establish a new WIPO standard for the exchange of patent legal status data by industrial property offices
  (CWS/4 BIS/5)

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Health, the patent system and public interest

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- Publication and dissemination of information
  - scope of publication
  - databases
  - legal status information
- Scope (Art. 28 TRIPs)
  and term of protection (Art. 33 TRIPs)
- Exclusions, exceptions and limitations to the rights, e.g.
  - Art. 27.2 TRIPs: protect *ordre public* or morality, including [...] health
  - Art. 27.3(a) TRIPs: diagnostic, therapeutic, surgical methods for treatment
  - Art. 30 TRIPs: research exemption, regulatory review exception, etc.
  - Art. 31 TRIPs: compulsory licenses

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Compulsory Licenses (CL) in the TRIPS Agreement

(Trilateral study, pages 174-177)

Article 31 TRIPS: Law of a Member allows use of patented subject matter without authorization of the right holder

- List of provisions to be respected, i.a.:
  - Prior efforts for voluntary license
    (not needed in case of national emergency, other circumstances of extreme urgency, anti-competitive behaviour)
  - Limited scope and duration
  - Non-exclusive and non-assignable
  - Adequate remuneration to the patent holder
  - 31 (f): any such use shall be authorized predominantly for the supply of the domestic market of the Member authorizing such use
- → Paragraph 6 system (Trilateral study, pages 177-180, Annex II)

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Efavirenz
Compulsory license in Brazil

- 2007- Brazilian compulsory licence for efavirenz (ARV drug)
- Importation of generic efavirenz from India where there was no patent on this product
- Brazil reported to the TRIPS Council that it had taken two years to locally produce the medicine, partly because the patent law does not require applicants to disclose all information necessary for the commercialization of an end product
- WTO document IP/C/57

Compulsory License: Example Sorafenib/Nexavar

Natco Pharma Ltd./Bayer Corporation - Controller of Patents, Mumbai

http://www.lawyerscollective.org/updates/supreme-court-says-no-to-bayer-upholds-compulsory-license-on-nexavar.html

- Indian Patent No. 215758 (PCT WO/2000/042012)
- Compulsory license granted March 9, 2012 (http://ipindia.nic.in/ipoNew/compulsory_License_12032012.pdf)
- Issues
  - worked in the territory of India
    - importation vs. local manufacture
    - supply by third parties
  - availability
    - reasonable price
    - internal differential pricing
  - → decided under the national law: Section 84
- International Framework
  - TRIPS Agreement Art. 31, Doha Declaration on TRIPS and Public Health, par. 5(b):
    "Each member has the right to grant compulsory licences and the freedom to determine the grounds upon which such licences are granted"
  - Paris Convention, Article 5A
    - prevent abuses, for example failure to work
    - not before the expiration of four years from the filing date or three years from the date of grant
    - refused if inaction is justified by legitimate reasons
    - non-exclusive and not transferable, even in the form of a sub-license, except with that part of the enterprise or goodwill which exploits such license

Shionogi vs. MSD

(Raltegravir/Isentress®) - EP1422218B1

- Landgericht Düsseldorf (4c O 48/15)
  - Injunction pending since 2015
  - Oral hearing 13 September 2016
- Federal Patent Court, Munich (3 LiQ 1/16)
  31 August 2016: Preliminary compulsory license
  Sections 24, 85 German Patent Law
  - Unsuccessful try to obtain a voluntary license
  - Public interest
    (i.a. availability of alternatives – Federal Court of Justice, BGH 5 December 1995 (X ZR 26/92) – Polyferon)
  - Urgency

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Health related flexibilities
(among others)

- Compulsory Licensing and government use
  Trilateral Study, page 174
- Exhaustion of rights and parallel imports
  Trilateral Study, page 181
- Research exemption
  Trilateral Study, page 134
- Regulatory review exception
  also known as the “Bolar exception”, after a well known 1984 U.S. case, Roche Products v Bolar Pharmaceuticals (733 F.2d. 858 Fed. Cir. 1984):
  Trilateral Study, page 174
- Patent examination and registration
  Trilateral Study, page 172
- Pre- and post-grant review procedures
  Trilateral Study, page 173
- Patent term extensions
  Trilateral Study, page 183

- For more info:

http://www.wipo.int/edocs/mdocs/mdocs/en/cdip_5/cdip_5_4-main1.pdf
http://www.wipo.int/edocs/mdocs/mdocs/en/cdip_5/cdip_5_4-annex1.pdf
http://www.wipo.int/edocs/mdocs/mdocs/en/cdip_5/cdip_5_4-annex2.pdf

http://www.wipo.int/edocs/mdocs/mdocs/en/cdip_7/cdip_7_3-main1.pdf
http://www.wipo.int/edocs/mdocs/mdocs/en/cdip_7/cdip_7_3-annex1.pdf
http://www.wipo.int/edocs/mdocs/mdocs/en/cdip_7/cdip_7_3-annex2.pdf

Certain Aspects of National/Regional Patent Laws

Revised Annex II of document SCP/12/3 Rev.2: Report on the International Patent System

- Prior Art [PDF]
- Novelty [PDF]
- Inventive Step (Obviousness) [PDF]
- Grace Period [PDF]
- Sufficiency of Disclosure [PDF]
- Exclusions from Patentable Subject Matter [PDF]
- Exceptions and Limitations of the Rights [PDF]

Mandate for Legal and Technical Assistance

- WIPO Convention

  Article 4(v)

  WIPO offers its cooperation to States requesting legal-technical assistance in the field of intellectual property

- Agreement between the WIPO and the WTO

  Article 4

  The IB and the WTO Secretariat cooperate in their legal-technical assistance and technical cooperation activities relating to the TRIPS Agreement for developing countries to maximize the usefulness of those activities and ensure their mutually supportive nature.

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Legislative Advice

http://www.wipo.int/ip-development/en/legislative_assistance/

- Comments on existing or draft laws
  - Request from Member States
  - WIPO provides comments taking into consideration multilateral environments and commitments
- Providing consultant to draft laws
  - Request from Member States
  - WIPO engages consultant to provide a draft based on regional practices
  - Draft provided to country for consideration and review
- Providing assistance and advice
  - Workshops
  - Internal drafting of regulations based on existing laws
  - Accession to WIPO Treaties
  - Specific projects, e.g TK
  - Other possible activities

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Technical Assistance

http://www.wipo.int/global_ip/en/activities/technicalassistance/

- Strengthening infrastructure:
  Customized automation solution to streamline patent administration processes
  - Advice and needs assessment
  - Infrastructure upgrade and tailor-made automation solution including training and technical support
- Human resource training: Specialized knowledge and technical skills
  - Training for patent examiners (focussed workshops, on-the-job training)
  - Study visits and orientation programs
- Awareness building/outreach: Programs and activities to enhance knowledge and understanding about the issues related to IP
  (e.g. seminars, policy fora, study visits, studies, information materials, etc)
- Goal:
  Enable Offices to participate effectively in the global IP system

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Thank you!

Hans Georg Bartels
Global Challenges Division
hansgeorg.bartels@wipo.int
http://www.wipo.int/globalchallenges/en/

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