



**Intellectual Property and Life Sciences  
Regulation  
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**Article 30 TRIPS and Regulatory  
Review Provisions:**

**The WTO Panel Report on *Canada-  
Patent Protection of Pharmaceutical  
Products* (WT/DS114/R)**

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# Introduction

- **Importance of a well-crafted exception provision for a balanced intellectual property regime that will meet its underlying public policy purposes:**
  - Article 7 TRIPS
- **Considerable diversity in different jurisdictions:**
  - example: experimental use exception
- **This presentation will set out:**
  - the approach in the TRIPS Agreement; and
  - the relevant jurisprudence in the WTO

# p.m.: « Patent Table »

Art.27.1: Patentable Subject-Matter



**Exclusions:  
Art.27.2 + 3**

Art.29: Patent Application



if granted

Art.28: Rights conferred



**Exceptions:  
Art. 30 + 31**

Art.33: Protection: 20 years from filing

# Approach in TRIPS Negotiations

- **Approaches to permissible exceptions to patent rights considered:**
  - **Silence**
  - **Closed list**
  - **Illustrative list, with or without general safeguards**
  - **General safeguards only**

# Approach in Article 30 TRIPS

- **Three-step test setting out general safeguards for use of exceptions:**
  - similar, but not identical to, Article 9(2) Berne Convention, Article 13 TRIPS
- **Optional, if exceptions:**
  - are limited
  - do not unreasonably conflict with normal exploitation of patent, and
  - do not unreasonably prejudice the legitimate interests of the patent owner, taking into account the legitimate interests of third parties
- **Examples of exceptions found in national legislations:**
  - Experimental use
  - Use to develop test data for marketing approval

# WTO Jurisprudence

- **Report of the Panel on *Canada – Patent Protection of Pharmaceutical Products* (WT/DS114/R), adopted on 7 April 2000**
- **Gives some guidance to interpretation of three-step test**
- **Relates to scope for WTO Members to enable generic pharmaceutical companies, prior to patent expiry, to use patented inventions for the purposes of:**
  - **securing regulatory approval of their generic equivalents (similar to the Bolar exception in the United States); and**
  - **stockpiling**
- **Did not relate to research exception**

# Main Findings (1): “Limited exceptions”

- **Combination of the words “limited” and “exceptions” to be read as narrow exception:**
  - one which makes only a small diminution of the rights
- **Measure:**
  - extent to which patent owner’s exclusive rights are curtailed
  - not: economic effects of such curtailment which are addressed by the other two tests
- **Findings:**
  - stockpiling exception = not limited
  - regulatory exception = limited because restricted to conduct necessary to comply with the requirements of the regulatory approval process

## **Main Findings (2): No Unreasonable Conflict with Normal Exploitation**

- **“Exploitation”**: understood to refer to commercial activity by which patent owners employ exclusive patent right to extract economic value from it
- **Additional period of de facto market exclusivity created by using patent rights to preclude submissions for regulatory authorization not to be considered part of “normal exploitation”**
- **No need to consider whether any prejudice to “normal exploitation” would be unreasonable**

## **Main Findings (3): No Unreasonable Prejudice to Patent Owner's Legitimate Interests, Taking Account of Third Parties' Legitimate Interests**

- **“Legitimate interests”:**
  - no reference to legal interests
  - but to broader normative concept relating to interests that are justifiable, i.e. supported by relevant public policies or other social norms
  - not covered: economic advantage to be gained from de facto extension of market exclusivity due to health regulatory system