



**2019 Pacific Update Conference  
3-5 July 2019**

**The University of the South Pacific & The  
Australian National University**

**Access to Medicine in the South Pacific: Endogenous  
Factors Impeding the Benefits of WTO-TRIPS  
Agreement**

**Salvin S. Nand**

Deputy Dean, School of Law (UOF)

# Outline

- Continuous struggle between Access to Medicine and Human Right Laws
- TRIPS and Access to Medicines –Looking beyond TRIPS
  - *Patent Law vs. Right to Health*
  - *TRIPS Flexibilities*

Factors Affecting Access to Medicine in Fiji

Recommendations

# Access to Medicine

- WHO – advocates – essential medicines as part of national medicine policies YET 1/3 of the worlds population is denied regular access to medicines
- Fiji – Health Ministry Agrees shortage of medicine and stock are persistent problem and a challenge for the countries health system for many years
- –WHO -These include irregular access to essential medicines, lack of quality assurance and effective regulation of pharmaceutical products, and irrational medicines use practices by health care providers and consumers. Besides, the geographical isolation of the islands and localities and low population densities present logistical problems and cost implications that are unique to Pacific island countries and areas.
- Variety of studies identified IP restrictions as major constraint

# Access to Medicine and Human Rights

- Right to health- art 38 (Fiji) — the most commonly mentioned basis for a right to access to medicine — as well as human rights aspects of intellectual property.
- Closely connected to the notion of economic, social, and cultural right
- Who's responsibility — Government, pharmaceutical companies and whether the WTO is bound by human rights law

# Patent Vs. Human Rights

- Realization of social human rights, such as the right to food or the right to health, is about the accessibility to important goods and resources.
- Patent rights, on the other hand, have, as a primary purpose, to restrict nonauthorized access to new inventions.
- This restriction in access is intended to promote inventiveness, commercialization of new products and access to new knowledge in the patent application

# Human Rights Protections for IP

## Universal Declaration of Human Rights (UDHR, 1948)

### Article 17

- (1) Everyone has the right to own property alone as well as in association with others.
- (2) No one shall be arbitrarily deprived of his property.

### Article 27

- (1) Everyone has the right freely to participate in the cultural life of the community, to enjoy the arts and to share in scientific advancement and its benefits.
- (2) Everyone has the right to the protection of the moral and material interests resulting from any scientific, literary or artistic production of which he is the author.

# TRIPS FLEXIBILITIES

## **TRIPS-consistent policy options for affordable medicines**

- Patentability Criteria
- Exceptions to patent rights (e.g., Bolar exception)
- Parallel Importation
- Compulsory License
- Government Use

# Criteria for Patentability

## What can be patented?

- Inventive step; novel (new); capable of industrial application
- Under TRIPS – obligation to patent products and processes
- Ample Flexibility in defining/scope.... national governments should be guided by development priorities; need to encourage more R & D and innovation and public interest considerations
- AVOID bad or trivial patents
- AVOID grant of patents on NEW USES of existing substances.....it will prolong monopoly/evergreening

# PARALLEL IMPORT

## Article 6 TRIPS

- Chapter 4, pg 37 of the Manual on Good Practices
- It is the import and resale in a country of a patented product that has been legitimately put on the market of the exporting country.
- No need consent of patent holder
- Doha Declaration on TRIPS and Public Health affirms the right to choose Exhaustion of rights: national, regional or international regimes

# COMPULSORY LICENCE (CL)

## Article 31 TRIPS (Reaffirmed in Doha Declaration on Public Health)

- Chapter 7, pg 69 of the Manual on Good Practices
- Govt grant of licence to 3<sup>rd</sup> party to use patent without consent of patent holder
- Right to determine grounds for compulsory licence (reaffirmed in the Doha Declaration on Public Health)
  - negotiations to obtain a license on reasonable terms and conditions from the patent holder failed
  - public interest, national emergencies,
  - to remedy anti competitive practices (Article 40)
- NOT just for emergencies and NOT limited to certain diseases (reaffirmed in Doha Declaration on Public Health)

# Conditions for grant of CL

- 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”

- CL has to be “predominantly for the supply of the domestic market”

# GOVERNMENT USE

## Article 31 TRIPS

- Chapter 5, pg 45 of the Manual on Good Practices
- "Public non-commercial use"
- Government right (govt. agency, dept. or contractor) to use patent in the public interest
- Fast-track approach to compulsory licences
- No need prior negotiation with patent holder
- Payment of "Adequate Remuneration" to patent holder
- State practice: US and UK legislation

# EXCEPTIONS TO PATENT RIGHTS

## Article 30 TRIPS

- Chapter 6, pg 55 of the Manual on Good Practices
- Limited exceptions to exclusive rights
- 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 legislation**

e.g. Research, Experimental, Production for export

e.g. "Bolar" exception: use of patent prior to expiry for approval for generic product

- NO specific conditions to use Article 30

## Compulsory Licenses – TRIPS article 31

- Based on individual merits
- Prior negotiation
- Scope and duration of use limited to purpose for which authorised
- Primarily for domestic use
- Subject to termination if need eliminated
- Adequate remuneration to patent owner
- Review of Comp License authorisation and remuneration

# Current Policies -Paragraph 6 System

- UN 2030 SDG Goal 3 (public health) target 3.b,
- Target 3.b: *Support the research and development of vaccines and medicines for the communicable and non-communicable diseases that primarily affect developing countries, provide access to affordable essential medicines and vaccines, in accordance with the Doha Declaration on the TRIPS Agreement and Public Health, which affirms the right of developing countries to use to the full the provisions in the Agreement on Trade-Related Aspects of Intellectual Property Rights regarding flexibilities to protect public health, and, in particular, provide access to medicines for all;*

# What does Doha Declaration say?

- Recognizes the “gravity” of public health problems in developing/least developed countries esp. those resulting from HIV/AIDS, tuberculosis, malaria....
- Recognizes **concerns of IP and its effects on prices**
- **AGREES** that the TRIPS Agreement “**DOES NOT and SHOULD NOT prevent Members from taking measures to protect public health**”
- Affirms “**the right of WTO Members to use, to the full, the provisions in the TRIPS Agreement which provide flexibility**” which include “the right to grant compulsory licenses and the freedom to determine the grounds upon which such licences are granted”

## What does Doha Declaration Say?

- “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”

## Paragraph 6 Doha Declaration

### ➤ **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 compulsory license
  - entire production can be exported
  - BUT many procedures have to be followed by exporting and importing countries
  - many of the view that procedures are cumbersome and may be a disincentive to use the decision

## Some Recent Compulsory Licenses for AIDS drugs

<b>Country</b>	<b>Grounds</b>	<b>Licensee</b>	<b>Exports</b>	<b>Royalty</b>
Indonesia	Emergency	One Manufacturer		.5%
Malaysia	Government use	One Importer		4% offer
Mozambique	Emergency	One Manufacturer		2%
South Africa	Competition	Small number Manufacturers	In Africa	5%
Swaziland	Emergency	Open		No remuneration
Zambia	Emergency	One Manufacturer	No	2.5%

## Fiji – TRIPS Plus

- As a developing island country with associated public health problems and lack of manufacturing (medicine) base the amendment provides Fiji with the option of using the TRIPS flexibilities to acquire affordable medicines especially during public health emergencies and pandemics.

## Challenges

- Lack of Collaboration Between Government Ministries, regulator and private sector on pharmaceutical sector
- MOH – faces challenges in identifying the appropriate procurement and stock management methods for the management of medicine and medical supplies

# Procurement of Medicine

## Factors affecting access to medicines

Khan (2018)	Walker et.al (2017)	Standing Committee on Foreign Affairs and Defence (2017)
finance,	finance,	finance,
pharmaceutical procurement and distribution system	pharmaceutical procurement and distribution system	pharmaceutical procurement and distribution system
lack of consistent monitoring system significantly contributed to a poor forecasting of medicines	lack of consistent monitoring system significantly contributed to a poor forecasting of medicines	lack of consistent monitoring system significantly contributed to a poor forecasting of medicines
Lack of trained professions in charge of procurement division was strongly cited as cause of delay in medicine supply	Lack of trained professions in charge of procurement division was strongly cited as cause of delay in medicine supply	
poor management, unqualified staff  miscommunication between hospitable and health ministry	Health sector including procurement division is concerned about providing health services and procurement of medicines is less of their priorities.	

## Way Forward

- Strengthen Procurement regime
- Harmonise public and private Procurement sector
- Create clear communication between hospitals and Procurement division of Fiji Pharmaceutical & Biomedical Services.
- **Consider Regional Procurement unit that harmonises most South Pacific Countries.**

# Cont...

- To tackle shortage of medicine there is a need to implement efficient supply chain management to better track sustainable supply and demand of medicines.
- The Standing Committee on Foreign Affairs and Defence in 2017
  - The Committee strongly recommends that there needs to be a strengthening of implementation of domestic legislation, systems and process relating to the procurement and distribution of medicines if Fiji is to realise the full benefits of the WTO-TRIPS Agreement. This includes effective monitoring of reforms in health, border control and pharmaceutical sectors

## Take home Message

- When medicines patents holders refuse to license their patents under public health friendly terms and conditions, trade/IP/competition law and the human rights framework offer powerful tools for governments to intervene
- Tools for citizens to demand government action include through the courts or competition authorities
  - Refusal to license on reasonable terms

## Take Home Message

- Access to safe and effective medicines are an essential component of the fulfillment of the right to health (art 38- 'C'-Fiji)
- **Access to medicines requires state action**
  - Selection of essential medicines
  - Quality assurance
  - Procurement and supply
  - Rational use



# Thank You

- [Salvinsaneel.nand@gmail.com](mailto:Salvinsaneel.nand@gmail.com)