

TRIPS Flexibilities (Post-Grant)

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POST GRANT FLEXIBILITIES

- **Exceptions to patents**
- **Early working exception**
- **Parallel importation**
- **Non-voluntary licenses (compulsory/government use license)**
- **Post Grant Opposition**

Post Grant Oppositions

- Wrongly granted patents unduly block competition and prejudice consumers. Challenging validity of patent before courts is costly and time- consuming.
- Supports patent examiners to conduct more rigorous examination of patent applications and are particularly important for poorly staffed patent offices (which is the case in most developing countries). e.g. India's patent law provides pre-grant opposition (any time before grant) and post grant opposition (one year from date of publication of grant).
- **Important Feature: Administrative (before patent office).**
- **Argentina**, 25 patent oppositions submitted by companies (for the HIV medicines and heart disease, diabetes, and arthritis) - efavirenz, ritonavir, lopinavir, raltegravir, elvitegravir and the fixed- dose combination TDF/FTC/EFV. Many of the opposed applications were finally rejected.
- **In India**, 25 out of 34 oppositions that were filed by local companies or NGOs against pharmaceutical patent applications filed between 2005 and 2008 resulted in rejections, i.e. a significantly high ratio of 73.5 per cent.

<i>MEDICINE</i>	<i>WHO HAS APPLIED FOR THE PATENT AND WHERE</i>	<i>WHO HAS OPPOSED THE PATENT APPLICATION (DOES NOT INCLUDE GENERIC COMPANIES)</i>	<i>WHAT IS THE STATUS OF THE PATENT APPLICATION</i>
<i>Ritonavir Second-line ARV</i>	<i>Abbott Laboratories Mumbai</i>	<i>Delhi Network of Positive People, and Indian Network for People living with HIV/AIDS</i>	<i>PATENT APPLICATION REJECTED</i>
<i>Efavirenz (post-grant opposition) First-line ARV</i>	<i>Bristol Myers Squibb Mumbai</i>	<i>Delhi Network of Positive People</i>	<i>Pending</i>
<i>Valgancyclovir (post-grant opposition) OI medicine</i>	<i>F Hoffmann- La Roche Chennai</i>	<i>Delhi Network of Positive People</i>	<i>PATENT OVERTURNED</i>
<i>Pegylated Interferon alpha 2a Hepatitis C</i>	<i>F Hoffmann- La Roche Chennai</i>	<i>Sankalp Rehabilitation Trust</i>	<i>PATENT OVERTURNED</i>

Exception to Patents (Article 30 of TRIPS)

- Patents are not absolute rights. Justified...in certain circumstances limited use of the patented inventions is required to achieve public policy purposes of encouraging innovation, facilitate production of generic medicines and protecting other interests.
- Article 30 does not define the nature and extent of these exceptions but, it provides a general test to be used to determine their admissibility.
- **Limited exceptions to exclusive rights** provided that 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 into account the legitimate interests of third parties
- Allows a third party to make specified and limited use of patent
- **No need consent of the patent holder.....automatically applicable IF provided for in national legislation**

Common exceptions include:

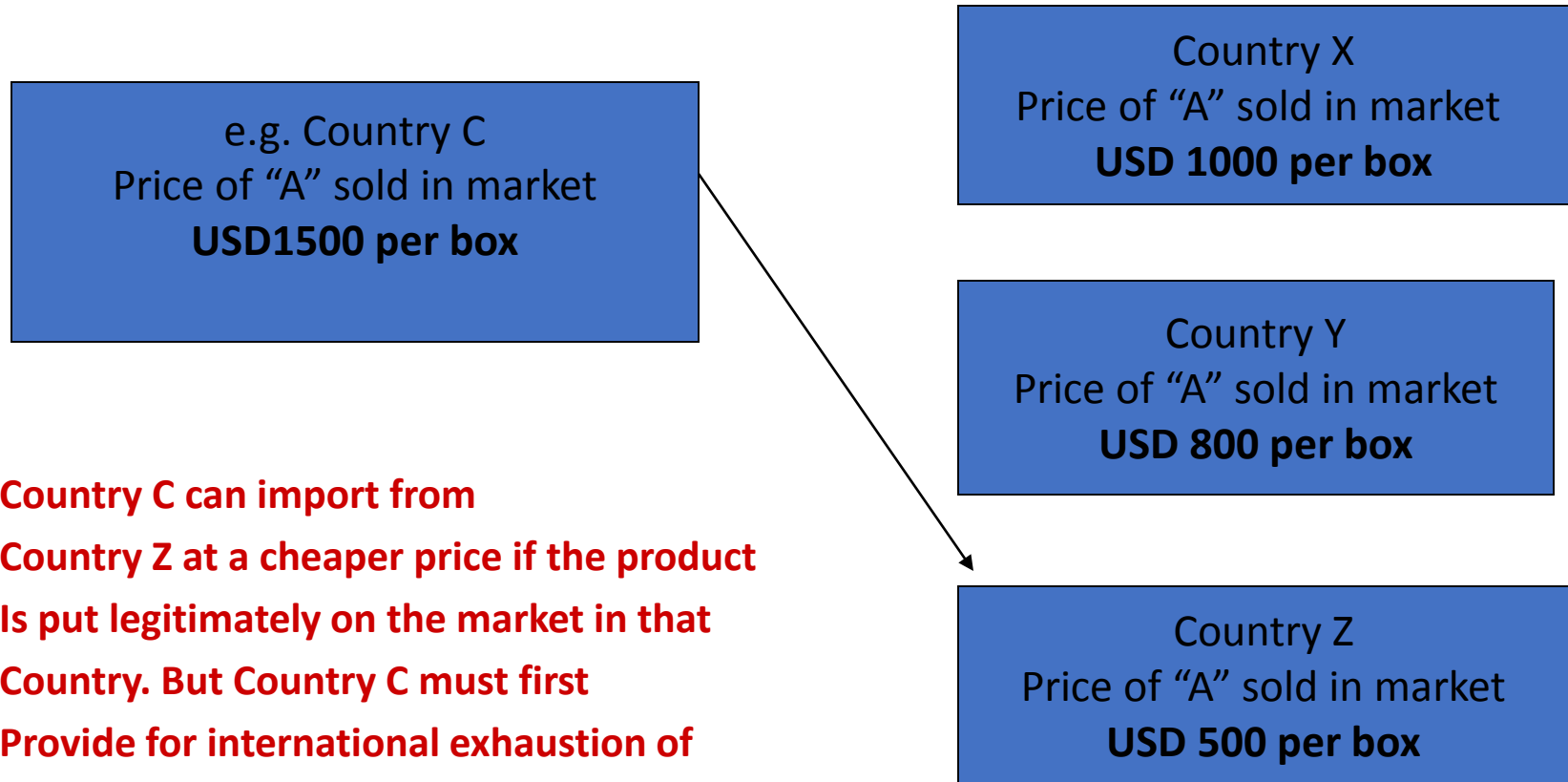
- Research
- Experimental use for scientific or commercial purposes
- Exception for individual prescriptions.
- *** **"Bolar" exception**: use of patented product prior to expiry of the patent period for obtaining marketing approval for generic products..... This procedure facilitates the marketing of a generic version promptly after the patent protection of the patented product expires.

Parallel Importation (Article 6 of TRIPS)

- Parallel import is the import and resale in a country, **without the consent of the patent holder**, of a patented product that has been legitimately put on the market of the exporting country under a parallel patent.
- Doha Declaration on TRIPS and Public Health affirms the right to choose Exhaustion of rights: national, regional or international regimes
- Recommendation: International exhaustion

Example of International Exhaustion of Rights

***Taking advantage of differential pricing**



Country C can import from Country Z at a cheaper price if the product is put legitimately on the market in that Country. But Country C must first provide for international exhaustion of rights

NonVoluntary Licenses: Compulsory/ Government Use License (Article 31 of TRIPS)

- Licenses granted to authorize use of a patent-protected invention by the government or third parties **without the consent of the patent holder.**
- Doha Declaration on TRIPS & Public Health:

“Each Member has the right to grant compulsory licences and the freedom to determine the grounds upon which such licences are granted”

“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 LICENSE

- **Right to determine grounds for compulsory licence** (reaffirmed in Doha Declaration)
 - negotiations to obtain a license on reasonable terms and conditions from the patent holder failed
 - public interest,
 - national emergencies,
 - public health nutrition,
 - failure to exploit or insufficiency of working
 - to remedy anti competitive practices
- **Need to show prior negotiations** to obtain license under reasonable terms from the patent holder failed **Except** when CL issued in cases of
 - national emergency
 - situation of extreme urgency including public health crises
 - Remedy anti-competitive practices
- **Payment of “adequate remuneration”**
- **Condition:** CL has to be “predominantly for the supply of the domestic market.

GOVERNMENT USE

- **"Public non-commercial use"**
- **Government right** (govt. agency, dept. or contractor) to use patent in the public interest **without the consent of the patent holder.**
- Fast-track approach
- No need prior negotiation with patent holder
- Payment of "Adequate Remuneration" to patent holder

EXAMPLES OF COUNTRIES USING COMPULSORY USE LICENSES

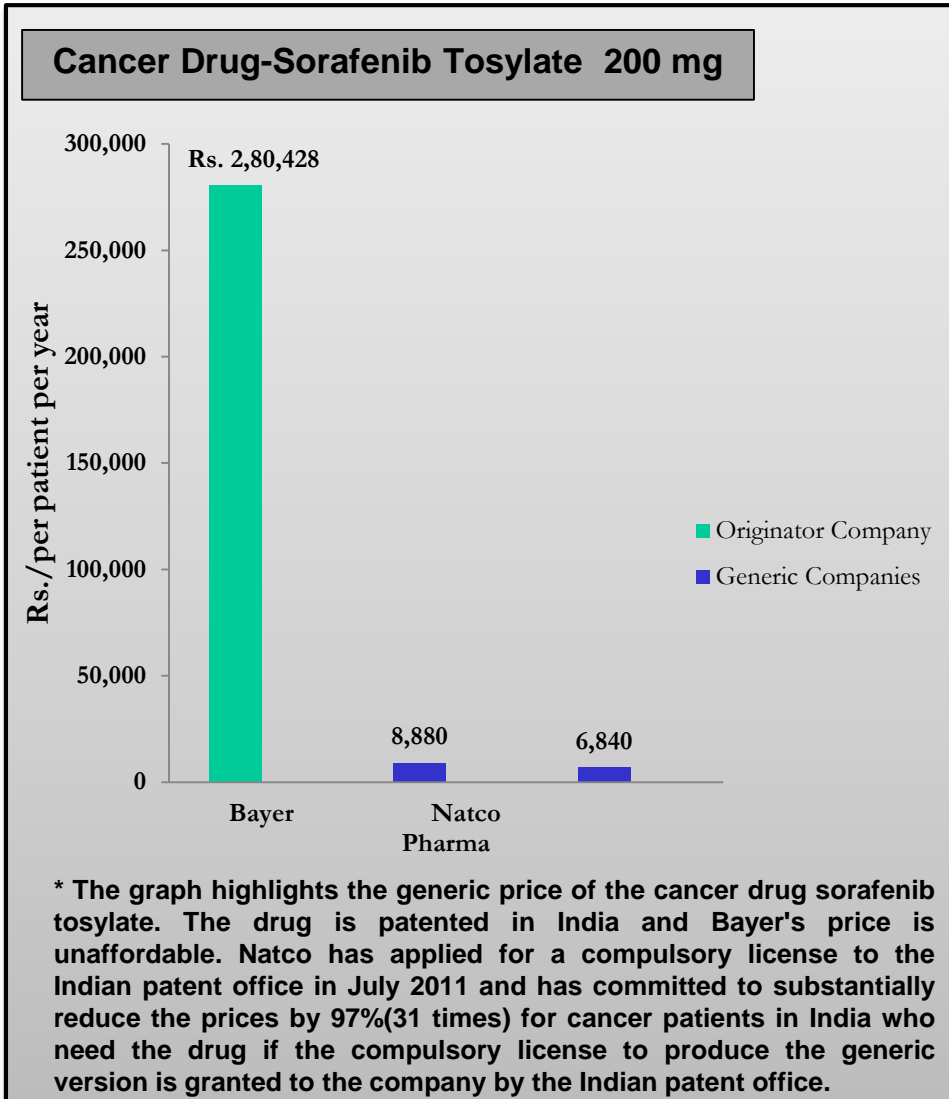
Government Use License: Malaysian Experience

- New direct acting antivirals (DAAs) has revolutionized HCV treatment.
- Estimated HCV burden: ~500,000 people with chronic HCV(2.5% of the adult population). Predominant genotype: GT3 (61.9%); GT1 (35.9%), GT2 (1.8%) and GT6 (0.5%).
- HCV treatment: Sofosbuvir (SOF) patented; Daclatasvir (DCV): no patent
- Excluded from Gilead's voluntary licensing agreement.
- Cost of Originator Sofosbuvir
 - Private health care 100% out of pocket payment for 12 week course of sofosbuvir costs MYR 300,000 (about 71,700 USD). Average monthly salary of Malaysians =1,200 USD
 - Gilead offers to Malaysia, about 12,000 USD for 12 weeks
- August 2017 - Malaysia's Cabinet approved a government use license for sofosbuvir under Section 84 (1) of Patents Act and imported generic versions of sofosbuvir from Egypt.
- **Impact: Cost of sofosbuvir + daclatasvir combination: less than US\$300 for a treatment course of HCV. Sofosbuvir costs about US\$100 for 12 week supply. Free treatment rolled out in 18 public hospitals.**

Brazil

- **In Dec. 2003 Brazil announced that CL could be adopted** for the production of Nelfinavir in Brazil. In 2004 Health Minister was successful in obtaining a price reduction for 5 drugs Nelfinavir, Lopinavir, Efavirenz, Tenofovir and Atazanavir. **Resulted in 37% reduction in the prices.**
- **In 2005, Brazil threatened to issue a CL** for a very important HIV/AIDS drug Kaletra. It was paying Abbott (patent holder) \$107m a year for Kaletra (Lopinavir + Ritonavir), which it (Brazil govt) provides to patients for free.
- As a **result of threat**, the patent holder of Kaletra agreed to reduce the price of the drug from USD 1.17 to USD 0.63 representing a saving of USD339.5 million between 2006 and 2011. Expected the number of Kaletra users to triple to about 60,000 people (by 2011) from 23,400 patients (in 2005).
- **May 2007, Brazil government issued a Government Use Order** to import generic versions of efavirenz. 75 000 patients using the drug. Long negotiation process with patent holder. Price stable since 2003 - US\$ 1,59/tb. But International price—US\$0,45/tb and Thailand with 17,000 patients—US\$0,67/tb .
- **As a result of CL**, Price reduction - from US\$1.59 to US\$0.43. Annual expenditure reduced from US\$ 580.00 to US\$166.36 with estimated saving of US **\$236.9 million by 2012 (when the patent expires).**

First CL in India



Natco Pharma requested for a CL for the anti-cancer drug **Nexavar** (*Sorafenib Tosylate*), patented by Bayer.

Granted in March 2012:

- Bayer's import was grossly **inadequate to the needs** (hardly 2%)
- No import in certain years
- Price **not reasonably affordable** to the public. Bayer price **5210 USD** for 120 tabs for a month; Natco **164 USD**
- Grant of CL challenged in Supreme Court of India but CL upheld.

In the UK: Bayer has priced the drug at nearly **£3,500 per month**

Zimbabwe Apr 2003	Declaration emergency (HIV/AIDS) for 5 years '03-' 08. CL given to company Varichem to manufacture & import	Not indicated	not indicated
Zambia Sept. 2004	Issued CL to Pharco Mocambique which presented a project to manufacture triple compound: lamivudine, stavudine & nevirapine	until notification of expiry of CL	2.5% of total turnover of pdts
Mozambique 2004	Issued CL to Pharco Mocambique which presented a project to manufacture triple compound: lamivudine, stavudine & nevirapine	until emergency comes to an end.	2% of total turnover of pdts at pharco
Eritrea 2005	Imported HIV/AIDS on the basis that LDC, declares emergency, for public non commercial use	not indicated	
Ghana Oct. 2005	Declared emergency: HIV/AIDS. Issued GU licence to import generic medicines	not indicated	Not indicated

Malaysia Oct 2003	Government Use (GU) licence to import: didanosine; zidovudine; didanosine+zidovudine	2 years	Offered 4%
Thailand Nov. 2006	GU: to import/manufacture Efavirenz	until 31 Dec. 2011	0.5%
Thailand Jan. 2006	GU to import/manufacture: clopidogrel	Patent expiry or no longer needed	0.5%
Thailand Jan 2007	GU to import/manufacture : lopinavir/ritonavir	Until 31st January 2012	0.5% of total sale value of the imported/locally produced
Thailand Jan 2008	3 GU licences for cancer drugs	Patent expiry or no longer needed	3-5%

Indonesia 2004/2007	2 GU manufacture: lamivudine, nevirapine	7/8 years (2007 replaces 2004)	0.5% of the net selling value of ARVs to patent holder
Indonesia 2012	GU manufacture Efavirenz	until patent expired in Aug. 2013	0.5%
Indonesia 2012	GU manufacture abacavir	Until patent expires in May 2018	0.5%
Indonesia 2012	GU manufacture didanosine	Until patent expires in Aug. 2018	0.5%
Indonesia 2012	3 GU for lopinavir+ritonavir; tenofovir; TDF+emtricitabine and TDF+emtricitabine+efaviren z	Until patents expire (2018; 2018; 2024)	0.5%

India March 2012	To manufacture: sorafenib/Nexavar	Until patent expires	6%
Brazil May 2007	GU to import efavirenz	5 years	1.5%
Ecuador April 2010	CL: to import ritonavir	until 30 Nov. 2014 (patent expiry)	US\$ 0.041 for each capsule of ritonavir 100mg and US\$ 0.02 for ritonavir+lopinavir combination
Ecuador Nov. 2012	CL: to manufacture abacavir/lamivudine	Patent expiry or no longer needed	US\$ 0.117 per capsule

Paragraph 6 Doha Declaration Problem

Recognized problem:

Post 2005.....TRIPS Agreement is fully implemented by major generic producing countries e.g. in India.....these countries can only produce under a compulsory license “predominantly for the supply of the domestic market” [Art. 31 (f) TRIPS Agreement]

- What does this mean? – 100 % production.
51% must be for supply to domestic market. 49% can be exported (non-predominant portion)

Problem is 49% may NOT be sufficient to meet all the needs of countries importing because they lack manufacturing capacity.

To resolve problem:

- The Doha Decl directed TRIPS Council “to find an expeditious solution to this problem and to report to the General Council before the end of 2002.
- **Decision reached on 30 August 2003**
 - waiver of Article 31(f) for countries producing under a CL
 - entire production can be exported
 - BUT many procedures have to be followed by exporting and importing countries
 - many view that procedures are cumbersome and may be a disincentive to use the decision
- 30 August 2003 decision was a temporary solution....but after heated discussions/negotiations, **it has been translated and incorporated as an amendment of the TRIPS Agreement on 6 December 2005 as Article 31bis**

When does the Amendment Apply ?

- **Product is patented in Exporting country** (Supplying Country) for e.g. India
- To produce and export, India has to issue a CL and so it will have the condition that it has to be predominantly for the supply of the domestic market
- **Decision applies**
 - >50% of production exported
(the predominant portion)

If less than 50%, the decision does not apply

Scenario 1

Case: If Zanzibar authority asks India to supply 100 000 pills of generic versions of product “X”. India produces and will export the entire production to Zanzibar

Q: Does the Decision Apply

INDIA
Product “X” is
Patented

ZANZIBAR
Product “X” is **not**
patented

India will have to issue a CL which will be limited by the condition that it is predominantly for the supply of the domestic market. (Art 31(f))

Answer: Yes

Scenario 2

Case: If India produces 500 000 pills of generic versions of product “X” under a compulsory licence. 300 000 is for its domestic market. 100 000 is for South Africa. 100 000 is for Zanzibar.

Q: Does the Decision Apply

INDIA
Product “X” is
Patented

ZANZIBAR
Product “X” is **not**
patented

India will have to issue a CL which will be limited by the condition that it is predominantly for the supply of the domestic market (Art. 31 (f) of TRIPS)

Answer: NO

Scenario 3

Case: If the Zanzibar authority asks India to supply 100 000 pills of generic versions of product

“X”. India produces and will export the entire production to Zanzibar

Q: Does the Decision Apply

INDIA
Product “X” is
NOT patented

Zanzibar
Product “X” is
patented

Answer: NO

So Zanzibar issues a government use order or a CL to import

The problem is with the exporting country being limited by the condition of predominantly for the supply of the domestic market. So if not patented in the exporting country.....then there is no need to apply the Decision

In deciding whether the Decision applies or not, it is irrelevant whether the product is patented or not in the importing country

Using the Decision As An Importing Country

Who can Import ? :

Decision says only “eligible importing members” defined as:

- i) **any LDC** (automatically qualifies and no need for notification)
- ii) **other WTO members** that has **notified** TRIPS Council of its **intention to use the system as an importer**
 - This is a “one time” notification
 - Notification is declaratory...No need approval

Must Notify TRIPS Council

- (i) specify names and expected quantities of products (not the exact quantities)
- (ii) confirm establishment of insufficient or no manufacturing capacities for the products specified (self – assessment)
*****This requirement does not apply to LDCs. Assumed not to have manufacturing capacity**
- (iii) confirm grant or intention to grant a CL if product is patented in that country (in accordance with Art. 31 TRIPS Ag.)

Using the Decision As An Exporting Country (1)

➤ Grant of CL and conditions attached to it

- To produce only amounts necessary to meet the needs of the eligible importing member and
- Entire production must be exported
- Clear identification of products through specific labelling or marking.
- Distinguishing products through special packaging and/or special colouring/shaping of products themselves

➤ Notification to TRIPS Council of:

- Grant of CL and the conditions including:
- name and address of licensee
- products for which licence granted
- quantity for which licence granted
- countries to which product to be supplied
- duration of licence

➤ To post on Website (before shipment) details of:

- Quantities being supplied to each destination
- Distinguishing features of products as required

Other Relevant Provisions

- **Remuneration** to the patent holder be payable in the Exporting Member.
Importing countries need not pay remuneration

- Importing Members shall take reasonable **measures to prevent re-exportation**
 - Within their means
 - Proportionate to their administrative capacities
 - Proportionate to the risk of trade diversion

- The Decision is **WITHOUT PREJUDICE** to the other rights, obligations and flexibilities that Members have under the provisions of the TRIPS Ag.

Other Relevant Provisions

- sub-para 6(i) in the 30 August Decision
 - with a view to harness economies of scale for the purposes of enhancing purchasing power for, and facilitating the local production of, pharmaceutical products
- another system is established...for where a regional trade agreement exist and at least half of the current membership are LDCs e.g. EAC, etc....
- e.g: Tanzania imports from India under this Decision and re exports to Kenyaunder EAC arrangement