



# **FLEXIBILITIES IN THE TRIPS AGREEMENT AND ITS IMPACT ON NATIONAL INTELLECTUAL PROPERTY POLICY**

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# INTRODUCTION

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- The World Trade Organization's Agreement on Trade-Related Aspects of Intellectual Property Rights, the TRIPS Agreement, which came into effect on 1 January 1995, is the most comprehensive multilateral agreement on intellectual property, and covers –
  - copyright and related rights;
  - trademarks including service marks;
  - geographical indications;
  - industrial designs;
  - patents;
  - layout-designs (topographies) of integrated circuits; and
  - undisclosed information including trade secrets.

# PRINCIPAL CHARACTERISTICS

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- *Article 1.1* - Members may, but shall not be obliged to, implement in their law more extensive protection than is required by the Agreement, provided that such protection does not contravene the provisions of the Agreement.
- Articles 3 and 4 - cover the fundamental rules on *national treatment and most-favoured-nation treatment of foreign nationals*.

# PRINCIPAL CHARACTERISTICS

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- In respect of each of the main areas of intellectual property, the Agreement sets out the *minimum standards of protection to be provided by each Member*.
- The Agreement defines each of the main elements of protection, namely the *subject-matter* to be protected, the *rights* to be conferred and permissible *exceptions* to those rights, and the minimum *duration* of protection.
- Members are required to provide *domestic procedures and remedies so that right holders can effectively enforce their rights*.

# FLEXIBILITIES - EXHAUSTION OF RIGHTS – Art. 6

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- Exhaustion of rights – refers to cases in which intellectual property rights are deemed exhausted after first sale of the protected product by the right holder or with his consent.
- Article 6 - For the purposes of dispute settlement under this Agreement, subject to most-favoured nation and national treatment, nothing in this Agreement shall be used to address the issue of exhaustion of rights.
- Doha Declaration on TRIPS and Public Health - the effect of the TRIPS provisions relevant to exhaustion of rights is to leave Members free to establish their own regimes for exhaustion, subject to most-favoured nation and national treatment.
- The Report of the United Kingdom Commission on Intellectual Property Rights urged developing countries to facilitate in their legislation their ability to import patented medicines if they can get them cheaper elsewhere in the world, such as through exhaustion of rights.

# FLEXIBILITIES - EXHAUSTION OF RIGHTS – Art. 6 (cont'd)

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- Parallel imports involve the import and resale in a country without the consent of the right holder, of a protected product which was put on the market of the exporting country by the right holder or in another legitimate manner ([www.southcentre.org](http://www.southcentre.org)).
- The doctrines of exhaustion of rights and parallel importation allow protected goods to be imported at a cheaper price from a foreign market.
- The Andean Group 'Common Regime on Industrial Property' (Decision 344 of 1993) states that the patent holder cannot prevent the 'importation of the patented product that has been marketed in any country with the consent of the owner, a licensee or any other authorized person' (Article 35(a)).

# FLEXIBILITIES – OBJECTIVES AND PRINCIPLES

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- Article 7 - the protection and enforcement of intellectual property rights should contribute to the promotion of technological innovation and to the transfer and dissemination of technology.
- Article 8 - recognizes the rights of Members to adopt measures for public health and other public interest reasons and to prevent the abuse of intellectual property rights, provided that such measures are consistent with the TRIPS Agreement.
- Doha Declaration on TRIPS and Public Health – 'each provision of the TRIPS Agreement shall be read in the light of the object and purpose of the Agreement as expressed, in particular, in its objectives and principles.'

# FLEXIBILITIES - EXCEPTIONS

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- The TRIPS Agreement permits Members to enact special or limited exceptions to the exclusive rights granted to the right holder (Articles 13 and 30).
- Such exceptions should not conflict with a normal exploitation of the copyright work or patent and should not unreasonably prejudice the legitimate interest of the right holder (Articles 13 and 30).
- In the case of patent exceptions, the legitimate interests of third parties should be safeguarded (Article 30).

# FLEXIBILITIES - EXCEPTIONS

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- The above TRIPS exception flexibilities have had a tremendous impact on the national intellectual property policies of many developing countries.
- Belize Copyright Act - copyright work is not infringed by the use of the work for purposes of research, private study, criticism, review, reporting, education, and parliamentary or judicial proceedings.
- Belize Patents Act – contains an exception for experimental use of a patented invention.

# FLEXIBILITIES - EXCEPTIONS

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- The United States Drug Price Competition and Patent Term Restoration Act (1984) introduced the 'Bolar' (early working) exception, following the case of *Roche v. Bolar Pharmaceuticals*.
- The Bolar exception allows testing to establish bio-equivalency of generic drugs before the patent expires in order to enable generic producers to market their lower priced drugs immediately after the patent expires.
- The Bolar exception has been adopted by Canada, Australia, Israel, Argentina and Thailand ([www.southcentre.org](http://www.southcentre.org)) and was ruled as consistent with the TRIPS Agreement by the WTO dispute settlement panel (WT/DS114: Canada – Pharmaceutical Patents).

# FLEXIBILITIES - EXCLUSIONS

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- **Article 27.2 – the commercial exploitation of an invention is contrary to ordre public or morality.**
- **Article 27.3(a) – diagnostic, therapeutic and surgical methods for the treatment of humans or animals.**
- **Article 27.3(b) – Members may exclude from patentability, plants, animals and essentially biological processes for their production.**

# FLEXIBILITIES - EXCLUSIONS

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- The above patent exclusions have been reflected in the intellectual property legislation of developing countries e.g. Section 12(1)(c) and (3) of the Belize Patents Act.
- Certain intellectual property experts have urged developing countries not to provide patent protection for new uses of known products, and plants 'because of the restrictions patents may place on use of seeds by farmers and researchers' (Report of the United Kingdom Commission on Intellectual Property Rights).
- Note – TRIPS gives Members the flexibility of providing protection for plant varieties either by patents or by an effective *sui generis* system or by a combination of both (Article 27.3(b)).

# FLEXIBILITIES - COMPULSORY LICENSING – Art. 31 (Main Conditions)

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- Article 31 – Main conditions for compulsory licensing/  
government use without authorization:
  - authorization of such use must be considered on its individual merits;
  - applicant must have made an unsuccessful attempt to obtain a voluntary licence from the patent holder (except national emergency/ extreme urgency/ public non-commercial use);
  - scope and duration of such use without the patent holder's authorization must be limited to the authorized purposes (limitations for semi-conductor technology);
  - authorization of such use must be non-exclusive;
  - authorization of such use must be non-assignable except with the part of the enterprise or goodwill entitled to such use;

# FLEXIBILITIES - COMPULSORY LICENSING – Art. 31 (Main Conditions)

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- authorization of such use must be predominantly for the supply of the domestic market of the Member authorizing such use;
- authorization of such use must be liable to be terminated if and when the justification for such use ceases to exist and are unlikely to recur (subject to adequate protection of the legitimate interests of the authorized persons);
- adequate remuneration must be paid to the patent holder, based on the economic value of the licence; and
- decisions relating to the authorization of, and remuneration for such use, must be subject to judicial or other independent review in the Member authorizing such use.

# FLEXIBILITIES - COMPULSORY LICENSING – Art. 31 (Main Conditions)

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- The compulsory licensing flexibility can be a useful bargaining tool in price negotiations with producers of patented medicines, as was seen when the United States envisaged the possibility of compulsory licensing when negotiating the price of Cipro following the anthrax attacks in 2001 (Report of the United Kingdom Commission on Intellectual Property Rights).
- Most developing countries found it almost impossible to benefit from this flexibility in their fight against public health crises such as the AIDS pandemic.
- This flows from the fact that Article 31(f) of the TRIPS Agreement states that patented products made under compulsory licensing must be 'predominantly for the supply of the domestic market'.
- Countries without the capacity to manufacture such drugs had difficulties finding other countries that could supply them with the drugs under compulsory licensing.

# FLEXIBILITIES - COMPULSORY LICENSING – Art. 31 (Main Conditions)

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- Attempts to circumvent this hurdle led to a flurry of legal actions, such as the clash pitting the Pharmaceutical Manufacturers' Association of South Africa (PMA) and 39 international drug makers against the South African government before the Pretoria High Court.
- The pharmaceutical companies argued that the enactment of the Medicines and Related Substances Control Amendment Act, that allows South Africa to import generic copies of patented drugs, violated the patent rights these companies had in respect of such drugs.
- The South African Government argued in reply that such cheaper generic drugs were needed to combat the aids pandemic that is affecting the country.
- After an international public outcry and agreement between the parties, the pharmaceutical companies withdrew their action.

# FLEXIBILITIES - COMPULSORY LICENSING – Art. 31 (Main Conditions)

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- Legal clashes such as this made a lot of countries unsure of how these flexibilities would be interpreted, and the scope of their right to use such flexibilities.
- An attempt to provide clarification was made at the WTO Ministerial Meeting in Doha, Qatar, in November 2001.
- DOHA Ministerial Declaration - the TRIPS Agreement should be interpreted in a manner supportive of public health, by promoting both access to existing medicines, and research and development into new medicines.
- The Ministers then adopted a separate Declaration on the TRIPS Agreement and Public Health ('the Declaration').

# **FLEXIBILITIES - COMPULSORY LICENSING – Art. 31 (Main Conditions)**

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- **The Ministers recognizing that Members with insufficient or no manufacturing capacities in the pharmaceutical sector could find it difficult to make use of the compulsory licensing flexibility, instructed the TRIPS Council to find an expeditious solution to this problem and to report to the General Council before the end of 2002.**
- **This problem became known as the 'Paragraph 6 issue' because it fell under that paragraph of the Declaration.**
- **The General Council Decision of 30 August 2003 was entitled 'Implementation of paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health' ('the Decision') and was later incorporated into an amendment of the TRIPS Agreement on December 6, 2005.**

# FLEXIBILITIES - COMPULSORY LICENSING

## – TRIPS Amendment (Main Conditions)

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- The Amendment of the TRIPS Agreement added a new Article 31 bis after Article 31 and also added an Annex to the TRIPS Agreement after Article 73.
- The new Article 31 bis (1) states that –

**'The obligations of an exporting Member under Article 31(f) shall not apply 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) in accordance with the terms set out in paragraph 2 of the Annex to this Agreement.'**

# FLEXIBILITIES - COMPULSORY LICENSING

## – TRIPS Amendment (Main Conditions)

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- According to paragraph 2 of the Annex, the terms for granting a compulsory licence for exports are that-
  - the eligible importing Member should notify the TRIPS Council of the names and expected quantities of the product needed.
  - a non-least developed country Member should confirm that it has insufficient or no manufacturing capacity for the pharmaceutical product in question in one of the ways set out in the Appendix to the Annex, and that, where a pharmaceutical product is patented in its territory, it has granted or intends to grant a compulsory licence.

# FLEXIBILITIES - COMPULSORY LICENSING – TRIPS Amendment (Main Conditions) (cont'd)

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- the compulsory licence issued by the exporting Member should state -
  - that only the amount necessary to meet the needs of the eligible importing Member may be manufactured, and the entire production must be exported to the latter;
  - that the manufactured products must be clearly identified as being produced under the system through special labelling or marking, special packaging and/or special colouring/shaping of the products (provided that such distinction is feasible and does not have a significant impact on price); and
  - that before shipping the products, the licensee should post on a website the quantities being supplied to each destination and the distinguishing features of the products.

# FLEXIBILITIES - COMPULSORY LICENSING

## – TRIPS Amendment (Main Conditions)

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- the exporting Member must notify the TRIPS Council of the grant of the licence, including the conditions attached to it.
- the notification provided shall include –
  - the name and address of the licensee;
  - the product(s) for which the licence has been granted;
  - the quantity(ies) for which it has been granted;
  - the country(ies) to which the product(s) is (are) to be supplied; and
  - the duration of the licence.

# FLEXIBILITIES - COMPULSORY LICENSING

## – TRIPS Amendment (Main Conditions)

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- The grant of the compulsory licence is subject to the payment of adequate remuneration to the patent holder under Article 31 (h) of the TRIPS Agreement.
- Members are required to provide effective legal measures, for preventing the re-exportation of the products that have actually been imported under the system, and the importation into, and sale in, their territories of products produced under the system.

# FLEXIBILITIES - COMPULSORY LICENSING

## – TRIPS Amendment (Main Conditions)

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- The Amendment defines a 'pharmaceutical product' as any patented product, or product manufactured through a patented process, of the pharmaceutical sector that is needed to address public health problems such as HIV/AIDS, tuberculosis, malaria, and other epidemics.
- This definition also covers active ingredients necessary for the manufacture of such pharmaceutical products and diagnostic kits needed for their use.
- An 'eligible importing Member' is defined as 'any least-developed country Member, and any other Member that has made a notification to the Council for TRIPS of its intention to use the system as an importer'.
- The term 'exporting Member' means a Member using the system to produce pharmaceutical products for export to eligible importing Members.

# FLEXIBILITIES - COMPULSORY LICENSING

## – TRIPS Amendment (Main Conditions)

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- The Amendment shall formally commence when two thirds of the WTO's Members have ratified it (Target: December 1, 2007).
- The Decision remains in force until the commencement of the Amendment.
- Indian Patents (Amendment) Act 2005 – 'Compulsory licence shall be available for manufacture and export of patented pharmaceutical products to any country having insufficient or no manufacturing capacity in the pharmaceutical sector for the concerned product to address public health problems' (Section 92A(1)).

# FLEXIBILITIES – TEST DATA PROTECTION – Art. 39.3

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- Article 39.3 – Members shall protect valuable undisclosed test or other data, submitted for regulatory approval of pharmaceutical or agro-chemical products, against unfair commercial use, or against disclosure, except where necessary to protect the public, or unless steps are taken to ensure that the data are protected against unfair commercial use.
- An inter-ministerial panel in India recently concluded that the TRIPS Agreement does not prevent Indian generic drug manufacturers from using costly research data, generated by multi-national pharmaceutical companies, to secure marketing approval for their generic drugs (Times News Network).

# FLEXIBILITIES – TRANSITIONAL ARRANGEMENTS

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1.1.1996 – developed countries (Article 65.1)

1.1.2000 – developing countries (Article 65.2)

1.1.2000 – economies in transition (Article 65.3)

1.1.2005 – additional five years for product patents in areas of technology not protected in a developing country (Article 65.4)

1.1.2006 – for Least Developed Countries (LDCs) with possible extensions (Article 66.1)

TRIPS Council – further extension up to 1.7.2013 for LDCs

Doha – 1.1.2016 for LDCs for pharmaceuticals (patents and undisclosed information)

# FLEXIBILITIES – TRANSITIONAL ARRANGEMENTS (cont'd)

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- India's pharmaceutical production sector really benefited from the transitional 5 year period given to developing countries to introduce product patent protection for pharmaceuticals.
- India's pharmaceutical production sector is now worth US\$4.5 billion and one of its generic drug manufacturers, Ranbaxy, has an annual turnover of US\$1 billion ([www.bbc.co.uk](http://www.bbc.co.uk)).
- However, due to expiry of the transitional period in 2005, India has now introduced product patent protection for pharmaceuticals.
- The India Patent Office is now processing 9,000 patent applications, mostly for drugs made by big international pharmaceutical companies (New York Times).

# FLEXIBILITIES – TRANSITIONAL ARRANGEMENTS (cont'd)

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- The Indian patent law amendment has also led to a flurry of patent litigation.
- In one such action, two Indian patients-rights groups have taken legal action to prevent an American biopharmaceutical company, Gilead Sciences, from patenting the anti-retroviral drug Viread (New York Times).
- The generic version of the drug is available in India and the groups argue that tenofovir is not a new drug and is therefore not patentable under India's new patent law (ibid).
- According to Leena Menghaney of Doctors Without Borders – 'These generic drugs are not only consumed in India. People in Africa and the Caribbean are relying on India to produce these drugs. The quality matches that of U.S. manufactured drugs, but the prices are affordable' (ibid).

# CONCLUSION

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- Intellectual property is a power tool for economic growth (Dr. Kamil Idris).
- Essential components of this power tool are the flexibilities of the TRIPS Agreement.
- Developing countries can use the TRIPS flexibilities to address problems of lack of access to medicines for diseases that affect their populations, high pharmaceutical prices and restrictions on availability (World Health Organization's Commission on Intellectual Property Rights, Innovation and Public Health (CIPRH)).
- Caribbean countries should jealously guard these TRIPS flexibilities during regional and bilateral Free Trade Agreement negotiations.