

## ACCESSIBILITY TO THE AFFORDABLE AND ADEQUATE MEDICINE UNDER INTELLECTUAL PROPERTY LAW\*

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### Abstract

The idea of protecting the pharmaceutical products including medicine under patent system of intellectual property law is designed to provide reward for the production industry and also to give incentive for further innovative and research. However, this will often put burden for some countries where the patented essential medicines are high price and out of reach for the poor. To encounter public health needs, changes were made in the Agreement on Trade Related Aspects of Intellectual Property Rights (TRIPS Agreement) by providing more flexibility to the poorer countries and to increase the safeguards that countries could use remaining within TRIPS obligations to improve public health care. This paper will aim to analyze these flexibilities provided by the TRIPS Agreements for the WTO member States to encounter public health crises in the countries where no or limited local production capacity for essential medicine.

**Keywords** - Public health, Flexibilities, Compulsory licensing, Parallel imports.

### Introduction

Intellectual Property (IP) simply refers to the ‘creation of mind’ and the intellectual property rights (IPRs) are the bundle of rights exclusively given to the creator or owner of IP for the enjoyment of his/her/their creation. IP system has been established primarily to reward the innovators and creators for their contributions to society. IP regimes are said to be justified because they encourage research, creative endeavor and innovation. It is so obvious that IPRs has simply focused on the private rights as reward and/or incentive for one’s own creation.

Recently, the impact of intellectual property rules and practices on the health of poor people in developing countries has generated substantial controversy in the World Trade Organization (WTO) negotiations. Accessibility to adequate and affordable medicines is one of the problems that developing countries might face and therefore, as a solution, a State may need to limit patent rights on some kinds of medicines or to limit the exclusive patent rights given to the patentee in order to make those medicines affordable in case of public health crisis.

Under international intellectual property law, there is a recognized principle that “*States need to consider the requirement to balancing the rights between creators and users in the enforcement of intellectual property*”. As international intellectual property rights instruments, the TRIPS Agreement can be employed with its flexibilities to bind States to design an intellectual property rights system that strikes a balance between promoting general public interests in areas of health, culture and education, whilst protecting the property rights of authors and inventors.

The research is aimed to emphasize the practice of WTO particularly for patent system by adopting the particular strategic plan for member States so as to balance between their protection given to the rights of creators and their responsibility to protection public interests in cases of national emergencies or public health crises.

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The research will be a contribution to the national implementation of IP system that how the TRIPS flexibilities can be employed so as to the establish of highest attainable standard of healthcare for the people in balancing of individual patentee rights.

### **Method of the Study**

Combination of the descriptive and analytical legal research methods are applied in this paper. The primary data of the research comes from international conventions and national legislation. Secondary data are literary books, articles, online resources, news as well as events.

### **Problem Statement**

Patent protection under intellectual property law is important for the development of new medicines. It is so obvious that patent protection always creates incentive for the research industry to develop new medicines in the pharmaceutical industry. By giving such right to monopoly as reward on the efforts, it could face problems for developing countries and create barriers to attain patented drugs adequately and affordably. As a consequence, countries have to take account of their obligation to adequate standard of health while they provide exclusive rights to the pharmaceutical industry on the products.

It is the idea of WTO to provide the balancing of IP Rights between creators and users by the TRIPS Agreement with its flexibilities which cause the accessibility of essential patented medicine by all. This paper will find out such kind of flexibilities provided under the TRIPS Agreement for member States to encounter public health crises dealing with access to patented medicines.

### **Protection of IPRs from Human Rights perspective**

In Article 15(1)(c) of the International Covenant on the Economic, Social and Cultural Rights (ICESCR) where Myanmar is a State-Party, it recognizes the right of everyone ‘to benefit from the protection of the moral and material interests resulting from any scientific, literary or artistic production of which he is the author’. This circumstance creates problems in terms of human rights if the product is essential for the enjoyment of human rights yet it becomes inaccessible to poor people.<sup>1</sup>

It is highlighted in Article 12 of the same Covenant that the right of everyone to the enjoyment of the highest attainable standard of physical and mental health. In respect of implementing this obligation, necessary steps to be taken by States which explicitly include the ‘prevention, treatment and control of epidemic, endemic, occupational and other diseases’ (Article 12(2) (c)) and the ‘creation of conditions which would assure to all medical service and medical attention in the event of sickness’ (Article 12(2) (d)).

The right to adequate health care is also recognized in Universal Declaration of Human Rights (UDHR) as everyone has the right to entitle the adequate standard of living for the health and well-being of himself and of his family, including food, clothing, housing, medical care and basic necessary social services.<sup>2</sup> A State’s obligation to support the right to health is reviewed

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<sup>1</sup> Sarah Joseph, “Blame it on the WTO?”, Oxford University Press, 2011, p- 214.

<sup>2</sup> Article 25 (1) of UDHR.

through various international human rights mechanisms, such as the Universal Periodic Review (UPR), or the Committee on Economic, Social and Cultural Rights.

The WHO Constitution (1946) envisages that "...the highest attainable standard of health as a fundamental right of every human being". For the enjoyment of 2030 WHO universal health coverage, one of the essential components of the right to health is "quality health care system". Quality includes the accessibility of health care services that may depend on affordability, and the availability of the essential medicines.

It is obvious that access to affordable and adequate medicine is one of the top priorities for States whether developed or developing ones in terms of their human rights obligations. All States actually recognizes 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 as Coronavirus. The establishment of intellectual property system should be implemented in a way supportive of a State's right to protect public health and essentially, to promote access to adequate medicines for all without concerns about the patent effects on prices while protecting the rights of patent holder.

### **Balancing Intellectual Property Rights and Public Interests**

The main international agreement relating to the intellectual property is the Agreement on Trade Related Aspects of Intellectual Property Rights (TRIPS Agreement). It is also a multilateral trade agreement annexed to the WTO Agreement<sup>1</sup> and therefore, all WTO members have to take responsibility to protect the intellectual property within their jurisdiction in line with minimum standards provided in the Agreement while recognizing the needs of the developing countries and giving assistance to those countries in the implementation of protection of IPRs. For least developed country WTO members, transition period to implement TRIPS provisions has been extended until 1 July 2021 and with respect to pharmaceutical products, extension is given until 1 January 2033, or until such a date on which they cease to be a least developed country member.<sup>2</sup>

The TRIPS Agreement should not prevent all members from taking measures to protect public health and it do recognize the right of all member States to adopt measures necessary to protect public health and nutrition.<sup>3</sup> It is also highlighted that the protection of IPRs in domestic levels of all member States is to ensure their mutual supportive manner and to take into account of public interests and national security interests. There are limited exceptions provided to the exclusive rights conferred by a patent with three conditions.<sup>4</sup> The first condition is that these exceptions do not unreasonably conflict with the normal exploitation of the patent and then, the second condition is the such exceptions are not unreasonably prejudice the legitimate interests of the patent owner, and the final condition is that in adoption of such exceptions, States must take into consideration of the legitimate interests of third parties.

In addition to these exceptions provided in Ar. 30, the TRIPS Agreement further recognizes the "*other use of patent*". Such the term "other use" includes the usage by the government itself, or any third party under government's permission without authorization from the patent holder. Under Article 31, governments may use by itself or allow third parties to use the subject matter of

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<sup>1</sup> Marrakesh Agreement Establishing the World Trade Organization (1994)

<sup>2</sup> IP/C/73 (6 November 2015)

<sup>3</sup> Article 8 of the TRIPS Agreement.

<sup>4</sup> Article 30 of the TRIPS Agreement.

a patent (Compulsory Licensing) without having authorization from the patent owner depending on its individual merits by using flexibilities under TRIPS Agreement.

### **Compulsory Licensing (CL)**

Compulsory licensing is that when a government allows someone else to produce a patented product or process without the consent of the patent owner or plans to use the patent-protected invention itself. However, the practice of compulsory licensing can only be done under a number of conditions aimed at protecting the legitimate interests of the patent holder.

The TRIPS Agreement allows “compulsory licensing” as part of the agreement’s overall attempt to strike a balance between promoting access to existing drugs and promoting research and development into new drugs. But the term “compulsory licensing” does not appear in the TRIPS Agreement. Instead, the phrase “other use without authorization of the right holder” appears in the title of Article 31. Compulsory licensing is only part of Article 31 since “other use” includes usage by governments for their own purposes.<sup>1</sup>

Under the conditions contained in Article 31, a compulsory license can be granted by a government, *inter alia*, to allow a third party to produce a generic version of a patented pharmaceutical product without the authorization of the patent holder, in so allowing low-price generic pharmaceuticals to be produced locally or imported from abroad. The confirmation that each member “has the right to grant compulsory licenses and the freedom to determine the grounds (e.g. national emergencies or public health crises situations) upon which such licenses are granted” has particular significance.

For allowing the permission to such use, the main condition for States is their responsibility to make sure that any such use is allowed “predominantly for the supply of the domestic market” in its own territories<sup>2</sup> and the right holder shall be paid adequate remuneration in the circumstances of each case by taking into account the economic value of the authorization.<sup>3</sup> Therefore, Article 31(f) of the TRIPS Agreement restricts that products made under compulsory licensing must be “predominantly for the supply of the domestic market”.

In a compulsory licensing, the patent holder retains intellectual property rights and ‘shall be paid adequate remuneration’ according to the circumstances. Generally, the grant of a compulsory license requires prior negotiation with the patent holder.<sup>4</sup> However, this prior negotiation is not necessarily to be a requirement in cases for “national emergencies”, “other circumstances of extreme urgency” or “public non-commercial use” (or “government use”) or anti-competitive practices.

Compulsory licensing as a policy mechanism can be used to address a number of situations including, among others: the high prices of medicines; or anti-competitive practices by pharmaceutical companies; or failure by pharmaceutical patent holders sufficiently to supply the market with needed medicines; or emergency public health situations, or the need for establishing a pharmaceutical industrial base.<sup>5</sup> In the pharmaceutical sector, compulsory licenses have been

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<sup>1</sup> [https://www.wto.org/english/tratop\\_e/trips\\_e/factsheet\\_pharm02\\_e.htm](https://www.wto.org/english/tratop_e/trips_e/factsheet_pharm02_e.htm) (last visited 25 July 2020)

<sup>2</sup> Article 31 (f) of the TRIPS Agreement.

<sup>3</sup> Article 31 (h) of the TRIPS Agreement.

<sup>4</sup> Pedro Roffe, “Negotiating health: intellectual property and access to medicines”, Earthscan, 2012, p- 6.

<sup>5</sup> South Center, ‘Utilizing TRIPS Flexibilities for Public Health Protection Through South-South Regional Frameworks’, 2004, p- 13.

used to stimulate price-lowering competition and to ensure the availability of needed medicines. For instance, if a new product is introduced to the market which plays an important role in public health, such as a vaccine against HIV/AIDS, malaria or perhaps Coronavirus, a country's national law could grant a compulsory license under Article 31 of the TRIPS Agreement in order to have benefits for the community.

Notably, compulsory licensing has certain additional requirements. In particular, it cannot be given exclusively to licensees (e.g. the patent-holder can continue to produce), and usually it must be granted mainly to supply the domestic market. It is so practical and beneficial for countries which have strong or sufficient local manufacturing capacity in the pharmaceutical industry.

### **Parallel Imports**

Under the TRIPS Agreement, a government can permit compulsory license, without knowing the patent holder, to a person or legal entity to import generic pharmaceuticals from other foreign resource if there is insufficient or inadequate local production capacity for a particular product.

Parallel importation occurs when a third party, without the consent of the patent holder, imports a medicine that has already been put on the market abroad more cheaply by the patent holder or a licensee. The practice is based on the principle that the patent holder has been compensated through the first sale of the product and that further control over the resale of the product would unreasonably restrain trade and competition.<sup>1</sup> It is also called the 'exhaustion of intellectual property rights'. In other words, parallel imports are not imports of counterfeit products or illegal copies. These are products marketed by the patent owner or with the patent owner's permission in one country and imported into another country without the approval of the patent owner.<sup>2</sup>

Parallel importation is used as a measure to prevent market division and price discrimination on a regional or international scale. Because most pharmaceutical companies set prices for the same products at different levels in different countries, parallel importation enables consumers to gain access to the product without affecting the right of the patent holder to receive remuneration in the country where the product is first sold.<sup>3</sup>

In order to be an effective pro-competitive measure in a scenario of full compliance with TRIPS, parallel imports should be allowed whenever the patentee's rights have been exhausted in the foreign country.<sup>4</sup> Since TRIPS allows countries to design their own exhaustion of rights regimes, developing countries should aim to facilitate parallel imports in their legislation to access the genuine patented medicine without impairing the patent holders' rights.

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<sup>1</sup> Pedro Roffe, "Negotiating health: intellectual property and access to medicines", Earthscan, 2012, p- 7.

<sup>2</sup> [https://www.wto.org/english/tratop\\_e/trips\\_e/factsheet\\_pharm02\\_e.htm](https://www.wto.org/english/tratop_e/trips_e/factsheet_pharm02_e.htm) (last visited 25 July 2020)

<sup>3</sup> South Center, 'Utilizing TRIPS Flexibilities for Public Health Protection Through South-South Regional Frameworks', 2004, p- 14.

<sup>4</sup> Commission on Intellectual Property Rights, "Report of the Commission on Intellectual Property Rights, Integrating Intellectual Property Rights and Development Policy", London, September 2002, p- 42.

### Doha Declaration on the TRIPS Agreement and Public Health (2001)

Though the TRIPS Agreement allows freedom to use its flexibilities, in practice, some governments were unsure of how the TRIPS flexibilities would be interpreted, and how far their right to use them would be respected.<sup>1</sup>

At the fourth Doha Ministerial Conference (2001), WTO Members also reaffirmed the right of each member to use the full provisions of the Agreement which provide flexibility for protecting public health and, in particular, for promoting access to medicines for all.<sup>2</sup> The Doha Declaration on the TRIPS Agreement and Public Health was adopted by WTO Member States – affirming the primacy of public health. The Doha Declaration highlighted the right to make use of flexibilities provided within TRIPS to enhance access to medicines for countries with low or no pharmaceutical production capacity.<sup>3</sup>

Paragraph 5 of the Doha Declaration reaffirmed some of the flexibilities available under the TRIPS Agreement<sup>4</sup>, notably those relating to parallel imports and compulsory licenses. Meanwhile, Paragraph 6 of the Declaration recognizes 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.

This is because ‘compulsory licensing’ is not always a solution for resource-limited countries. For instance, when prior authorization from the patent owner is required, as in the normal case, negotiations can be lengthy and complicated, and a country may not have the necessary legal expertise. In addition, the manufacturing process for a pharmaceutical product may be protected under a separate patent or as a trade secret. Moreover, countries may lack the technical expertise or facilities necessary to copy and manufacture the product or to attain the economies of scale that make such a decision feasible.<sup>5</sup>

Eventually, the WTO General Council adopted in its Decision on the Implementation of Paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health<sup>6</sup> on 30 August 2003. It is also known as “**August Decision**”. This Decision noted the existence of exceptional circumstances justifying a waiver of obligations under TRIPS Article 31 (f) (domestic market requirement) and (g) (authority of review) for pharmaceuticals products and adopted measures that, in effect, created rules permitting a two-country compulsory license.<sup>7</sup> The TRIPS Council responded by implementing a temporary waiver of Article 31 (f) concerning the “domestic market” limitation and proposing a new amendment to the TRIPS Agreement to allow *waiver* of the “domestic market” limitation on compulsory licensing.

All WTO Member countries are allowed to import under this decision, but the decision lists 23 developed countries that voluntarily announced that they would not use the system as importing Members: Australia, Austria, Belgium, Canada, Denmark, Finland, France, Germany, Greece,

<sup>1</sup> [https://www.wto.org/english/tratop\\_e/trips\\_e/factsheet\\_pharm02\\_e.htm](https://www.wto.org/english/tratop_e/trips_e/factsheet_pharm02_e.htm) (last visited 25 July 2020)

<sup>2</sup> South Center, ‘Utilizing TRIPS Flexibilities for Public Health Protection Through South-South Regional Frameworks’, 2004, p- 11.

<sup>3</sup> Chikosa Banda, “Intellectual property and access to essential pharmaceuticals: recent law and policy reforms in the southern Africa development community region.” *Md. J. Int’l L.* 31 (2016): 44, p- 4.

<sup>4</sup> Article 31 of the TRIPS Agreement.

<sup>5</sup> Pedro Roffe, “Negotiating health: intellectual property and access to medicines”, Earthscan, 2012, p- 7.

<sup>6</sup> WT/L/540 (2 September 2003)

<sup>7</sup> Judy Winegar Goans, ‘Intellectual Property; Principles and Practice’, 2014, p- 136.

Ireland, Iceland, Italy, Japan, Luxembourg, New Zealand, Norway, Portugal, Spain, Sweden, Switzerland and the United Kingdom. After joining the EU in 2004, 10 more countries have been added to the list: Cyprus, Slovenia, Estonia, Hungary, Latvia, Lithuania, Malta, Poland, the Czech Republic and the Slovak Republic.<sup>1</sup> On the other hand, Australia recently adopted legislation and regulations to authorize domestic drug manufacturers to produce generic drugs for export to countries exercising their compulsory licensing rights.<sup>2</sup>

### **Amendment of the TRIPS Agreement (Article 31<sup>bis</sup>)**

Although, as discussed above, these flexibilities under TRIPS agreement addressed some concerns for least-developed countries, the question of access to pharmaceutical products remained for countries that lacked local manufacturing capacity.

On 6 December 2005, WTO Members approved *Amendment to the TRIPS Agreement*<sup>3</sup> in order to make permanent decision on patents and public health originally adopted in 2003, August Decision. This was the first WTO multilateral treaty amendment since its formation. Accepting of the Protocol amending the TRIPS Agreement by two thirds of the WTO's members, the amendment took effect on 23 January 2017.

Following the entry into force of the Amendment, members to which the amended TRIPS Agreement applies may derogate from the obligations set out in paragraphs (f) and (h) of Article 31 of the TRIPS Agreement with respect to pharmaceutical products pursuant to Article 31bis, the Annex and the Appendix to the TRIPS Agreement. For other Members that have yet to accept the Protocol, the waiver provisions established under the August Decision continue to apply.<sup>4</sup> Myanmar has approved the Amendment on 16 December 2015 and then it takes the responsibility to follow the new amendment (Article 31<sup>bis</sup>) of TRIPS Agreement.

The new Article 31<sup>bis</sup> of the TRIPS Agreement gives full legal effect to compulsory licensing system and allows low cost generic medicines to be produced and exported under a compulsory license exclusively for the purpose of serving the needs of countries that cannot manufacture those products themselves. When a country produces the pharmaceutical products under compulsory license and wish to export as 'eligible export country' to a recognized 'eligible importing member'<sup>5</sup>, the former TRIPS requirement for "the supply of domestic market" shall not apply with respect to the grant by it of a compulsory license. However, the country must fulfill its responsibilities in Annex of the Agreement.

However, companies have been pressuring governments not to import medicines from countries that produce generic versions, claiming that the practice is a breach of the TRIPS agreement. Countries that have used compulsory licensing have drawn sharp criticism from foreign governments as well as retaliatory measures from pharmaceutical firms. When Thailand used compulsory licensing to get cheaper access to Abbott's combination lopinavir/ ritonavir antiretroviral product, Abbott withdrew seven pending applications for registration of new

<sup>1</sup> Pedro Roffe, "Negotiating health: intellectual property and access to medicines", Earthscan, 2012, p - 7.

<sup>2</sup> Dreyfuss, Rochelle Cooper, and Justine Pila, eds. "The Oxford handbook of intellectual property law", Oxford University Press, 2018, p- 21.

<sup>3</sup> WT/L/641 (8 December 2005)

<sup>4</sup> www.wto.org (as of: February 2020)

<sup>5</sup> Any least-developed country Member, and any other Member that has made a notification to the Council for TRIPS of its intention to use the system set out in Article 31bis and this Annex ("system") as an importer. (Annex to the TRIPS Agreement)

medicines from the Thai Food and Drug Administration, temporarily withholding those drugs from patients in Thailand. These tactics may have discouraged developing nations from exercising their rights under TRIPS.

### **Myanmar Patent System and Compulsory Licensing**

Myanmar Patent Law was enacted by the Pyidaungsu Hluttaw on 11 March 2019 as the Law No.7/2019 with the primary objectives to protect the rights and interests of the patentee and the inventor as well as to support the balancing of rights and responsibilities between the innovators and users.<sup>1</sup>

This Law including 25 Chapters with 119 Sections will come into force on such date of confirmation notified by the President. Being the members of LDCs, Myanmar can enjoy the TRIPS extension for protection of IP Rights. Particularly a product or process relating to the drugs manufacturing cannot be patentable in Myanmar until 1 January 2033 under the policy of the Council of WTO.<sup>2</sup> According to this policy, there are some inventions\_ agricultural chemical products; foodstuffs; and microbiological items\_ which cannot be patentability until 1 July 2021.

There is a particular chapter<sup>3</sup> in the Myanmar Patent Law which provides for the compulsory licensing. The main responsible body for intellectual property, IP Agency, has the authority to grant the compulsory license with the approval of the Central Committee.

Any person or legal entity may apply to the Registration Officer for a compulsory license under the following conditions:-

- (a) Special requirements of public interests as union security, public nutrition and health, or important national economic sectors;
- (b) Such use is permitted to remedy a practice determined by the judicial or administrative body to be anti-competitive;
- (c) Misuse of his exclusive rights by the patentee, or neglect to deter such misuse by his authorized person;
- (d) Such invention cannot be available, by local production or importation, in the domestic level with sufficient quality or quantity, or fair price;
- (e) Claim for the protection of second patent that involves an important technical advance of considerable economic significance in relation to the invention claimed in the first patent and without infringing the first patent, the second patent cannot be performed.<sup>4</sup>

When issuing compulsory license, it is the duty of IP Agency to inform the patent holder promptly about the issuance of license and also the starting date of the license, the conditions of the license including the term, and the damages payable to the patentee. In considering the amount of damages for compulsory license, the stipulations contained in the WTO General Council Decision dated 30 August 2003 (August Decision) may take into account by the Agency.

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<sup>1</sup> Section 3 of the Patent Law (2019).

<sup>2</sup> WT/L/971 (2 December 2015)

<sup>3</sup> Chapter 17 of the Patent Law.

<sup>4</sup> Section 66 of the Patent Law.



The exception is that no compulsory license can be applied due to the reason of the insufficient quantity of production of the patented products or such production which can only be produced by using patented process either before 4 year from the date of patent application or before 3 year from the date of patent granting.<sup>1</sup>

When applying compulsory license, the applicant must submit his/ her prior effort for voluntary license as the evidence that he has not been received the permit from the patentee within the reasonable time. However, such evidence of voluntary license does not need to prove in case of public emergency, or the circumstances of extreme urgency, or in the case of public non-commercial use, or the remedies determined by the judicial or administrative procedures to be anti-competitive.<sup>2</sup>

Under Section 71 of the Law, the use of compulsory license shall be authorized for the supply of domestic market of the Union. However, this “domestic market supply” requirement is not essential in the following cases

- when the practice is to be anti-competitive, or
- the compulsory license is connected with the patent either for the pharmaceuticals product or for the process of such products, and
- the authorization of compulsory license is to export said products in accordance with the WTO General Council August Decision to any foreign countries where no local production capacity or no ability to produce such products exists.

It is notable that Myanmar Patent law designs to use TRIPs flexibilities by allowing compulsory licensing in line with TRIPS Amendment. Compulsory Licensing can be granted in cases of pharmaceutical products or to export such products to other countries with lack of capacity to product such products.

For using the compulsory license on the pharmaceutical products, the amendment (Article 31<sup>bis</sup>) of the TRIPS Agreement contains the specific guidelines and requirements for eligible importing members and for exporting members. Being a member of LDCs, Myanmar should take the benefits from its level of development and urgent need to adopt adequate policies and mechanism as ‘eligible importing member’ in order to get essential patented medicines to meet the need of the people.

When Myanmar government recognizes and applies compulsory license as the eligible exporting members for pharmaceutical products, it will need to provide legal rules and mechanisms and also will need to notify to the TRIPS Council with conditions contains in its Annex. In such notification, Myanmar shall have to include the conditions attached to it. The information provided shall include the name and address of the licensee, the product(s) for which the license has been granted, the quantities for which it has been granted, the country or countries to which the products are to be supplied and the duration of the license.

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<sup>1</sup> Section 69 of the Patent Law.

<sup>2</sup> Section 70 of the Patent Law.

## **Findings**

Providing effective legislation and procedures for compulsory licensing may have an important role to play in maintaining a pro-competitive IPR policy in the new environment. Resource limited countries including Myanmar should establish effective legal mechanisms to practice TRIPS flexibilities. Myanmar needs to consider the adoption of the appropriate provisions for government and non-commercial use by taking into consideration of patent holders' rights. Developed countries should maintain and strengthen their legislative regimes to prevent imports of low priced pharmaceutical products originating from developing countries. Meanwhile developing countries like Myanmar should not eliminate potential sources of low cost imports from other developing or developed countries.

## **Recommendation**

In such cases where the country has insufficient or no pharmaceutical production capacity on the particular medicine/products which are essential for public needs, Myanmar can take benefits from TRIPS flexibilities under Article 31<sup>bis</sup> by notifying to the TRIPS Council as an eligible importing member specifying the names and expected quantities of the products needed in the country.

When Myanmar provide national policy and legal mechanisms concerning "compulsory license" system to facilitate access to genuine medicines with affordably and adequately, it should establish strong legal system to protect of IPRs that can promote the innovation and creation for new medicines and to attract foreign investment that can enhance country's economic development.

## **Conclusion**

The reminder of the flexibilities under TRIPS broadly covers all countries and users of technology both in developed and developing countries. The particular advantage of the flexibilities for developing countries lies in their level of development. They can benefit from the utilization of the TRIPS flexibilities to deal with public health crisis in the case where access to patented drugs becomes unaffordable and patent needs to be diluted to make generic copies of the needed drugs. For those countries with insufficient or no manufacturing capacities in the pharmaceutical sector, the TRIPS Agreement provides a solution by its flexibilities in order to encounter their concerns for access to adequate and affordable patented medicines.

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