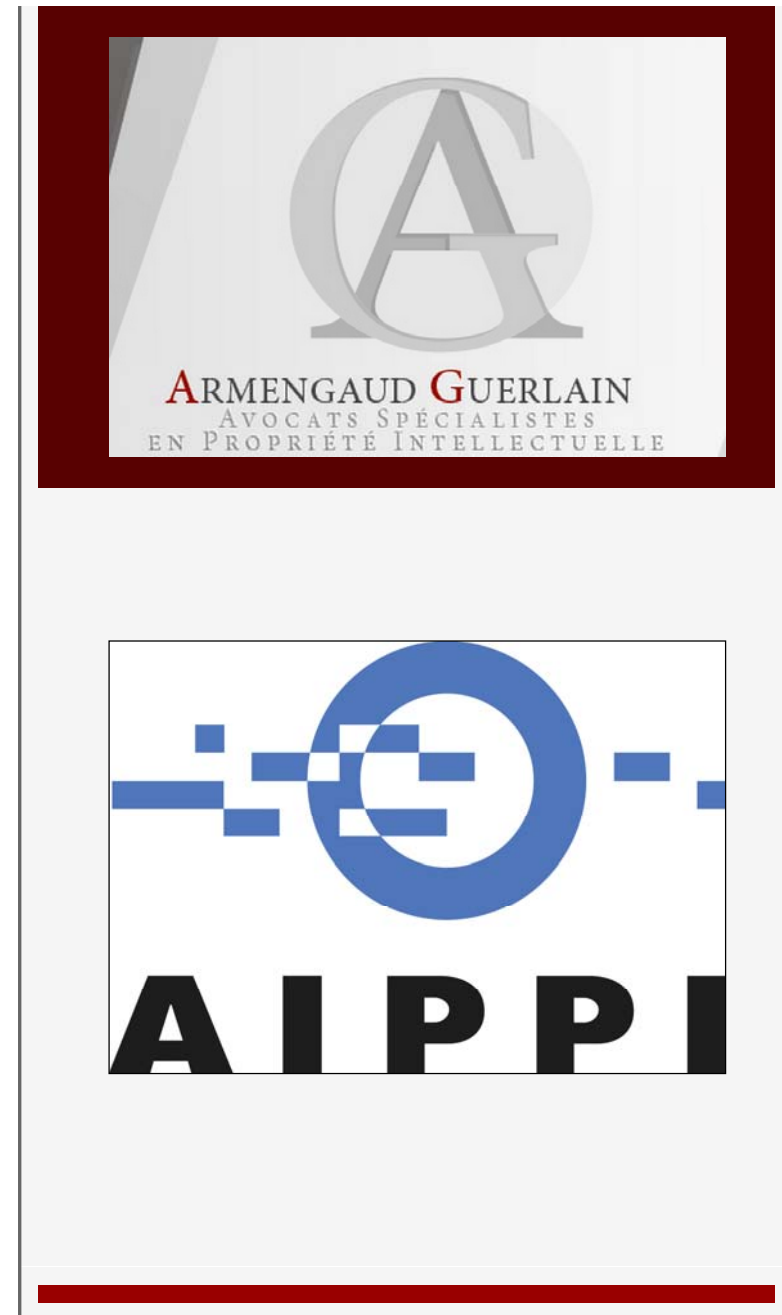


TRIPS, from the WTO to businesses

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BACKGROUND ON TRIPS AGREEMENT^L

History:

Outcome of the Uruguay Round Negotiations;
Annex 1C of the Marrakesh Agreement creating the WTO
(entry into force: 01.01.1995)

Notable content for patent practitioners:

General provisions & standards

Provisions on Patent law

Protection of undisclosed information

Enforcement

WTO disputes

TRANSITIONAL ARRANGEMENTS for the “least-developed countries” (1)

Art. 66 TRIPS – Least-Developed Country Members

*1. In view of the special needs and requirements of least-developed country Members, their economic, financial and administrative constraints, and their need for flexibility to create a viable technological base, such Members **shall not be required to apply the provisions of this Agreement**, other than Articles 3, 4 and 5, **for a period of 10 years from the date of application** as defined under paragraph 1 of Article 65. The Council of TRIPS shall, upon duly motivated request by a least-developed country Member, accord extensions of this period.*

2. Developed country Members shall provide incentives to enterprises and institutions in their territories for the purpose of promoting and encouraging technology transfer to least-developed country Members in order to enable them to create a sound and viable technological base.

TRANSITIONAL ARRANGEMENTS for the “least-developed countries”

DECLARATION ON THE TRIPS AGREEMENT AND PUBLIC
HEALTH - Ministerial Conference, Fourth Session - DOHA, 14.11.2001
(WT/MIN(01)/DEC/2)

Art. 7 [...] We also agree that the least-developed country Members will not be obliged, with respect to pharmaceutical products, to implement or apply Section 5 and 7 of Part II of the TRIPS Agreement or to enforce rights provided under these Sections until 1 January 2016, without prejudice to the right of least-developed country Members to seek other extensions of the transition periods as provided for in Article 66.1 of the TRIPS Agreement. [...]

TRANSITIONAL ARRANGEMENTS for the “least-developed countries”

DECISION OF THE COUNCIL FOR TRIPs IP/C/40 of 30.11.2005

I. Extension of the transition period under Article 66.1 of the Agreement for the least-developed country Members

1. Least-developed country Members shall not be required to apply the provisions of the Agreement, other than Articles 3, 4 and 5, until 1 July 2013, or until such a date on which they cease to be a least-developed country Member, whichever date is earlier.

TRANSITIONAL ARRANGEMENTS for the “least-developed countries”

DECISION OF THE COUNCIL FOR TRIPS IP/C/64 of
11.06.2013

1. Least-developed country Members shall not be required to apply the provisions of the Agreement, other Articles 3, 4 and 5, until 1 July 2021, or until such a date on which they cease to be a least-developed country Member, whichever date is earlier.

TRANSITIONAL ARRANGEMENTS for the “least-developed countries”

- Look back into the Nairobi Ministerial Declaration of 19.12.2015
- E-News No.47, WTO 10th Ministerial Conference in Nairobi – December 15-19, 2015, by Manoj Menda, Co-Chair of the Standing Committee on TRIPS

A REFERENCE IN IP LAW

Widely quoted in
the Report of the UN Secretary-General's high-level panel
on access to medicines,
September 2016.

DIRECT EFFECT ⁽¹⁾

ECJ 11.09.2007, Merck Genericos – Produtos Farmaceuticos v. Merck & Co Inc., Merck Sharp & Dohme. No. C-431/05

“As Community legislation in the sphere of patents now stands, it is not contrary to Community law for Article 33 of the Agreement on Trade-Related Aspects of Intellectual Property Rights (...) to be directly applied by a national court subject to the conditions provided for by national law.”

DIRECT EFFECT (2)

ECJ, 18.07.2013, Daiichi Sankyo Co. Ltd., Sanofi-Aventis Deutschland GmbH v. DEMO Anonimos Viomikhaniki Kai Emporiki Etairia Farmakon. No. C-414/11

“Article 27 of the Agreement on Trade-Related Aspects of Intellectual Property Rights [...], falls within the field of the common commercial policy.

Article 27 [...] must be interpreted as meaning that the invention of a pharmaceutical product [...] is, in the absence of a derogation in accordance to article 27(2) or (3), capable of being the subject-matter of a patent [...].”

DIRECT EFFECT (3)

AIPPI E-News No.46 “TRIPS Agreement influenced interpretation of patent law in Finnish patent dispute (J. Palm) (Decision No.821/15 dated 25.11.2015).

“The Article 34 of TRIPS Agreement obligates the member states to ensure that “the judicial authorities shall have the authority to order the defendant to prove that the process to obtain an identical product is different from the patented process”

“The TRIPS Agreement did not contain any specific restriction according to which the reversed burden of proof in Article 34 could not be applied in temporary injunction proceedings”.

DIRECT EFFECT (3)

AIPPI E-News No.46 “TRIPS Agreement influenced interpretation of patent law in Finnish patent dispute (J. Palm) (Decision No.821/15 dated 25.11.2015).

“The Article 34 of TRIPS Agreement obligates the member states to ensure that “the judicial authorities shall have the authority to order the defendant to prove that the process to obtain an identical product is different from the patented process”

“The TRIPS Agreement did not contain any specific restriction according to which the reversed burden of proof in Article 34 could not be applied in temporary injunction proceedings”.

DIRECT EFFECT (3)

AIPPI E-News No.47 “The Finnish Market Court Considered the Meaning of “Identical” under Article 34 of the TRIPS Agreement by Juhani Sinkkonen (Roschier, Attorneys Ltd. – Finland)

“The defendant argued that the product obtained by its process was not identical because different starting materials and a different process resulted in a different product. The defendant stated that its product contained a mixture of a wide range of hydrocarbons (C1 to C21) as well as other side products and water, and had been registered as a new product by the European Chemicals Agency. Furthermore, the defendant claimed that the patented process gave anhydrous middle distillate the main component of which was C18 n-paraffin. The Court stated that, in light of the TRIPS Agreement, the product obtained by the allegedly infringing process does not have to be fully identical with the new product obtained by the patented process in order to be considered identical within the meaning of Section 57a FPA. Instead, the refinery products in question were to be deemed identical if they were identical as to their essential composition, purpose of use and qualities.”

DIRECT EFFECT ⁽⁴⁾

Supreme Court, December 21, 2015,
Resolution No 722/2015

Barcelona Court of Appeals, Juzgado Mercantil No 4,
Sentencia No 338/14 of 20.10.2014

Barcelona Court of Appeals, Juzgado Mercantil No 7,
Sentencia No174/2016 of 20.07.2016

MOST-FAVORED-NATION

Art. 4 TRIPS - Most-Favoured-Nation Treatment

With regard to the protection of intellectual property, any advantage, favour, privilege or immunity granted by a Member to the nationals of any other country shall be accorded immediately and unconditionally to the nationals of all other Members. Exempted from this obligation are any advantage, favour, privilege or immunity accorded by a Member:

- (a) deriving from international agreements on judicial assistance or law enforcement of a general nature and not particularly confined to the protection of intellectual property;*
- (b) granted in accordance with the provisions of the Berne Convention (1971) or the Rome Convention authorizing that the treatment accorded be a function not of national treatment but of the treatment accorded in another country;*
- (c) in respect of the rights of performers, producers of phonograms and broadcasting organizations not provided under this Agreement;*
- (d) deriving from international agreements related to the protection of intellectual property which entered into force prior to the entry into force of the WTO Agreement, provided that such agreements are notified to the Council for TRIPS and do not constitute an arbitrary or unjustifiable discrimination against nationals of other Members.*

NON-DISCRIMINATION

Art. 27 TRIPS - Patentable Subject Matter

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.⁵ 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.*
2. *Members may exclude from patentability inventions, the prevention within their territory of the commercial exploitation of which is necessary to protect ordre public or morality, including to protect human, animal or plant life or health or to avoid serious prejudice to the environment, provided that such exclusion is not made merely because the exploitation is prohibited by their law.*

TRADE SECRETS (1)

Section 7, Art. 39 TRIPS

1. In the course of ensuring effective protection against unfair competition as provided in Article 10bis of the Paris Convention (1967), Members shall protect undisclosed information in accordance with paragraph 2 and data submitted to governments or governmental agencies in accordance with paragraph 3.

2. Natural and legal persons shall have the possibility of preventing information lawfully within their control from being disclosed to, acquired by, or used by others without their consent in a manner contrary to honest commercial practices so long as such information:

- (a) is secret in the sense that it is not, as a body or in the precise configuration and assembly of its components, generally known among or readily accessible to persons within the circles that normally deal with the kind of information in question;*
- (b) has commercial value because it is secret; and*
- (c) has been subject to reasonable steps under the circumstances, by the person lawfully in control of the information, to keep it secret.*

[...]

TRADE SECRETS (2)

Directive 2016/943 of the European Parliament and of the Council - 08.06.2016 - On the protection of undisclosed know-how and business information (trade secrets) against their unlawful acquisition, use and disclosure

Article 2 : Definitions

For the purposes of this Directive, the following definitions apply:

(1) 'trade secret' means information which meets all of the following requirements:

(a) it is secret in the sense that it is not, as a body or in the precise configuration and assembly of its components, generally known among or readily accessible to persons within the circles that normally deal with the kind of information in question;

(b) it has commercial value because it is secret;

(c) it has been subject to reasonable steps under the circumstances, by the person lawfully in control of the information, to keep it secret;

[...]

TRADE SECRETS (3)

Judgment of the Court of First Instance of Montpellier, 17.09.2015 No. 13/05047, *MVF3 APS, Vestergaard Frandsen & Disease Control Textiles v. Intelligent Insect Control & M. Ole Skovmand*.

- Direct implementation of articles 39-1 and 39-2 of the TRIPS Agreement.
- Control of the conditions laid down by article 39-2.
- Extension of the responsibility further than unfair competition solely (breach of confidentiality obligation in a non formal contract).
- Is reference to art. 39 TRIPS by a national court to remain an exception ? (EU Directive 2016/943)

COMPULSORY LICENSES ⁽¹⁾

Art. 30 TRIPS - Exceptions to Rights Conferred

Members may provide limited exceptions to the exclusive rights conferred by a patent, provided that such exceptions do not unreasonably conflict with a normal exploitation of the patent and do not unreasonably prejudice the legitimate interests of the patent owner, taking account of the legitimate interests of third parties.

Art. 31 TRIPS - Other Use Without Authorization of the Right Holder

Where the law of a Member allows for other use of the subject matter of a patent without the authorization of the right holder, including use by the government or third parties authorized by the government, the following provisions shall be respected: [...]

COMPULSORY LICENSES (2)

DECLARATION ON THE TRIPS AGREEMENT AND PUBLIC HEALTH - Ministerial Conference, Fourth Session - DOHA, 14.11.2001 (WT/MIN(01)/DEC/2)

Art. 5. *Accordingly and in the light of paragraph 4 above, while maintaining our commitments in the TRIPS Agreement, we recognize that these flexibilities include:*
[...]

(b) *Each Member has the right to grant compulsory licences and the freedom to determine the grounds upon which such licences are granted.*

(c) *Each Member has the right to determine what constitutes a national emergency or other circumstances of extreme urgency, it being understood that public health crises, including those relating to HIV/AIDS, tuberculosis, malaria and other epidemics, can represent a national emergency or other circumstances of extreme urgency.*

COMPULSORY LICENSES (3)

“Paragraph 6” Decision: Amendment of the TRIPS Agreement - Decision of December 6th, 2005 (WT/L/641).

Import/Export system for LDCs Member regarding pharmaceutical products under compulsory licenses.

See Also :

- Report of the United Nations Secretary-General’s High Level Panel on Access to Medicines (Sept. 2016). 2. Intellectual property laws and access to health technologies. 2.2.2. Compulsory Licenses.
- AIPPI E-News No. 47 “WTO 10th Ministerial Conference in Nairobi - 15-19.12.2015” (Manoj Menda)
- First notification of compulsory license (ApoTriavir) by Canada for export to Rwanda (4.10.2007)
- Columbia’s declaration to grant a compulsory license on Imatinib (“Glivec”) by Novartis (April 2016)

RESEARCH EXCEPTION (1)

Article 30 TRIPS - Exceptions to Rights Conferred

Members may provide limited exceptions to the exclusive rights conferred by a patent, provided that such exceptions do not unreasonably conflict with a normal exploitation of the patent and do not unreasonably prejudice the legitimate interests of the patent owner, taking account of the legitimate interests of third parties.

RESEARCH EXCEPTION (2)

See:

- Roche Products, Inc. c. Bolar Pharmaceutical Co., Inc., 733 F .2d 858 (1984)
- Canada - Patent protection of pharmaceutical products - Arbitration - 18.08.2000 (WT/DS114/13)
- First French evocation (defense argument) : Paris Court of first Instance, *Sanofi-Aventis Deutschland GmbH v. Lilly France SA*, 15.12.2014, No.14/58023
- Poland Supreme Court, Astellas c. Polypharma (CSK 92/13)
- Art. 27 Agreement on a Unified Patent Court
- Decision of the Spanish Supreme Court No. 7269/2011 (11.11.2011)

GOODS IN TRANSIT ⁽¹⁾

Article 51 TRIPS - Suspension of Release by Customs Authorities

Members shall, in conformity with the provisions set out below, adopt procedures to enable a right holder, who has valid grounds for suspecting that the importation of counterfeit trademark or pirated copyright goods may take place, to lodge an application in writing with competent authorities, administrative or judicial, for the suspension by the customs authorities of the release into free circulation of such goods. Members may enable such an application to be made in respect of goods which involve other infringements of intellectual property rights, provided that the requirements of this Section are met. Members may also provide for corresponding procedures concerning the suspension by the customs authorities of the release of infringing goods destined for exportation from their territories.

GOODS IN TRANSIT (2)

Article 52 TRIPS - Application

Any right holder initiating the procedures under Article 51 shall be required to provide adequate evidence to satisfy the competent authorities that, under the laws of the country of importation, there is prima facie an infringement of the right holder's intellectual property right and to supply a sufficiently detailed description of the goods to make them readily recognizable by the customs authorities. The competent authorities shall inform the applicant within a reasonable period whether they have accepted the application and, where determined by the competent authorities, the period for which the customs authorities will take action.

GOODS IN TRANSIT (3)

See:

- Brazil and India's complaints to the WTO against the Netherlands and the EU for seizure of generic drugs in Transit - 19.05.2010. (WT/DS408/1 & WT/DS409/1)
- AIPPI Question Q208 Working Guidelines "Border Measures and other Measures of Customs Intervention against Infringers"
- AIPPI Question Q230 Summary Report "Infringement of Trademarks by Goods in Transit"

TRANS-PACIFIC PARTNERSHIP

➤ Final proposal signed in Auckland, New Zealand (4.02.2016)

CHAPTER 18 - INTELLECTUAL PROPERTY

Art. 18.6 - *Understandings Regarding Certain Public Health Measures*

1. The Parties affirm their commitment to the Declaration on TRIPS and Public Health (...)

Art. 18.41 - *Other Use Without Authorisation of the Right Holder*

The Parties understand that nothing in this Chapter limits a Party's rights and obligations under Article 31 of the TRIPS Agreement, any waiver or any amendment to that Article that the Parties accept

CHAPTER 30 - FINAL PROVISIONS

Art. 30.3 - *Amendment of the WTO Agreement*

In the event of an amendment of the WTO Agreement that amends a provision that the Parties have incorporated into this Agreement, the Parties shall, unless otherwise provided for in this Agreement, consult on whether to amend this Agreement.

NAGOYA PROTOCOL

NAGOYA PROTOCOL on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from their Utilisation
(adoption on 29.10.2010 ; entry into force on 12.10.2014)

See also:

- AIPPI Question Q94 & Q166 The requirement of indicating in patent applications the sources or country of origin of genetic resources and traditional knowledge involved in the making of the invention.
- AIPPI Question Q232 The relevance of traditional knowledge to intellectual property law

IP & AI

AIPPI E-News No. 47 IP of A.I. - New type of intellectual property ? How the TRIPS Agreement is involved ? (T.S. Komatani).



Merci.
Gracias.
Thank you.
