IP and public health
The regional perspective

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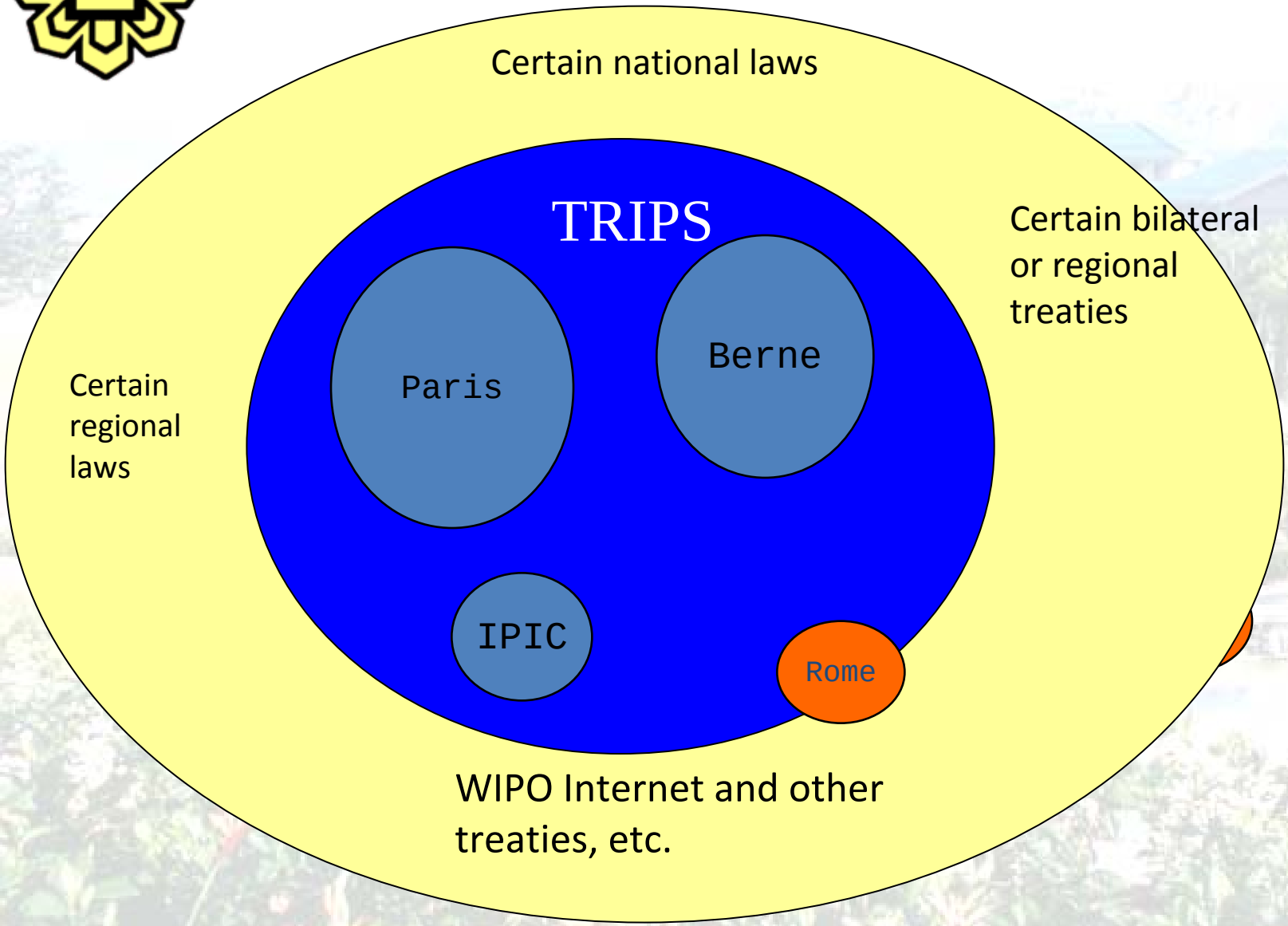
What do we know about the Asia Pacific Region?

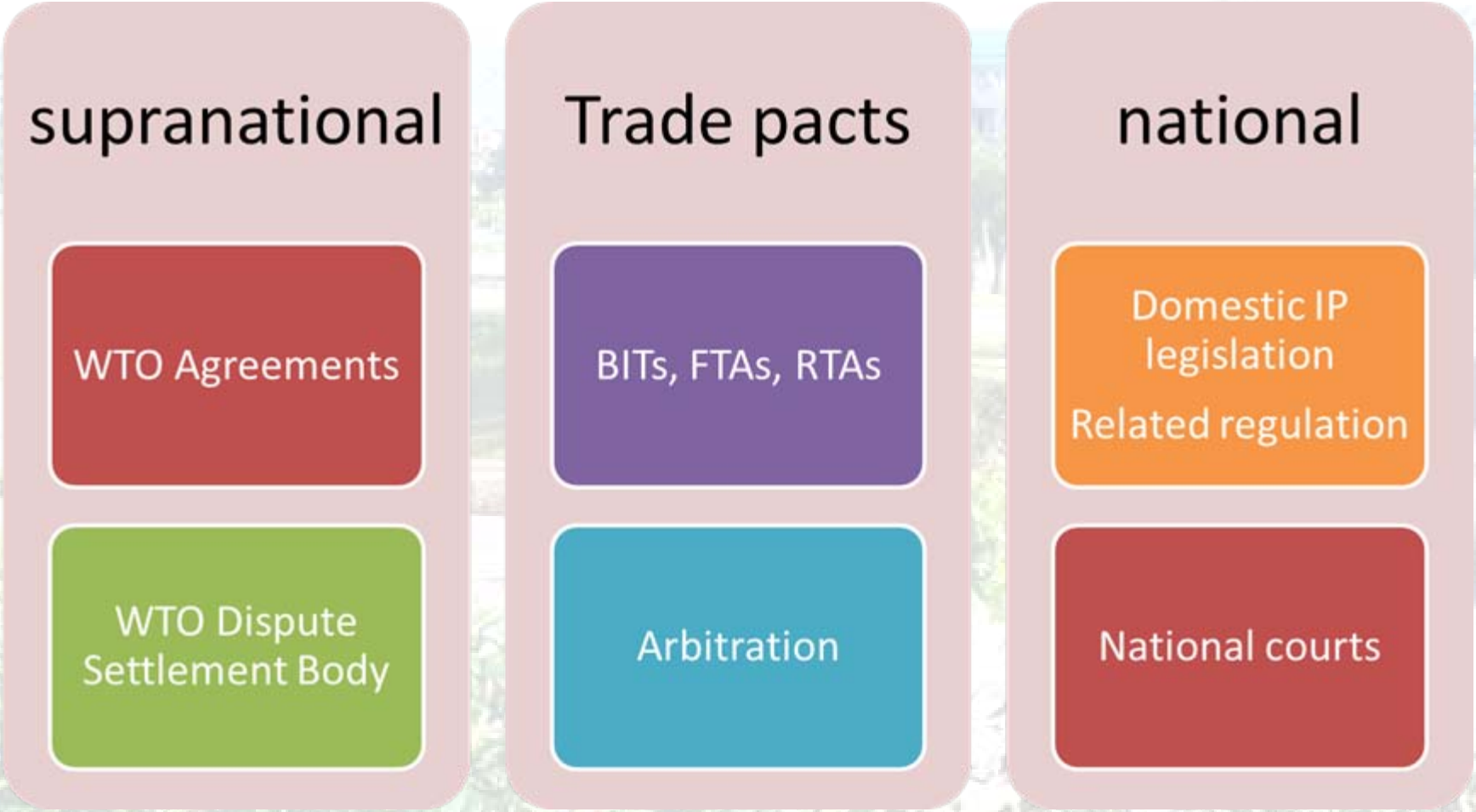
Massive Discrepancies in economic development

Diverse in public health needs

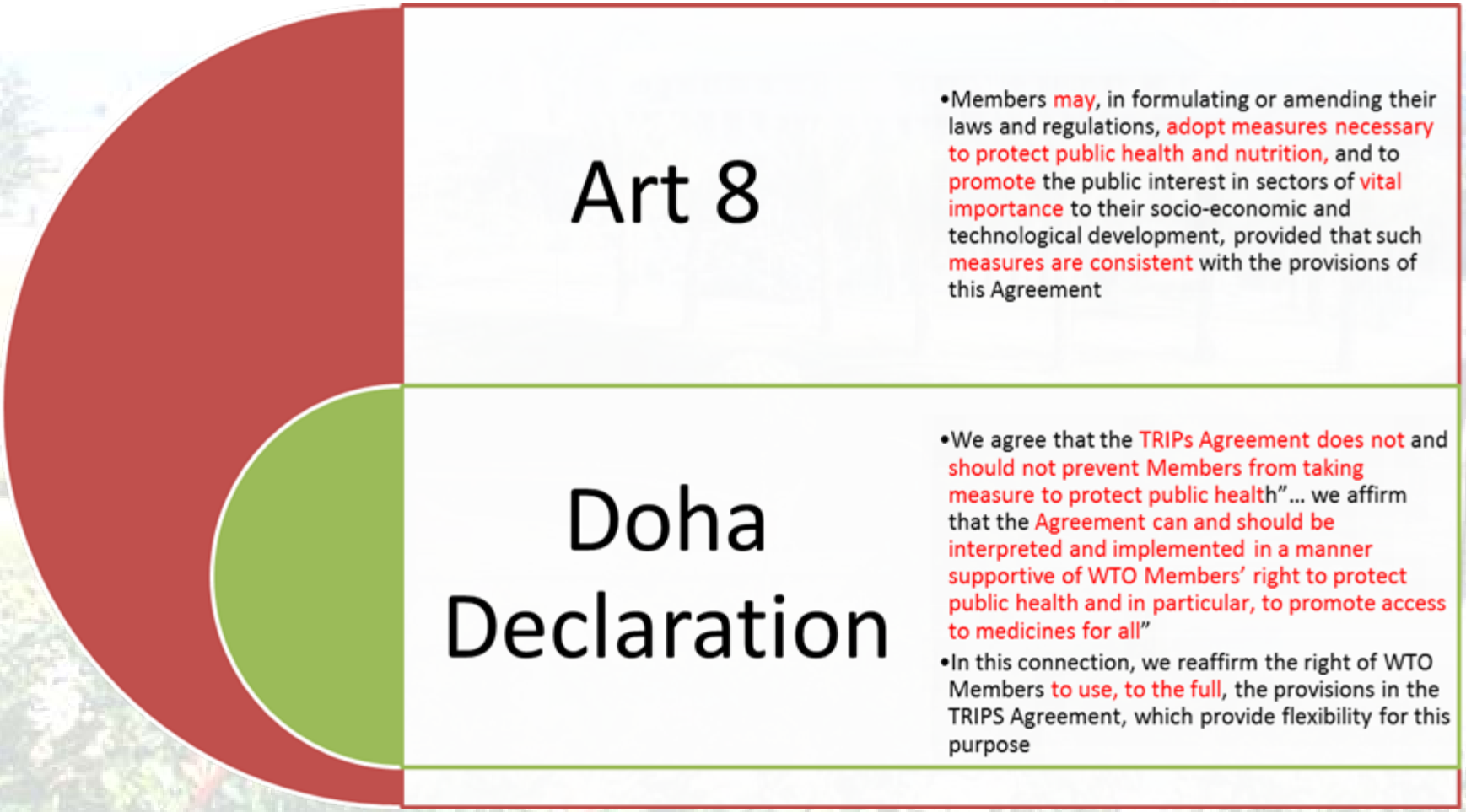
The "IP world" : Paris, Berne; Paris and Berne plus (TRIPS); beyond TRIPS



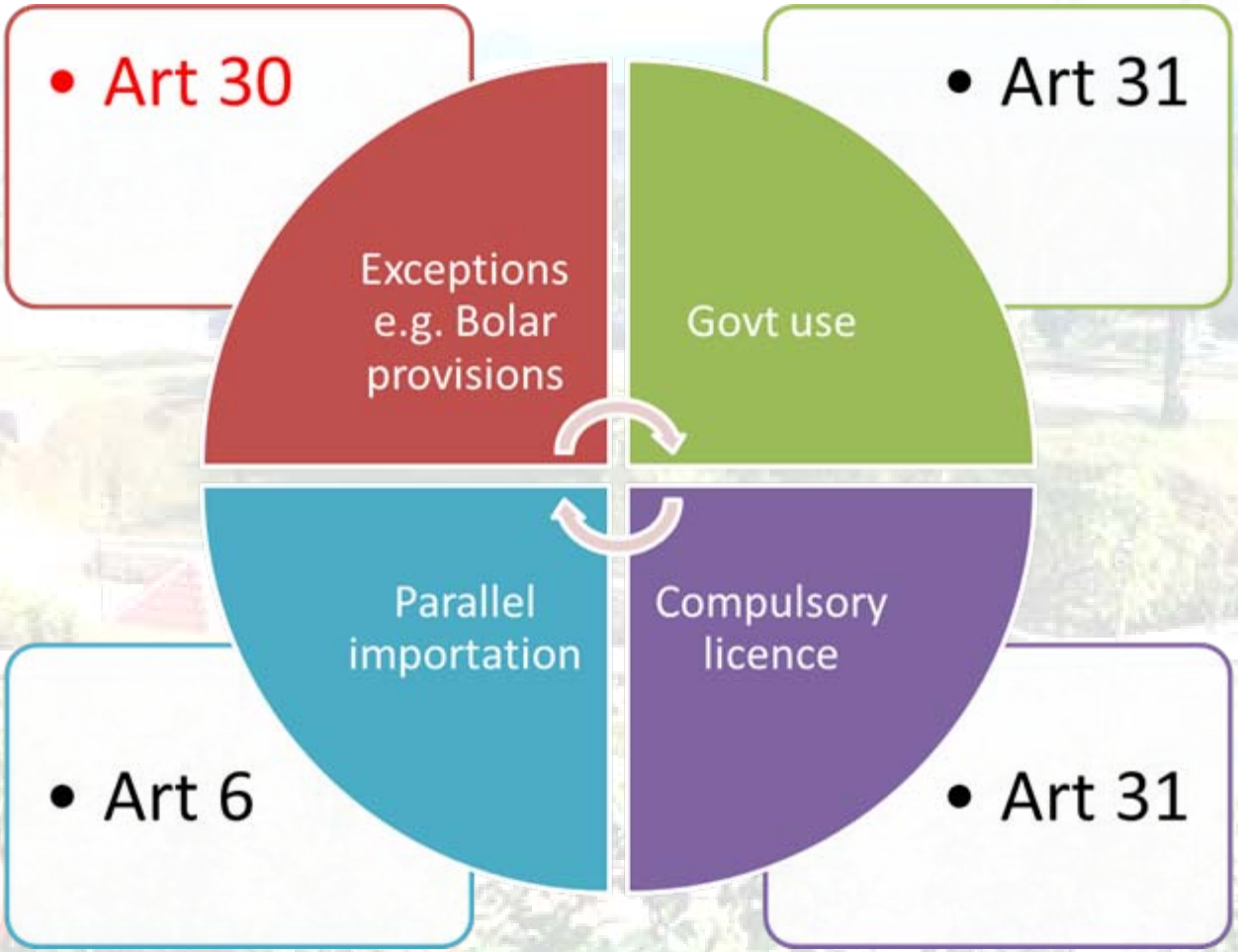
What do we know about IP laws?



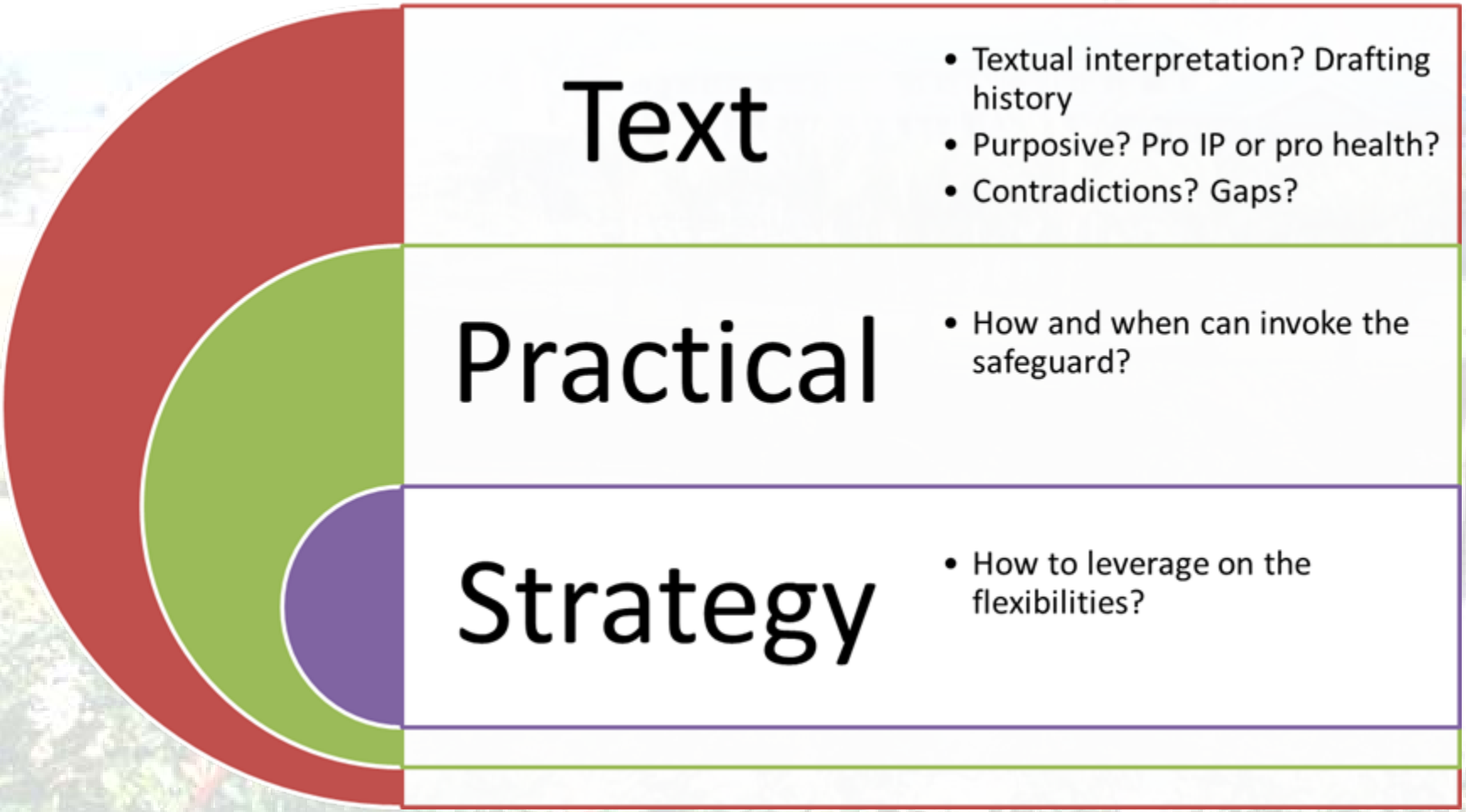
Overriding consideration?



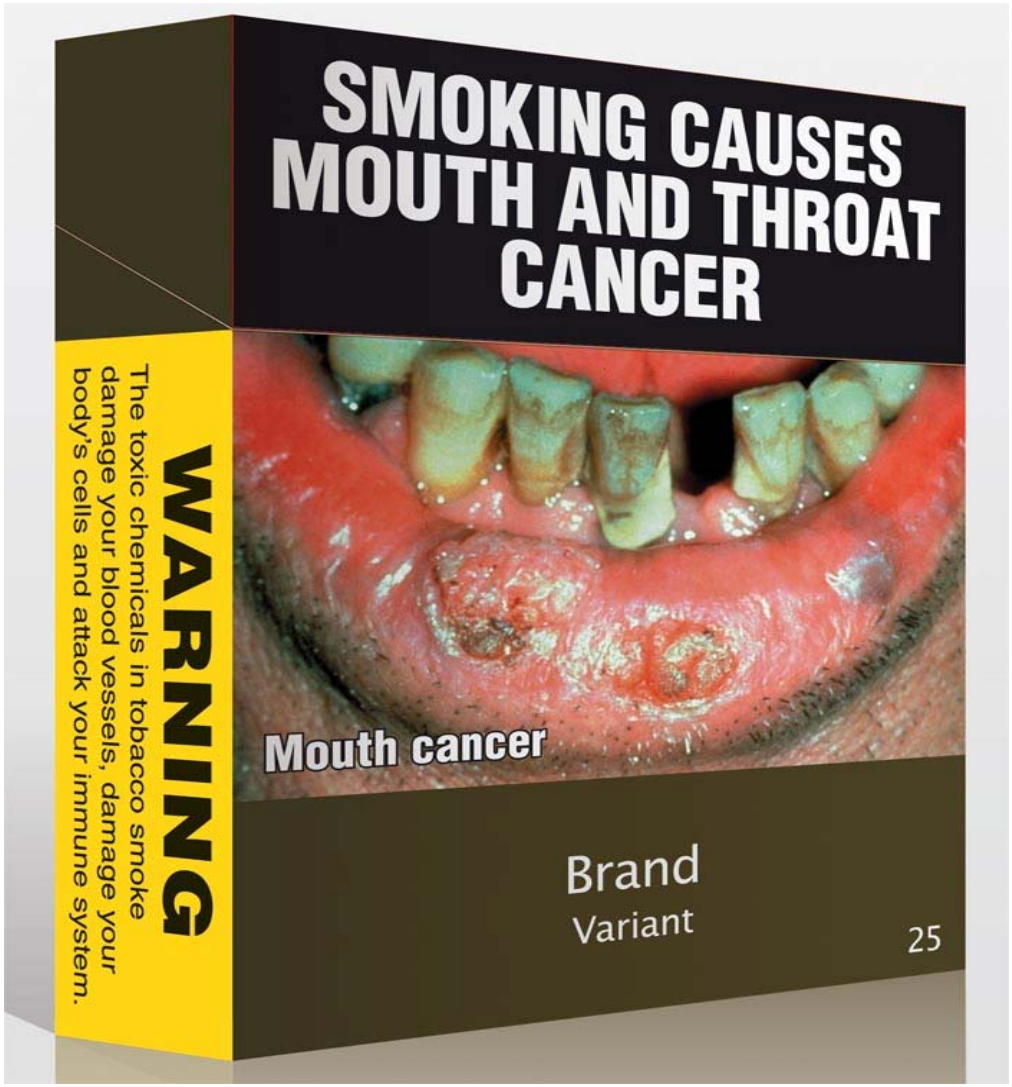
TRIPS flexibilities

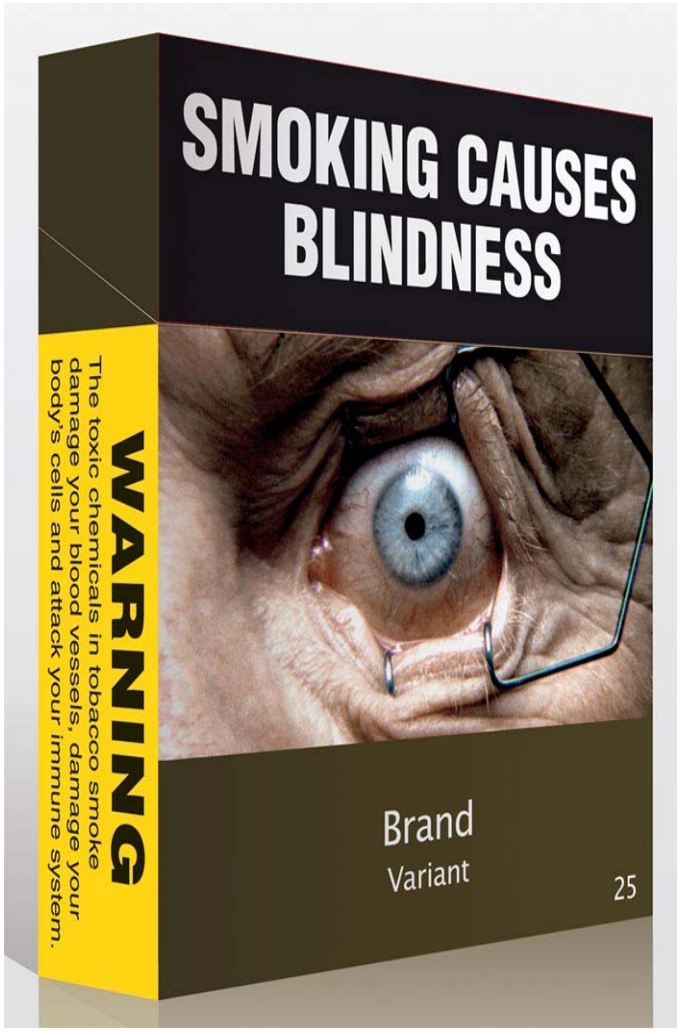


Between binding minimum standards and policy space



Plain packaging

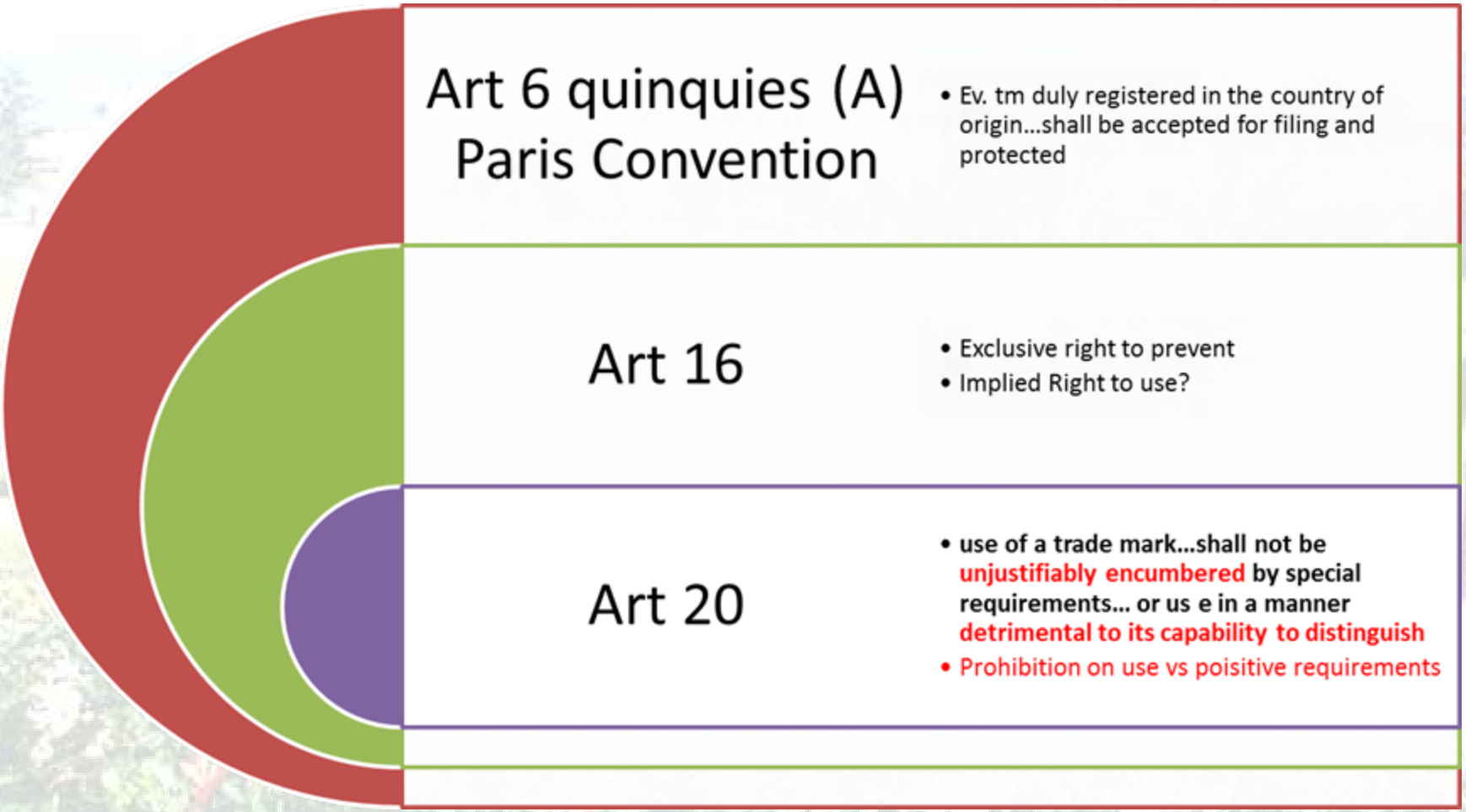




- Australia introduced 2 laws:
  - Tobacco Plain Packaging Act 2011
  - Trademarks Amendment (Tobacco Plain Packaging) Act 2011) (passed 21 Nov 2012)
- June 2012 Phillip Morris International = investor state dispute settlement provisions under the Australia Hong Kong Bilateral Investment Treaty (BIT) demanding compensation
- Ukraine (March) Honduras filed complaint at the WTO (April 2012)
- Philip Morris Internation Inc. (PM), Imperial Tobacco Group Plc (IMP), British American Tobacco Plc (BATS) and Japan Tobacco Inc challenge the validity of the laws (April 2012)

- Philip Morris sues Uruguay cigarette-labeling regulations
- Health warnings must cover 80% of each cigarette package
- Claiming violations of the Switzerland-Uruguay bilateral investment treaty
- Arguing it to be = expropriation of IP without compensation

Legal conundrum



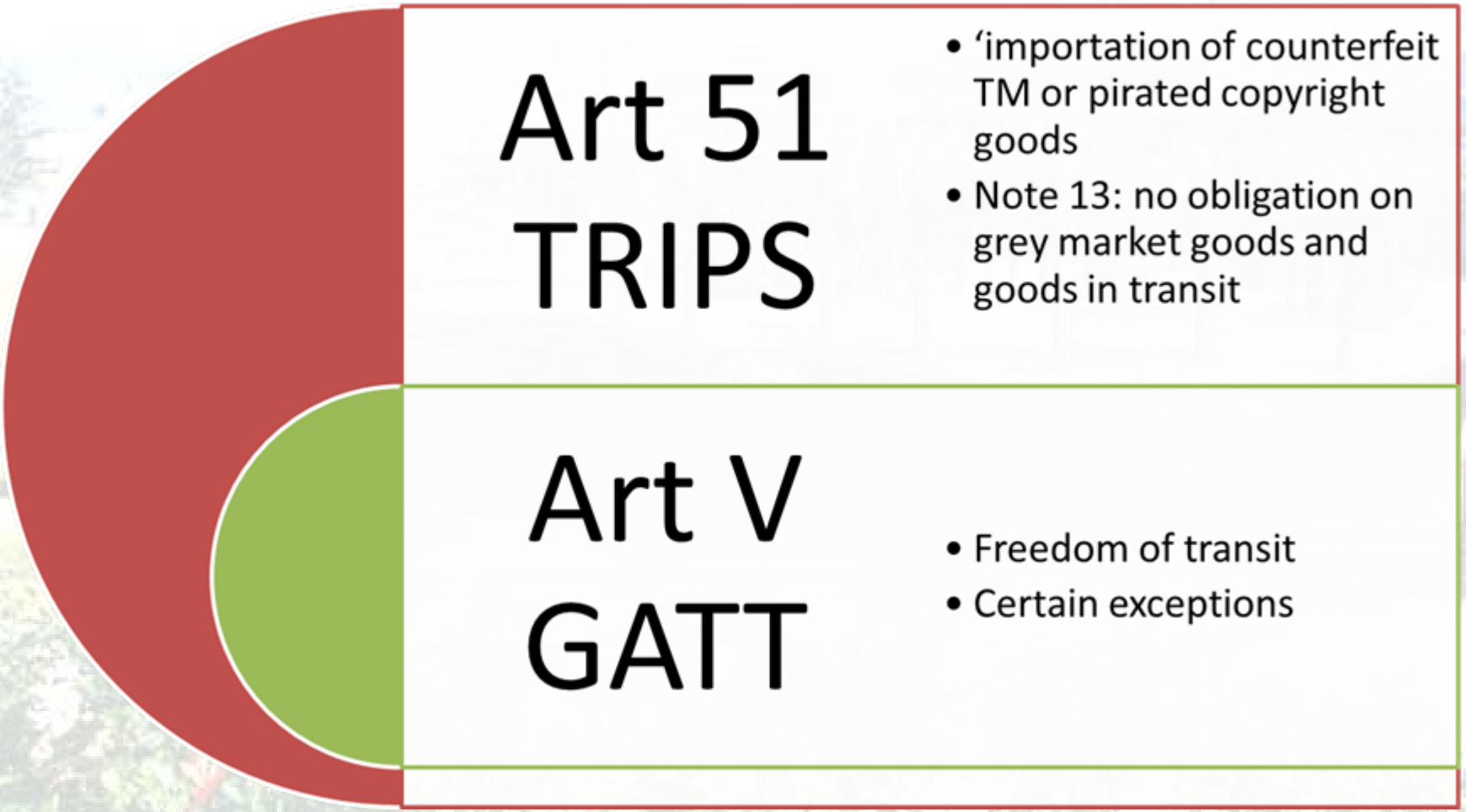
Seizure of generics in transit

- Starting 2008, customs in EU Mbs seized, delayed and returned shipments of generics transiting EU ports on account of suspected patent infringements in the transit country
- The shipments originated in India and were destined to developing countries such as Brazil, Venezuela, Colombia, Peru or Nigeria
- The drugs at issue are protected in the EU transit country, but not in the countries of origin or destination.

- In 19 cases, Dutch customs seized transiting generics
- Customs in EU acted pursuant to the EU Regulation 1383/2003 on border measures
- In May 2010 India and Brazil initiated WTO dispute settlement (WT/DS408 & DS409)
- Dispute now resolved- press release by the Indian Ministry of Commerce and Industry of he Govt of India (28 July 2011)
- Stronger enforcement provisions under ACTA?

Dutch customs seize Indian drugs in transit, industry frets, Jan 23, 2012

Legal basis


Art 51
TRIPS
• 'importation of counterfeit TM or pirated copyright goods
• Note 13: no obligation on grey market goods and goods in transit
Art V
GATT
• Freedom of transit
• Certain exceptions

GAPS IN TRIPS…POLICY SPACE?

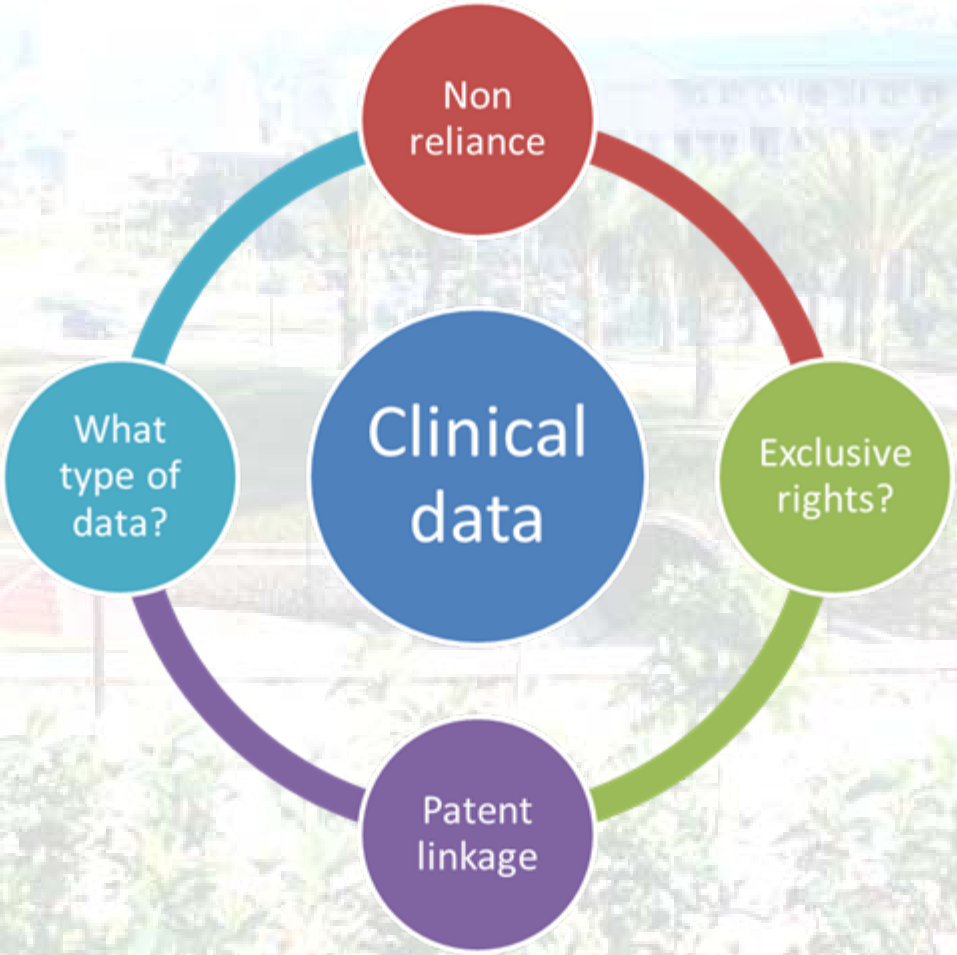
Gaps in TRIPS

- Clinical data
- Patent extension term
- Bolar provision
- Parallel import
- 2nd medical use
- Grounds for compulsory licence

Clinical data

- ***Article 39***
- **3. Members, when requiring, as a condition of approving the marketing of pharmaceutical or of agricultural chemical products which utilize new chemical entities, the submission of undisclosed test or other data, the origination of which involves a considerable effort, shall protect such data against unfair commercial use. In addition, Members shall protect such data 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.**

Concerns


Non reliance
Exclusive rights?
Patent linkage
What type of data?
Clinical data

Patent term

Art 33 TRIPS

- Shall not end before the expiration of a period of 20 years from the filing date

FTAs

- Supplementary patent certificate
- Additional period in lieu of delay as a result of approval of patents

Second medical use

TRIPS Agreement

- Article 27 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. 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

Indian Patents Act

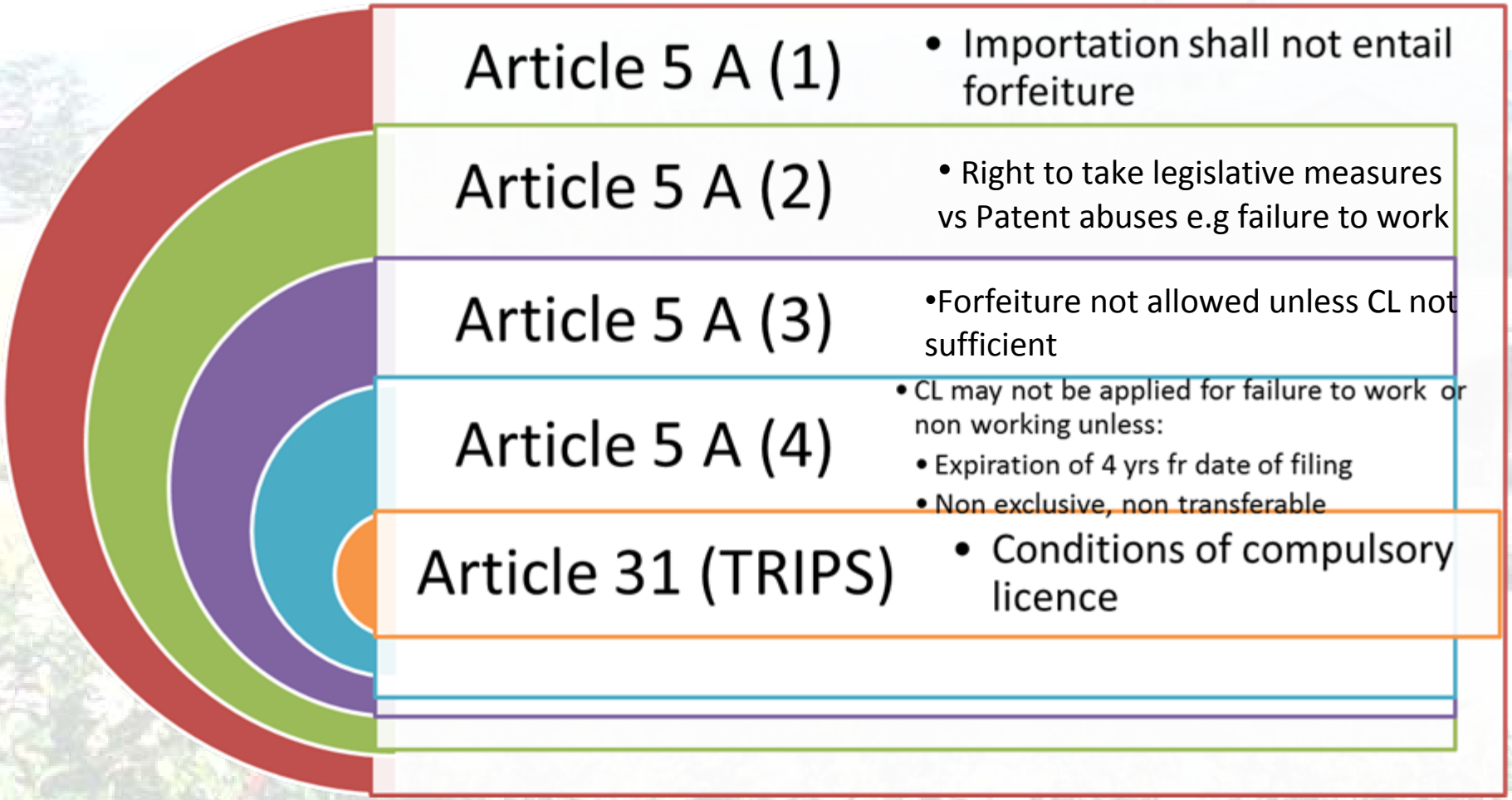
- *Section 3 (d) the mere discovery of a new form of a known substance which does not result in the enhancement of the known efficacy of that substance or the mere discovery of any new property or new use for a known substance or of the mere use of a known process, machine or apparatus unless such known 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;"*

Second medical use: Evergreening?

- Novarties applies patent for 'Glivec' (imatinib mesylate drug.
- Novarties claimed that increased bioavailabilty of the s imatinib meant increased efficacy, entitling it to a pate imatinib mesylate.
- The Indian Patent Office rejected the application.
- Novarties brought the case to the High Court
- Madras High Court: efficacy to mean "therapeutic effect in healing a disease"
- Treatment with Glivec currently costs around $2,500 per month, "a sum that the vast majority of Indians simply cannot afford", whilst local generic versions are available for around 10% of that price.

- The Indian Patent Appellate Board (IPAB) – held that the salt form of imatinib mesylate did not meet the test of therapeutic efficacy, and therefore confirmed the rejection of Novartis's patent application.
- Novarties appeal to the Supreme Court
- Case postponed to July 2012

Grounds for Compulsory Licence : A 5 PC and 31 TRIPS



Compulsory licence/govt use (conditions)

- Applications are considered on their individual merits
- First attempt to obtain voluntary licence
- Scope and duration are limited to the purpose
- Licence are to be non exclusive
- Predominantly for the supply of the domestic market
- Rightholder to be paid adequate remuneration
- Decision on grant and remuneration are to be subject to judicial or other independent review

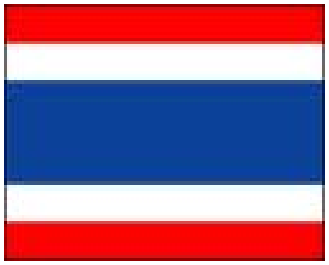
Asia Pacific Countries: Compulsory licence & govt use

Date	Country	Drugs	Validity
Oct 2003	Malaysia	Didanosine Zidovudine Didanosine+ zidovudine	2 years
October 2004	Indonesia	Lamivudine nevirapine	7-8 years (end of the patent term)
Nov 2006	Thailand	efavirenz	Until 31 Dec 2011
March 2012	India	sorafenib tosylate	Until the end of the patent term

Survey of patent laws in 6 ASEAN countries

Indonesia

Philippine



Thailand

Malaysia

Singapore

Viet Nam

As of 2010

Flexibilities under the patent system

Country	Bolar provision	Scientific research	Compulsory licence	Government use	Parallel imports
Indonesia	x	√	√	√	x
Malaysia	√	√	√	√	international
Philippines	X	√	√	√	National or international
Singapore	X	√	√	√	local
Thailand		√	√	√	X clear
Vietnam	X	√	√	X	international

Grounds for the issuance of compulsory licence

		I	MY	PH	S	T	V
Abuse of patent rights	The reasonable req of the public not being met		√		√	√	
	Not available at reasonable price		√		√	√	
	Not being worked/ insufficient working in the country	√	No production or application	√		√	√
	Exercise of right inconsistent with public interest	√		√			

Grounds for the issuance of compulsory licence

	ID	MY	PH	SG	TH	VN
Remedy anti competitive practice			√	√		
Inter-dependent on existing patent	√	√	√		√	√
National emergency			√			
Circumstances of extreme urgency			√			

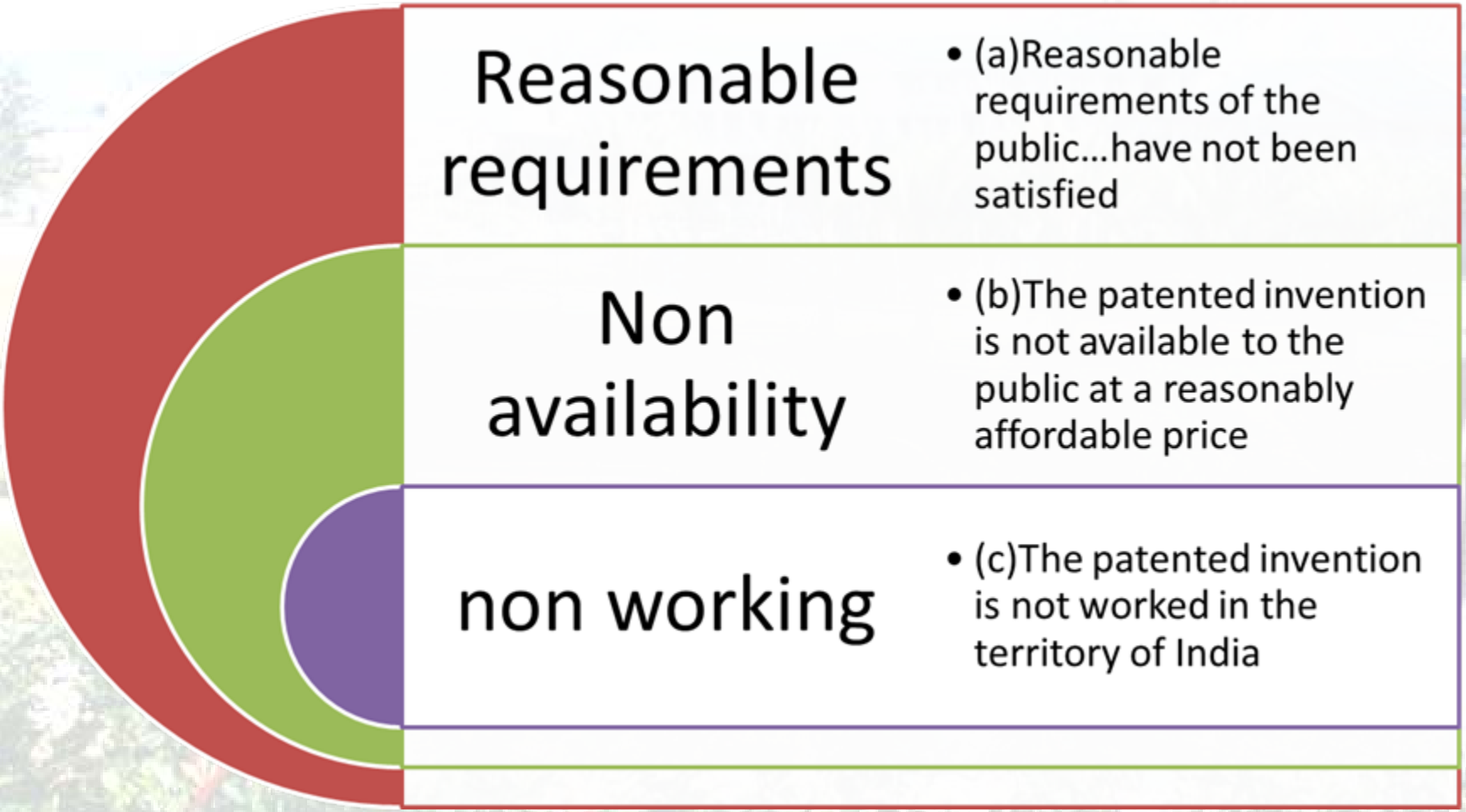
Grounds for the issuance of compulsory licence

	ID	MY	PH	SG	TH	VN
Public non commercial use			√		√	√
Defense and security purpose						√
Prevent/relieve a severe shortage of drugs					√	
Other public interest			Nutrition, health and developme nt of other vital sectors			Disease prevention, treatment and nutrition and other urgent social needs

Government use

	ID	MY	PH	SG	TH	VN
State of war					√	
emergency		√	√	Other cir. of extreme urgency	√	
Relieve severe shortage of drugs			Demand not being met to an adequate extent and on reasonable terns		√	
Public interest	√	National security, nutrition, health or the dev of other vital sectors	National security, nutrition, health or the development o other sectors		Any service for public consumption, preservation or realization of natural resources or the environment	
Anti competitive practices		√	√			
Defence and security of state	√		√			√
Non commercial				√		√

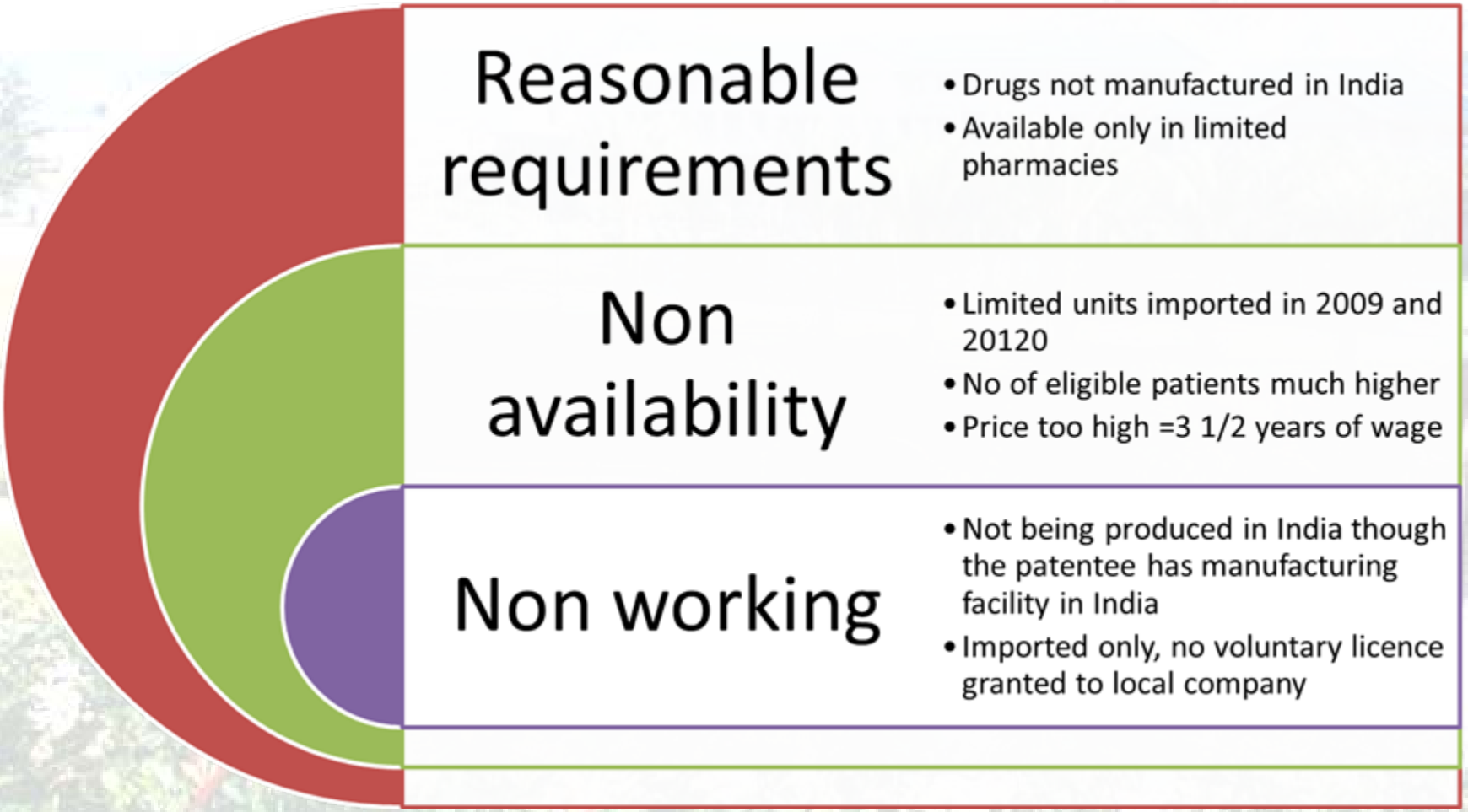
Grounds for Compulsory Licence – s 84(1) Indian Patents Act 1970



Compulsory licence – non working?

- Natco Pharma Limited v Bayer Corporation (2011)
- 'sorafenib tosylate' – compund covered by Patent No 215758 sold under the brand name NEXAVAR – treatment for kidney and liver cancer.
- Cost about Rs2,80,428 one month theraphy

Grounds satisfied?



Between binding minimum standards and policy space: does the policy space exists?