PARLIAMENT OF THE REPUBLIC OF FIJI

STANDING COMMITTEE ON FOREIGN AFFAIRS AND DEFENCE

REPORT ON THE PROTOCOL AMENDING THE WTO TRADE–RELATED ASPECTS OF INTELLECTUAL PROPERTY RIGHTS (TRIPS) AGREEMENT

Parliament of the Republic of Fiji

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CHAIR'S FOREWORD

I am pleased to present this Report of the Fiji Parliament Standing Committee on Foreign Affairs and Defence (SCFAD), on the review of the Treaty on the Protocol Amending the World Trade Organisation (WTO) Trade Related Aspects of Intellectual Property Rights (TRIPS) 2005.

This report provides a summary and examination of written submissions and oral evidence received at the Committee meetings during 12th October to 25th November 2016.The report is divided into four parts:

Part 1 covers the role and responsibilities of the Standing Committee and the inquiry process undertaken;
Part 2 provides a brief overview of the WTO-TRIPS Agreement and the Protocol amending the Agreement;
Part 3 outlines the Standing Committee's observations and areas of concern; and
Part 4 provides the Committee's conclusion.

The appendices include: texts of the amendment to the WTO-TRIPS Agreement; submissions from stakeholders and; partial verbatim of oral submissions. The full verbatim of the oral submissions will be made available on the Parliament website.

The *Constitution of the Republic of Fiji* (Section 70) requires Parliament to establish committees to scrutinise Government administration, examine Bills and subordinate legislation, and undertake other functions as required under the rules and orders of Parliament. One of the functions of the Standing Committees as stipulated in Standing Orders 110(e) is to review international treaties and conventions ratified by the Government and monitor their implementation.

The Standing Committee on Foreign Affairs and Defence undertook the inquiry into the amendment of the WTO-TRIPS Agreement with the view of ensuring that the changes would be in the national interest and benefit all Fijians.

On behalf the Committee, I would like to express my sincere appreciation to all organisations, Government Ministries and individuals who made a submission and/or attended the public hearings. The outcome of the consultations and submissions from key stakeholders provided the Committee with the necessary information and insights to be able to provide its report and opinion on Parliament's proposed ratification of the Amending Protocol to WTO-TRIPS Agreement.

I also wish to acknowledge the Honourable Members of the Committee and the Secretariat Staff for their commitment and contribution that have resulted in the completion and tabling of this bi-partisan report. The Members who participated in this inquiry were Hon. Mataiasi Niumataiwalu, Hon. Mosese Bulitavu, Hon. Ratu Suliano Matanitobua. During the course of the Committee's inquiry Hon. Jilila Kumar, Hon. Jiosefa Dulakiverata, Hon. Viliame Gavoka, Hon. Salote Radrodro, Hon. Ro Kiniviliame Kiliraki, and Hon. Howard R. Politini participated as Alternate Members.

I commend this report to Parliament for its consideration.

Hon. Netani B. Rika
Chairman

LIST OF ACRONYMS

BAF	Bio-security Authority of Fiji
FRCA	Fiji Customs and Revenue Authority
IPRs	Intellectual Property Rights
LDCs	Least Developed Countries
SCFAD	Standing Committee on Foreign Affairs and Defence
SO	Standing Orders
TRIPS	Trade-Related Aspects of Intellectual Property Rights
WTO	World Trade Organisation
WTO-TRIPS	World Trade Organisation Agreement on Trade-Related Aspects of Intellectual Property Rights

RECOMMENDATION

The Committee recommends that:

Parliament ratifies the Protocol Amending the WTO Trade-Related Aspects of Intellectual Property Rights Agreement.

PART 1

1.0 INTRODUCTION

The Parliament Standing Committee on Foreign Affairs and Defence (SCFAD) undertook a review of the proposal by the Government of the Republic of Fiji for Parliament to ratify the Protocol Amending the WTO-TRIPS Agreement.

1.1 The Standing Committee on Foreign Affairs and Defence

The Committee is established under Standing Orders 109(2) (e) of the Parliament of the Republic of Fiji. The Standing Committee is mandated to examine matters related to Fiji's relations with other countries, development aid, foreign direct investment, oversight of the military and relations with multi-lateral organisations. Under SO 110(1)(e) the Committee responsible for reviewing international treaties and conventions ratified by the Government and monitor their implementation.

The Committee comprises five Honourable Members drawn from both sides of the House.

1.2 Committee Members

The Members of the Standing Committee on Foreign Affairs and Defence are:

Hon. Netani Rika (Chairman)
Hon. Mataiasi Niumatawalu
Hon. Mosese Bulitavu
Hon. Alexander O'Connor
Hon. Ratu Suliano Matanitobua

In the course the SCFAD's inquiry and deliberations, the following were Alternate Members pursuant to SO 115(5):

Hon. Jilila Kumar
Hon. Jiosefa Dulakiverata
Hon.Viliame Gavoka
Hon.Salote Radrodro
Hon. Ro Kiniviliame Kiliraki
Hon. Howard R. Politini

1.3 Procedure and Programme

The Committee met in the Parliament Complex from Monday 3rd October 2016 to discuss and plan its strategy for this inquiry which amongst other matters included soliciting and receiving public submissions.

The Committee placed advertisements in the local newspapers, *Fiji Sun* and *Fiji Times* from the 2nd to 13th of November 2016. The advertisement was also placed on the Parliament website: www.parliament.gov.fj

Oral submissions from stakeholders were received at the Parliament Complex, Suva between 12th October and 25th November. The Committee also undertook hearings in the Western Divisions on 14th to Tuesday 15th November 2016.

PART 2

2.0 Background

On 26th September, the Protocol Amending the World Trade Organisation (WTO) Agreement on TRIPS (Trade Related Aspects of Intellectual Property Rights) was referred to the Standing Committee on Foreign Affairs and Defence Committee for its deliberation.

Under Section 51 of the *Constitution*, "an international treaty or convention binds the State only after it has been approved by Parliament."

2.1 WTO Agreement on Trade-Related Aspects of Intellectual Property Rights

The Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) is an international agreement administered by the WTO (See summary Appendix 1). The WTO-TRIPS agreement was negotiated during the Uruguay Round between 1986 to1994. It came into effect on 1st January 1994[1] and was the first set of intellectual property (IP) rules introduced into the multilateral system for the first time. [2] As a WTO member, Fiji is a party to the TRIPS Agreement.

Intellectual Property Rights (IPRs) under the TRIPS Agreement, amongst others include:

- copyright related rights and industrial property, such as patents;
- patents are legal rights granted for eligible inventions and;
- they generally provide the patent owner with the legal means to prevent others from making, using or selling the invention for a limited period of time.

2.1.2 Origins of the rules-based system

Ideas and knowledge are an increasingly important part of trade. Most of the value of new medicines and other high technology products lies in the amount of invention, innovation, research, design and testing involved. Creators can be given the right to prevent others from using their inventions, designs or other creations-and to use that right to negotiate payment in return for others using them. These are "intellectual property rights" (IPRs). For example, books, paintings and films come under copyright; inventions can be patented; brand names and product logos can be registered as trademarks; and so on. Governments and parliaments have given creators these rights as an incentive to produce ideas that will benefit society as a whole.

The WTO-TRIPS Agreement was established to narrow the gaps in the way these rights were protected around the world, and to bring them under common international rules. It establishes minimum levels of protection that each government has to give to the intellectual property of fellow WTO members. In doing so it strikes a balance between the long term benefits and possible short terms costs to society. Society benefits in the long

[1] WTO, 'Overview: the Trips Agreement'. Available at: www.wto.org/english/tratop_e/trips_e/intel2_e.htm
[2] WTO TRIPS Treaty Brief, Solicitor General's Office, September 2016.

term when intellectual property protection encourages creation and invention, especially when the period of protection expires and the creations and inventions enter the public domain.

Governments are allowed to reduce any short term costs through various exceptions, for example to tackle public health problems. Moreover when there are trade disputes over intellectual property rights, the WTO's dispute settlement system is now available.

2.2 Protocol Amending the WTO Agreement on TRIPS

The WTO General Council on 6 December 2005, adopted the Protocol Amending the TRIPS Agreement and opened it for acceptance by the WTO members (See Annex 2). This Protocol is the first multilateral treaty amendment agreed by the WTO members since the Agreement came into force in 1995. The amendment seeks to permanently incorporate into the TRIPS Agreement additional flexibilities to grant special compulsory licenses for the export of medicines, referred to as the "Paragraph 6 System".

2.2.1 What is the Paragraph 6 System?

The "Paragraph 6 System" was first established by a Ministerial Declaration adopted on 14 November 2001 (Doha Development Round of negotiations) in order to facilitate access to medicines under the TRIPS Agreement to those WTO Members with insufficient or no manufacturing capacities in the pharmaceutical sector and who could face difficulties in making effective use of **compulsory licencing** under the Agreement. **Compulsory licensing** is when a government allows someone else to produce the patented product or process, without the consent of the patent owner. Generally, a request for **voluntary license** is necessary before the use of compulsory license. However, the request for voluntary licence may be waived in certain situations, in particular cases of national emergency or extreme urgency or in cases of public non-commercial use.[3] A **voluntary license** occurs when the person or company applying for a licence has to have tried to negotiate a voluntary license with the patent holder on reasonable commercial terms. Only if that fails a compulsory license be issued.[4]

[3] *Ibid.*
[4] *ibid*

PART 3

3.0 COMMITTEE'S OBSERVATIONS AND AREAS OF CONCERN

3.1 Consideration of the Protocol Amending WTO-TRIPS

The Committee considered the text of the Amendment of the WTO-TRIPS. A copy of the text of the Amendment is attached as Appendix 3.

This is also available online at: www.wto.org/english/tratop_e/trips_e/wtl641_e.htm#fnt-6

3.1 Requirements for Implementation

The implementation of the Protocol Amending the TRIPS Agreement will be an important signal that will ensure a legally secure, predictable, effective and sustainable solution for those countries wishing to use the TRIPS flexibilities to get affordable medicines[5]. It is also worth noting that the **instrument of acceptance of the amendment is a new flexibility and not a new obligation on WTO Members**. It is an optional measure for the WTO Members to use the flexibility if they wish so as to advance their public health interests.[6] The Amendment does not impose any additional obligations on the WTO members to implement this flexibility in their domestic laws.[7]

3.2 Impact of Ratification

It is prudent to note that in February 2016 the Fijian Government in its WTO Policy Review made a commitment towards ratifying the Protocol Amending the TRIPS Agreement by the end of that year.[8] Many developing countries and Least Developed Countries (LDCs) suffer from public health problems and access to medicines still remains a problem for most developing counties and LDCs. Thus, Acceptance of the Protocol which seeks to amend the TRIPS Agreement will help developing countries and LDCs to obtain greater access to affordable medicines when needed.[9]

3.3 Benefits

The Committee concurs that Fiji's acceptance of Protocol Amending the WTO-TRIPS Agreement has potential benefits. 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. However, the Committee has also noted the challenges faced by stakeholders in the pharmaceutical sector as discovered during its inquiry. These are highlighted in 3.4.

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[5] *ibid*
[6] *ibid*
[7] *ibid*
[8] *ibid*
[9] *ibid*

3.4 Challenges

These are some of the challenges and issues raised by key stakeholders in the pharmaceutical sector. The Committee is of the opinion that these need to be addressed by the Government and all stakeholders to ensure that Fiji fully benefits from the amendment to the WTO-TRIPS Agreement.

3.4.1 The Consumer Council of Fiji has raised the issue of lack of collaboration between Government ministries, regulators and the private sector in terms of raising the awareness on consumer rights and related issues in the pharmaceutical sector.

3.4.2 FRCA has highlighted the need for more funds for the border control agency to acquire new technologies to make their work more efficient and effective.

3.4.3 Superdrug Pharmacy, Cost U Less Fiji Limited and Makan's Drug Pharmaceutical suggest that the Biosecurity Authority of Fiji (BAF) needs to maintain consistent procedures and policies in terms of fees and charges, and services.

3.4.4 The Ministry of Health revealed that it faces challenges in identifying the appropriate procurement and stock management methods for the management of medicines and medical supplies.

3.4.5 There is a need for better collaboration between the Ministry of Health, Fiji Pharmaceuticals Society and Bio-medical Service to make medicines readily available and accessible to the general population.

3.4.6. In recognition of the important contribution of complementary medicines, the Ministry of iTaukei Affairs highlighted the importance of the *Wai vaka Viti* database on traditional medicines. It said there was a need for funding to update the database amongst Fiji's 14 provinces.

3.4.7 Douglas Pharmaceutical suggested that in order for Fiji to achieve the Sustainable Development Goals (SDGs) pertaining to Health it must ensure that key stakeholders in the Health Sector consult broadly and have an open door policy to ensure medicines are accessible and affordable to the general public. Douglas Pharmaceuticals was of the view that a strong collaborative approach was needed between Government and manufacturers to advance research and development, and expand manufacturing of medicines locally.

3.5 Way Forward

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.

3.6 Stakeholders' Observations

There was a general consensus from the stakeholders to the Government to ratify the protocol. These stakeholders were:

Consumer Council of Fiji
Fiji Revenue and Customs
Authority (FRCA)
Superdrug Pharmacy
Makan's Drugs and Pharmaceuticals
Fiji Pharmaceutical Society
Ministry of Health (Government Pharmacy)
Ministry of iTaukei Affairs
Bio-Security Authority of Fiji (BAF)
Digicel Fiji Limited
Vodafone Fiji Limited
Cost U Less Fiji Limited
Douglas Pharmaceuticals Fiji Limited

3.7 Gender Analysis

The Parliament of Fiji Standing Orders 110(2) requires standing committees give full consideration the principle of gender equality so as to ensure all matters are considered with regard to the impact and benefit on both men and women equally. The Committee is satisfied that the matters considered in this report, impacts on both women and men equally. The ratification of the Protocol Amending the WTO-TRIPS Agreement will not have any adverse effect on gender equality.

PART 4

4.0 Conclusion

The committee noted that Parliament's ratification of the Protocol Amending the WTO-TRIPS Agreement will require the necessary commitment from the Government and the relevant agencies in terms of effective implementation of domestic legislation, systems and processes relating to the procurement of medicines under the Agreement. It will also mean that ensuring a robust, sustainable and effective monitoring of reforms in the border control and health sectors.

The Committee has concluded that Fiji's ratification of the Treaty on the Protocol Amending the WTO Trade-Related Aspects of Intellectual Property Rights Agreement is in the national interest. The acceptance and ratification of the Treaty will provide safeguards to the health sector in terms of accessibility to essential medicines particularly should the need arise during national or public health emergencies or pandemics. The evidence provided by key stakeholders provides overwhelming support for ratification. The Committee recommends Parliament to expedite ratification of the Treaty.

REFERENCES

- *Constitution of the Republic of Fiji* (2013).
- Parliament of the Republic of Fiji (2016) *Standing Orders of the Parliament of the Republic of Fiji*, 19th February 2016.
- WTO, 'Overview: the Trips Agreement'. Available at: www.wto.org/english/tratop_e/trips_e/intel2_e.htm [Accessed 04/10/16]
- WTO General Council, Amendment of the TRIPS Agreement (Text), 8 December 2005. Available at: https://www.wto.org/english/tratop_e/trips_e/wtl641_e.htm#fnt-6
- Protocol Amending the WTO-TRIPS Agreement Brief, Solicitor General's Office, September 2016.

APPENDIX 1

SUMMARY OF WTO-TRIPS AGREEMENT

APPENDIX 1

WORLD TRADE ORGANIZATION

UNDERSTANDING THE WTO: THE AGREEMENTS

Intellectual property: protection and enforcement

The WTO's **Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS)**, negotiated in the 1986-94 Uruguay Round, introduced intellectual property rules into the multilateral trading system for the first time.

Origins: into the rule-based trade system

Ideas and knowledge are an increasingly important part of trade. Most of the value of new medicines and other high technology products lies in the amount of invention, innovation, research, design and testing involved. Films, music recordings, books, computer software and on-line services are bought and sold because of the information and creativity they contain, not usually because of the plastic, metal or paper used to make them. Many products that used to be traded as low-technology goods or commodities now contain a higher proportion of invention and design in their value — for example brandnamed clothing or new varieties of plants.

Creators can be given the right to prevent others from using their inventions, designs or other creations — and to use that right to negotiate payment in return for others using them. These are "intellectual property rights". They take a number of forms. For example, books, paintings and films come under copyright; inventions can be patented; brandnames and product logos can be registered as trademarks; and so on. Governments and parliaments have given creators these rights as an incentive to produce ideas that will benefit society as a whole.
The extent of protection and enforcement of these rights varied widely around the world; and as intellectual property became more important in trade, these differences became a source of tension in international economic relations. New internationally-agreed trade rules for intellectual property rights were seen as a way to introduce more order and predictability, and for disputes to be settled more systematically.

The Uruguay Round achieved that. The WTO's TRIPS Agreement is an attempt to narrow the gaps in the way these rights are protected around the world, and to bring them under common international rules. It establishes minimum levels of protection that each government has to give to the intellectual property of fellow WTO members. In doing so, it strikes a balance between the long term benefits and possible short term costs to society. Society benefits in the long term when intellectual property protection encourages creation and invention, especially when the period of protection expires and the creations and inventions enter the public domain. Governments are allowed to reduce any short term costs through various exceptions, for

example to tackle public health problems. And, when there are trade disputes over intellectual property rights, the WTO's dispute settlement system is now available.

The agreement covers five broad issues:

- how basic principles of the trading system and other international intellectual property agreements should be applied
- how to give adequate protection to intellectual property rights
- how countries should enforce those rights adequately in their own territories
- how to settle disputes on intellectual property between members of the WTO
- special transitional arrangements during the period when the new system is being introduced.

Basic principles: national treatment, MFN, and balanced protection

As in GATT and GATS, the starting point of the intellectual property agreement is basic principles. And as in the two other agreements, non-discrimination features prominently: national treatment (treating one's own nationals and foreigners equally), and most-favoured-nation treatment (equal treatment for nationals of all trading partners in the WTO). National treatment is also a key principle in other intellectual property agreements outside the WTO.
The TRIPS Agreement has an additional important principle: intellectual property protection should contribute to technical innovation and the transfer of technology. Both producers and users should benefit, and economic and social welfare should be enhanced, the agreement says.

How to protect intellectual property: common ground-rules

The second part of the TRIPS agreement looks at different kinds of intellectual property rights and how to protect them. The purpose is to ensure that adequate standards of protection exist in all member countries. Here the starting point is the obligations of the main international agreements of the World Intellectual Property Organization (WIPO) that already existed before the WTO was created:

- the Paris Convention for the Protection of Industrial Property (patents, industrial designs, etc.)
- the Berne Convention for the Protection of Literary and Artistic Works (copyright).

Some areas are not covered by these conventions. In some cases, the standards of protection prescribed were thought inadequate. So the TRIPS agreement adds a significant number of new or higher standards.

Copyright

The TRIPS agreement ensures that computer programs will be protected as literary works under the Berne Convention and outlines how databases should be protected.

It also expands international copyright rules to cover rental rights. Authors of computer programs and producers of sound recordings must have the right to prohibit the commercial rental of their works to the public. A similar exclusive right applies to films where commercial rental has led to widespread copying, affecting copyright-owners' potential earnings from their films.

The agreement says performers must also have the right to prevent unauthorized recording, reproduction and broadcast of live performances (bootlegging) for no less than 50 years. Producers of sound recordings must have the right to prevent the unauthorized reproduction of recordings for a period of 50 years.

Trademarks

The agreement defines what types of signs must be eligible for protection as trademarks, and what the minimum rights conferred on their owners must be. It says that service marks must be protected in the same way as trademarks used for goods. Marks that have become well-known in a particular country enjoy additional protection.

Geographical indications

A place name is sometimes used to identify a product. This "geographical indication" does not only say where the product was made. More importantly, it identifies the product's special characteristics, which are the result of the product's origins.

Well-known examples include "Champagne", "Scotch", "Tequila", and "Roquefort" cheese. Wine and spirits makers are particularly concerned about the use of place-names to identify products, and the TRIPS Agreement contains special provisions for these products. But the issue is also important for other types of goods.

Using the place name when the product was made elsewhere or when it does not have the usual characteristics can mislead consumers, and it can lead to unfair competition. The TRIPS Agreement says countries have to prevent this misuse of place names.

For wines and spirits, the agreement provides higher levels of protection, i.e. even where there is no danger of the public being misled.

Some exceptions are allowed, for example if the name is already protected as a trademark or if it has become a generic term. For example, "cheddar" now refers to a particular type of cheese not necessarily made in Cheddar, in the UK. But any country wanting to make an exception for these reasons must be willing to negotiate with the country which wants to protect the geographical indication in question.
The agreement provides for further negotiations in the WTO to establish a multilateral system of notification and registration of geographical indications for wines. These are now part of the

Doha Development Agenda and they include spirits. Also debated in the WTO is whether to negotiate extending this higher level of protection beyond wines and spirits.

Industrial designs

Under the TRIPS Agreement, industrial designs must be protected for at least 10 years. Owners of protected designs must be able to prevent the manufacture, sale or importation of articles bearing or embodying a design which is a copy of the protected design.

Patents

The agreement says patent protection must be available for inventions for at least 20 years. Patent protection must be available for both products and processes, in almost all fields of technology. Governments can refuse to issue a patent for an invention if its commercial exploitation is prohibited for reasons of public order or morality. They can also exclude diagnostic, therapeutic and surgical methods, plants and animals (other than microorganisms), and biological processes for the production of plants or animals (other than microbiological processes).

Plant varieties, however, must be protectable by patents or by a special system (such as the breeder's rights provided in the conventions of UPOV — the International Union for the Protection of New Varieties of Plants).

The agreement describes the minimum rights that a patent owner must enjoy. But it also allows certain exceptions. A patent owner could abuse his rights, for example by failing to supply the product on the market. To deal with that possibility, the agreement says governments can issue "compulsory licences", allowing a competitor to produce the product or use the process under licence. But this can only be done under certain conditions aimed at safeguarding the legitimate interests of the patent-holder.

If a patent is issued for a production process, then the rights must extend to the product directly obtained from the process. Under certain conditions alleged infringers may be ordered by a court to prove that they have not used the patented process.

An issue that has arisen recently is how to ensure patent protection for pharmaceutical products does not prevent people in poor countries from having access to medicines — while at the same time maintaining the patent system's role in providing incentives for research and development into new medicines. Flexibilities such as compulsory licensing are written into the TRIPS Agreement, but some governments were unsure of how these would be interpreted, and how far their right to use them would be respected.

A large part of this was settled when WTO ministers issued a special declaration at the Doha Ministerial Conference in November 2001. They agreed that the TRIPS Agreement does not and should not prevent members from taking measures to protect public health. They

underscored countries' ability to use the flexibilities that are built into the TRIPS Agreement. And they agreed to extend exemptions on pharmaceutical patent protection for least-developed countries until 2016. On one remaining question, they assigned further work to the TRIPS Council — to sort out how to provide extra flexibility, so that countries unable to produce pharmaceuticals domestically can import patented drugs made under compulsory licensing. A waiver providing this flexibility was agreed on 30 August 2003.

Integrated circuits layout designs

The basis for protecting integrated circuit designs ("topographies") in the TRIPS agreement is the Washington Treaty on Intellectual Property in Respect of Integrated Circuits, which comes under the World Intellectual Property Organization. This was adopted in 1989 but has not yet entered into force. The TRIPS agreement adds a number of provisions: for example, protection must be available for at least 10 years.

Undisclosed information and trade secrets

Trade secrets and other types of "undisclosed information" which have commercial value must be protected against breach of confidence and other acts contrary to honest commercial practices. But reasonable steps must have been taken to keep the information secret. Test data submitted to governments in order to obtain marketing approval for new pharmaceutical or agricultural chemicals must also be protected against unfair commercial use.

Curbing anti-competitive licensing contracts

The owner of a copyright, patent or other form of intellectual property right can issue a licence for someone else to produce or copy the protected trademark, work, invention, design, etc. The agreement recognizes that the terms of a licensing contract could restrict competition or impede technology transfer. It says that under certain conditions, governments have the right to take action to prevent anti-competitive licensing that abuses intellectual property rights. It also says governments must be prepared to consult each other on controlling anti-competitive licensing.

Enforcement: tough but fair

Having intellectual property laws is not enough. They have to be enforced. This is covered in Part 3 of TRIPS. The agreement says governments have to ensure that intellectual property rights can be enforced under their laws, and that the penalties for infringement are tough enough to deter further violations. The procedures must be fair and equitable, and not unnecessarily complicated or costly. They should not entail unreasonable time-limits or unwarranted delays. People involved should be able to ask a court to review an administrative decision or to appeal a lower court's ruling.

The agreement describes in some detail how enforcement should be handled, including rules for obtaining evidence, provisional measures, injunctions, damages and other penalties. It says

courts should have the right, under certain conditions, to order the disposal or destruction of pirated or counterfeit goods. Wilful trademark counterfeiting or copyright piracy on a commercial scale should be criminal offences. Governments should make sure that intellectual property rights owners can receive the assistance of customs authorities to prevent imports of counterfeit and pirated goods.

Technology transfer

Developing countries in particular, see technology transfer as part of the bargain in which they have agreed to protect intellectual property rights. The TRIPS Agreement includes a number of provisions on this. For example, it requires developed countries' governments to provide incentives for their companies to transfer technology to least-developed countries.

Transition arrangements: 1, 5 or 11 years or more

When the WTO agreements took effect on 1 January 1995, developed countries were given one year to ensure that their laws and practices conform with the TRIPS agreement. Developing countries and (under certain conditions) transition economies were given five years, until 2000. Least-developed countries had 11 years, until 2006 — now extended to 2013 in general, and to 2016 for pharmaceutical patents and undisclosed information.

If a developing country did not provide product patent protection in a particular area of technology when the TRIPS Agreement became applicable to it (1 January 2000), it had up to five additional years to introduce the protection. But for pharmaceutical and agricultural chemical products, the country had to accept the filing of patent applications from the beginning of the transitional period (i.e. 1 January 1995), though the patent did not need to be granted until the end of this period. If the government allowed the relevant pharmaceutical or agricultural chemical to be marketed during the transition period, it had to — subject to certain conditions — provide an exclusive marketing right for the product for five years, or until a product patent was granted, whichever was shorter.

Subject to certain exceptions, the general rule is that obligations in the agreement apply to intellectual property rights that existed at the end of a country's transition period as well as to new ones.

SOURCE: World Trade Organisation, UNDERSTANDING THE WTO: THE AGREEMENTS, Intellectual property: protection and enforcementhttps://www.wto.org/english/thewto_e/whatis_e/tif_e/agrm7_e.htm#top

APPENDIX 2

WTO MINISTERIAL DECLARATION 2001

APPENDIX 2

WORLD TRADE ORGANIZATION

WT/MIN(01)/DEC/2
20 November 2001

(01-5860)

MINISTERIAL CONFERENCE
Fourth Session
Doha, 9 - 14 November 2001

DECLARATION ON THE TRIPS AGREEMENT AND PUBLIC HEALTH

Adopted on 14 November 2001

1. We recognize the gravity of the public health problems afflicting many developing and least-developed countries, especially those resulting from HIV/AIDS, tuberculosis, malaria and other epidemics.

2. We stress the need for the WTO Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS Agreement) to be part of the wider national and international action to address these problems.

3. We recognize that intellectual property protection is important for the development of new medicines. We also recognize the concerns about its effects on prices.

4. We agree that the TRIPS Agreement does not and should not prevent Members from taking measures to protect public health. Accordingly, while reiterating our commitment to the TRIPS Agreement, we affirm that the Agreement can and should be interpreted and implemented in a manner supportive of WTO Members' right to protect public health and, in particular, to promote access to medicines for all.

In this connection, we reaffirm the right of WTO Members to use, to the full, the provisions in the TRIPS Agreement, which provide flexibility for this purpose.

5. Accordingly and in the light of paragraph 4 above, while maintaining our commitments in the TRIPS Agreement, we recognize that these flexibilities include:

(a) In applying the customary rules of interpretation of public international law, 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.

(b) Each Member has the right to grant compulsory licences and the freedom to determine the grounds upon which such licences are granted.

(c) 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.

(d) The effect of the provisions in the TRIPS Agreement that are relevant to the exhaustion of intellectual property rights is to leave each Member free to establish its own regime for such exhaustion without challenge, subject to the MFN and national treatment provisions of Articles 3 and 4.

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6. We recognize that WTO Members with insufficient or no manufacturing capacities in the pharmaceutical sector could face difficulties in making effective use of compulsory licensing under the TRIPS Agreement. We instruct the Council for TRIPS to find an expeditious solution to this problem and to report to the General Council before the end of 2002.

7. We reaffirm the commitment of developed-country Members to provide incentives to their enterprises and institutions to promote and encourage technology transfer to least-developed country Members pursuant to Article 66.2. We also agree that the least-developed country Members will not be obliged, with respect to pharmaceutical products, to implement or apply Sections 5 and 7 of Part II of the TRIPS Agreement or to enforce rights provided for under these Sections until 1 January 2016, without prejudice to the right of least-developed country Members to seek other extensions of the transition periods as provided for in Article 66.1 of the TRIPS Agreement. We instruct the Council for TRIPS to take the necessary action to give effect to this pursuant to Article 66.1 of the TRIPS Agreement.

APPENDIX 3

WTO GENERAL COUNCIL, AMENDMENTS OF THE WTO-TRIPS AGREEMENT (ONLINE TEXT)

APPENDIX 3

GENERAL COUNCIL
WT/L/641
8 December 2005

Amendment of the TRIPS Agreement

Decision of 6 December 2005

The General Council;
Having regard to paragraph 1 of Article X of the Marrakesh Agreement Establishing the World Trade Organization ("the WTO Agreement");

Conducting the functions of the Ministerial Conference in the interval between meetings pursuant to paragraph 2 of Article IV of the WTO Agreement;

Noting the Declaration on the TRIPS Agreement and Public Health (WT/MIN(01)/DEC/2) and, in particular, the instruction of the Ministerial Conference to the Council for TRIPS contained in paragraph 6 of the Declaration to find an expeditious solution to the problem of the difficulties that WTO Members with insufficient or no manufacturing capacities in the pharmaceutical sector could face in making effective use of compulsory licensing under the TRIPS Agreement;

Recognizing, where eligible importing Members seek to obtain supplies under the system set out in the proposed amendment of the TRIPS Agreement, the importance of a rapid response to those needs consistent with the provisions of the proposed amendment of the TRIPS Agreement;

Recalling paragraph 11 of the General Council Decision of 30 August 2003 on the Implementation of Paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health;

Having considered the proposal to amend the TRIPS Agreement submitted by the Council for TRIPS (IP/C/41);

Noting the consensus to submit this proposed amendment to the Members for acceptance;

Decides as follows:

1. The Protocol amending the TRIPS Agreement attached to this Decision is hereby adopted and submitted to the Members for acceptance.
2. The Protocol shall be open for acceptance by Members until 1 December 2007 or such later date as may be decided by the Ministerial Conference.
3. The Protocol shall take effect in accordance with the provisions of paragraph 3 of Article X of the WTO Agreement.

ATTACHMENT
PROTOCOL AMENDING THE TRIPS AGREEMENT
Members of the World Trade Organization;

Having regard to the Decision of the General Council in document WT/L/641, adopted pursuant to paragraph 1 of Article X of the Marrakesh Agreement Establishing the World Trade Organization ("the WTO Agreement");

Hereby agree as follows:

1. The Agreement on Trade-Related Aspects of Intellectual Property Rights (the "TRIPS Agreement") shall, upon the entry into force of the Protocol pursuant to paragraph 4, be amended as set out in the Annex to this Protocol, by inserting Article 31bis after Article 31 and by inserting the Annex to the TRIPS Agreement after Article 73.

2. Reservations may not be entered in respect of any of the provisions of this Protocol without the consent of the other Members.
3. This Protocol shall be open for acceptance by Members until 1 December 2007 or such later date as may be decided by the Ministerial Conference.

4. This Protocol shall enter into force in accordance with paragraph 3 of Article X of the WTO Agreement.

5. This Protocol shall be deposited with the Director-General of the World Trade Organization who shall promptly furnish to each Member a certified copy thereof and a notification of each acceptance thereof pursuant to paragraph 3.

6. This Protocol shall be registered in accordance with the provisions of Article 102 of the Charter of the United Nations.

Done at Geneva this sixth day of December two thousand and five, in a single copy in the English, French and Spanish languages, each text being authentic.

ANNEX TO THE PROTOCOL AMENDING THE TRIPS AGREEMENT

Article 31bis

1. 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.

2. Where a compulsory licence is granted by an exporting Member under the system set out in this Article and the Annex to this Agreement, adequate remuneration pursuant to Article 31(h) shall be paid in that Member taking into account the economic value to the importing Member of the use that has been authorized in the exporting Member. Where a compulsory licence is granted for the same products in the eligible importing Member, the obligation of that Member under Article 31(h) shall not apply in respect of those products for which remuneration in accordance with the first sentence of this paragraph is paid in the exporting Member.

3. With a view to harnessing economies of scale for the purposes of enhancing purchasing power for, and facilitating the local production of, pharmaceutical products: where a developing or least developed country WTO Member is a party to a regional trade agreement within the meaning of Article XXIV of the GATT 1994 and the Decision of 28 November 1979 on Differential and More Favourable Treatment Reciprocity and Fuller Participation of Developing Countries (L/4903), at least half of the current membership of which is made up of countries presently on the United Nations list of least developed countries, the obligation of that Member under Article 31(f) shall not apply to the extent necessary to enable a pharmaceutical product produced or imported under a compulsory licence in that Member to be exported to the markets of those other developing or least developed country parties to the regional trade agreement that share the health problem in question. It is understood that this will not prejudice the territorial nature of the patent rights in question.

4. Members shall not challenge any measures taken in conformity with the provisions of this Article and the Annex to this Agreement under subparagraphs 1(b) and 1(c) of Article XXIII of GATT 1994.

5. This Article and the Annex to this Agreement are without prejudice to the rights, obligations and flexibilities that Members have under the provisions of this Agreement other than paragraphs (f) and (h) of Article 31, including those reaffirmed by the Declaration on the TRIPS Agreement and Public Health (WT/MIN(01)/DEC/2), and to their interpretation. They are also without prejudice to the extent to which pharmaceutical products produced under a compulsory licence can be exported under the provisions of Article 31(f).

ANNEX TO THE TRIPS AGREEMENT

1. For the purposes of Article 31bis and this Annex:

(a) “pharmaceutical product” means any patented product, or product manufactured through a patented process, of the pharmaceutical sector needed to address the public health problems as recognized in paragraph 1 of the Declaration on the TRIPS Agreement and Public Health (WT/MIN(01)/DEC/2). It is understood that active ingredients necessary for its manufacture and diagnostic kits needed for its use would be[(1)];

(b) “eligible importing Member” means any least-developed country Member, and any other Member that has made a notification[(2)] to the Council for TRIPS of its intention to use the system set out in Article 31bis and this Annex (“system”) as an importer, it being understood that a Member may notify at any time that it will use the system in whole or in a limited way, for example only in the case of a national emergency or other circumstances of extreme urgency or in cases of public non-commercial use. It is noted that some Members will not use the system as importing Members[(3)] and that some other Members have stated that, if they use the system, it would be in no more than situations of national emergency or other circumstances of extreme urgency;

(c) “exporting Member” means a Member using the system to produce pharmaceutical products for, and export them to, an eligible importing Member.

2. The terms referred to in paragraph 1 of Article 31bis are that:

(a) the eligible importing Member(s)[(4)] has made a notification[2] to the Council for TRIPS, that:

(i) specifies the names and expected quantities of the product(s) needed[(5)];

(ii) confirms that the eligible importing Member in question, other than a least developed country Member, has established that it has insufficient or no manufacturing capacities in the pharmaceutical sector for the product(s) in question in one of the ways set out in the Appendix to this Annex; and

(iii) confirms that, where a pharmaceutical product is patented in its territory, it has granted or intends to grant a compulsory licence in accordance with Articles 31 and 31bis of this Agreement and the provisions of this Annex[(6)];

(b) the compulsory licence issued by the exporting Member under the system shall contain the following conditions:

(i) only the amount necessary to meet the needs of the eligible importing Member(s) may be manufactured under the licence and the entirety of this production shall be exported to the Member(s) which has notified its needs to the Council for TRIPS;

(ii) products produced under the licence shall be clearly identified as being produced under the system through specific labelling or marking. Suppliers should distinguish such products through special packaging and/or special colouring/shaping of the products themselves, provided that such distinction is feasible and does not have a significant impact on price; and

(iii) before shipment begins, the licensee shall post on a website the following information:

— the quantities being supplied to each destination as referred to in indent (i) above; and

— the distinguishing features of the product(s) referred to in indent (ii) above;

(c) the exporting Member shall notify[(8)] the Council for TRIPS of the grant of the licence, including the conditions attached to it.[(9)] The information 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. The notification shall also indicate the address of the website referred to in subparagraph (b)(iii) above.

3. In order to ensure that the products imported under the system are used for the public health purposes underlying their importation, eligible importing Members shall take reasonable measures within their means, proportionate to their administrative capacities and to the risk of trade diversion to prevent re-exportation of the products that have actually been imported into their territories under the system. In the event that an eligible importing Member that is a developing country Member or a least-developed country Member experiences difficulty in implementing this provision, developed country Members shall provide, on request and on mutually agreed terms and conditions, technical and financial cooperation in order to facilitate its implementation.

4. Members shall ensure the availability of effective legal means to prevent the importation into, and sale in, their territories of products produced under the system and diverted to their markets inconsistently with its provisions, using the means already required to be available under this Agreement. If any Member considers that such measures are proving insufficient for this purpose, the matter may be reviewed in the Council for TRIPS at the request of that Member.

5. With a view to harnessing economies of scale for the purposes of enhancing purchasing power for, and facilitating the local production of, pharmaceutical products, it is recognized that the development of systems providing for the grant of regional patents to be applicable in the Members described in paragraph 3 of Article 31bis should be promoted. To this end, developed country Members undertake to provide technical cooperation in accordance with Article 67 of this Agreement, including in conjunction with other relevant intergovernmental organizations.

6. Members recognize the desirability of promoting the transfer of technology and capacity building in the pharmaceutical sector in order to overcome the problem faced by Members with insufficient or no manufacturing capacities in the pharmaceutical sector. To this end, eligible importing Members and exporting Members are encouraged to use the system in a way which would promote this objective. Members undertake to cooperate in paying special attention to the transfer of technology and capacity building in the pharmaceutical sector in the work to be undertaken pursuant to Article 66.2 of this Agreement, paragraph 7 of the Declaration on the TRIPS Agreement and Public Health and any other relevant work of the Council for TRIPS.

7. The Council for TRIPS shall review annually the functioning of the system with a view to ensuring its effective operation and shall annually report on its operation to the General Council.

APPENDIX TO THE ANNEX TO THE TRIPS AGREEMENT
Assessment of Manufacturing Capacities in the Pharmaceutical Sector

Least-developed country Members are deemed to have insufficient or no manufacturing capacities in the pharmaceutical sector.

For other eligible importing Members insufficient or no manufacturing capacities for the product(s) in question may be established in either of the following ways:

(i) the Member in question has established that it has no manufacturing capacity in the pharmaceutical sector;

or

(ii) where the Member has some manufacturing capacity in this sector, it has examined this capacity and found that, excluding any capacity owned or controlled by the patent owner, it is currently insufficient for the purposes of meeting its needs. When it is established that such capacity has become sufficient to meet the Member's needs, the system shall no longer apply

1. This subparagraph is without prejudice to subparagraph 1(b).
2. It is understood that this notification does not need to be approved by a WTO body in order to use the system.
3. Australia, Canada, the European Communities with, for the purposes of Article 31bis and this Annex, its member States, Iceland, Japan, New Zealand, Norway, Switzerland, and the United States.
4. Joint notifications providing the information required under this subparagraph may be made by the regional organizations referred to in paragraph 3 of Article 31bis on behalf of eligible importing Members using the system that are parties to them, with the agreement of those parties.
5. The notification will be made available publicly by the WTO Secretariat through a page on the WTO website dedicated to the system.
6. This subparagraph is without prejudice to Article 66.1 of this Agreement.
7. The licensee may use for this purpose its own website or, with the assistance of the WTO Secretariat, the page on the WTO website dedicated to the system.
8. It is understood that this notification does not need to be approved by a WTO body in order to use the system.
9. The notification will be made available publicly by the WTO Secretariat through a page on the WTO website dedicated to the system.

SOURCE: https://www.wto.org/english/tratop_e/trips_e/wtl641_e.htm#fnt-6 [Accessed 04/10/16]

APPENDIX 4

SOLICITOR-GENERALS OFFICE BRIEF/SUMMARY OF PROTOCOL AMENDING THE WTO-TRIPS

APPENDIX 4

PROTOCOL AMNEDING THE WORKD TRADE ORGANISATION (WTO) TRADE RELATED INTELLECUTAL PROPERTY RIGHTS Agreement

1.0 **Summary of the Agreement**

1.1 The WTO Agreement on TRIPS was negotiated during the Uruguay Round between 1986 - 1994. This was when intellectual property rules were introduced into the multilateral trading system for the first time.

1.2 Intellectual Property Rights (IPRs) under the TRIPS Agreement, amongst others includes, copyright related rights and industrial property, such as patents. Patents are legal rights granted for eligible inventions. They generally provide the patent owner with the legal means to prevent others from making, using or selling the invention for a limited period of time.

1.3 The WTO General Council on 6 December 2005, adopted the Protocol Amending the TRIPS Agreement and opened it for acceptance by the WTO members.

1.4 This Protocol is the first multilateral treaty amendment agreed by the WTO members since the WTO Agreement came into force in 1995. The Protocol Amending the WTO TRIPS Agreement seeks to permanently incorporate into TRIPS Agreement additional flexibilities to grant special compulsory licenses for the export of medicines, referred to as the "Paragraph 6 System".

1.5 The "Paragraph 6 System" was first established by a Ministerial Declaration adopted on 14 November 2001 (Doha Development Round of negotiations launched) in order to facilitate access to medicines under the TRIPS Agreement to those WTO Members with insufficient or no manufacturing capacities in the pharmaceutical sector and who could face difficulties in making effective use of compulsory licensing under the TRIPS Agreement.

1.6 The Protocol Amending the WTO TRIPS Agreement seeks to permanently incorporate into TRIPS Agreement additional flexibilities to grant special compulsory licenses for the export of medicines.

1.7 Compulsory licensing is when a government allows someone else to produce the patented product or process, without the consent of the patent owner. Generally, a request for voluntary license is necessary before the use of compulsory license. However, the request for voluntary license may be waived in certain situations, in particular cases of national emergency or extreme urgency or in cases of public non-commercial use.

1.8 With Voluntary License – normally the person or company applying for a license has to have tried to negotiate a voluntary license with the patent holder on reasonable commercial terms. Only if that fails a compulsory license be issued.

2.0 **Requirements for Implementation**

2.1 The entry into the force of the Protocol Amending the TRIPS Agreement will be an important signal that will ensure a legally secure, predictable, effective and sustainable solution for those countries wishing to use the TRIPS flexibilities to get affordable medicines.

2.2 It is also worth noting that the Instrument of acceptance of the Protocol Amending the TRIPS Agreement is a new flexibility and not a new obligation on WTO Members. It is an optional measure for the WTO Members to use the flexibility if they wish so as to advance their public health interests.

2.3 Specifically, the Protocol Amending the TRIPS Agreement does not impose any additional obligations on the WTO members to implement this flexibility in their domestic laws.

3.0 **Impact of Ratification**

3.1 It is prudent to note that February this year, the Fijian Government in its World Trade Organisation Trade Policy Review made a commitment towards ratifying the Protocol Amending the TRIPS Agreement by the end of 2016.

3.2 Many developing countries and Least Developed Countries (LDCs) suffer from public health problems and access to medicines still remains a problem for most developing countries and LDCs. Thus, Acceptance of the Protocol which seeks to amend the TRIPS Agreement will help developing countries and LDCs to obtain greater access to affordable medicines when needed.

3.3 The entry into the force of the Protocol Amending the TRIPS Agreement will be an important signal that will ensure a legally secure, predictable, effective and sustainable solution for those countries wishing to use the TRIPS flexibilities to get affordable medicines.

3.4 Having an effective and efficient functioning health system is a priority of this government and access to affordable medicines is a major complement to this.

3.5 Effectively, the step of accepting the Protocol Amending the TRIPS Agreement means that a member is confirming its agreement that other members are entitled to use the system of special compulsory licences for trade in pharmaceuticals if they so wish. It is an important step to accept the Protocol Amending the TRIPS Agreement, but essentially because it will mainly give other members legal certainty and confidence to use the system. As a developing country, Fiji stands to benefit from this flexibility also.

APPENDIX 5

VERBATIM OF ORAL SUBMISSIONS