

3 A CONTEXTUAL FRAMEWORK FOR DESIGNING AND IMPLEMENTING LAWS AND POLICIES TO PROMOTE ACCESS TO MEDICINES IN CAMBODIA

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ABSTRACT

This paper briefly reviews the TRIPS public health-related flexibilities within the international legal framework, as well as Cambodia's national policies, laws and regulations, and then assesses to what extent such flexibilities have been incorporated and utilized under its intellectual property (IP) policies, laws and regulations. It concludes that Cambodia has failed to incorporate and utilize fully the TRIPS public health-related flexibilities for three reasons. First, the Patent Law followed the WIPO Draft Industrial Property Act, which was developed many years ago and lacked these flexibilities. Second, since its adoption in 2003, the Cambodian Patent Law has never been reviewed and modified so as to take advantage of these flexibilities, in particular those envisaged in the Doha Declaration and put in place after its adoption, such as the transitional period for pharmaceutical products until 2033 and the special compulsory licensing system under the August 30 Decision. Third and lastly, the draft Compulsory Licensing Law (CL), incorporating the flexibilities under the August 30 Decision, was finalized but has not been endorsed or adopted. These reasons also serve as lessons learned for other countries that need to address the same issue in relation to IP and public health.

Keywords: *Intellectual property, TRIPS Agreement, flexibilities, public health, compulsory licence, Doha Declaration, August 30 Decision, Paragraph 6*

I. INTRODUCTION

As a least developed country (LDC), Cambodia is not obliged to comply with the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS Agreement) until the lapse of the transitional period in July 2021.¹ In particular, Cambodia is not obliged to provide patent protection of pharmaceutical products under its patent law. Accordingly, at present Cambodia's patent law excludes pharmaceutical products from the subject matters of the patent protection. Although

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¹ In its draft working party report, Cambodia requested a 2009 transition period. Finally, WTO Members pressed Cambodia to accept a 2007 transition period. However, due to the status of Cambodia as an LDC, it is entitled to the general transitional period agreed upon by all WTO Members.

Cambodia does not provide patent protection for pharmaceutical products, it faces three main challenges in relation to intellectual property (IP) and public health.

The first challenge is access to affordable medicines. Cambodia has so far made significant progress in promoting access to affordable medicines for the anti-retroviral (ARV) treatment of persons living with HIV and for the treatment of both communicable and non-communicable diseases, such as hepatitis C, heart and vascular diseases, diabetes and cancer.² This achievement has been made possible owing to various global sources of funds and the increasing competition among generic versions of patent-protected medicines. However, Cambodia's access to affordable generic medicines is not guaranteed in the long term because the global fund resources on which Cambodia depends on to pay for the treatment are rapidly declining.³

The second challenge is diminished competition among generic versions of patent-protected pharmaceutical products in developing countries which have largely supplied those pharmaceutical products to Cambodian patients. Countries that supply Cambodia with generic medicines such as India could soon or later enter into bilateral or regional free trade agreements that might restrict them from exporting cheap and affordable generic medicines to Cambodia⁴ and consequently restrict Cambodia's access to cheaper generic versions of essential drugs that are under patent protection.

The third and last challenge is when Cambodia graduates from its LDC status due to its strong economic growth, an economic performance estimated by the Asia Development Bank and the World Bank to have shown solid growth in the previous three years. Such prolonged expansion has lifted Cambodia's gross national income per capita toward the \$1,045 threshold for entry into lower-middle-income status.⁵ As part of its economic development strategy, Cambodia plans to graduate from a lower-middle income country to a

² See World Bank, Overview: Cambodia <<http://www.worldbank.org/en/country/cambodia/overview#2>> accessed 17 January 2016. According to the World Bank, Cambodia has also been successful in combating HIV/AIDS, tuberculosis and malaria. HIV prevalence among adults aged 15 to 49 decreased from 0.9 per cent in 2006 to 0.7 per cent in 2012. In 2014, 89 per cent of active AIDS patients in Cambodia had access to antiretroviral treatment, a rate of coverage that is among the highest in the developing world.

³ It is expected that there will be a decline in the total global fund of 55.3% for the next three years 2015, 2016 and 2017. See the National Aids Authority, *Cambodia Country Progress Report* (National Aids Authority 2015) 33.

⁴ Those countries include India and other countries which are involved in bilateral and regional trade agreements such as TPP and the India-EU Trade Agreement.

⁵ See May Kunmakara and Ananth Baliga, *Nearing Lower-Middle Income* Phnom Penh Post (Phnom Penh 17 July 2015) <<http://www.phnompenhpost.com/business/nearing-lower-middle-income>>

higher-middle income country in 2030.⁶ At that juncture, Cambodia will no longer be classified as an LDC and will be obliged to comply fully with the TRIPS Agreement, in particular regarding the protection of pharmaceutical products.

In promoting access to affordable medicines, Cambodia recognizes this as a critical issue of public health and human rights, and ultimately of poverty reduction and human development. Cambodia has thus recently adopted the National Intellectual Property Strategy (NIPS), which addresses access to affordable medicines throughout the text. Cambodia is also in the process of drafting a law on compulsory licensing for public health, in order to address a public health crisis in the event of a national health emergency, extreme urgency or public non-commercial use.

The NIPS was questionable, however, in respect of its assumption, information and evidence and failed to give adequate consideration to the public health implications of patented pharmaceutical products. The drafting of the law on compulsory licensing for public health has also met, both at the national and international levels, with various political and legal challenges. Even its future adoption and implementation cannot be precisely predicted. Moreover, several other existing related laws and policies, including a law on patents and a law on the management of pharmaceutical products, have not been reviewed to assess whether they are supportive of public health and to what extent they have incorporated and utilized flexibilities available under the TRIPS Agreement and the Doha Declaration on TRIPS and Public Health.⁷

These challenges and failures raise three key questions: (1) how to promote access to affordable medicines, as a critical issue of public health and human rights, and ultimately of poverty reduction and human development; (2) how Cambodia's existing laws and policies should be reviewed and revised within the national and international context; and (3) how to balance public health interests and the interests protected by IP laws and policies.

In order to address these three questions, this paper will briefly review the international legal framework of IP and public health in Part II, and the flexibilities provided to WTO Members in relation to public health. Part III of this Paper will review Cambodia's national laws and policies relating to IP and public health and assess whether they promote or obstruct access to affordable

medicines. Part IV will assess to what extent Cambodia has taken advantage of the IP and public health international legal framework and relevant flexibilities, and draw lessons learned and implications for other countries. Finally, after discussion, Part V will draw the relevant conclusions.

II. THE INTERNATIONAL LEGAL FRAMEWORK OF IP AND PUBLIC HEALTH

The TRIPS Agreement was adopted in 1994 and represents the most far-reaching international agreement that sets the global minimum substantive standard of protection for IPRs such as protectable subject matters, requirements and conditions for protection, protected rights, and minimum duration of protection, as well as enforcement obligations and dispute settlement mechanism.⁸ Regardless of its adoption, debates on the balance between the private interests of right holders and the public interests of users and governments for their development needs have started and continued both prior to and after the adoption of the TRIPS Agreement.

After continuous debates among WTO State Members, a number of flexible provisions were incorporated under the TRIPS Agreement to promote public health and access to medicines, and a declaration and decision on the intersection between IP and public health was adopted. The following sections will provide an overview of the public health-related flexibilities contained in the TRIPS Agreement, along with the declaration and decision within the international legal framework of the TRIPS Agreement.⁹

⁶ See National Strategic Development Plan 2014-2018 (RGC 2014) 118.

⁷ WTO, *Doha Declaration on the TRIPS Agreement and Public Health*, 14 November 2001 (the Doha Declaration) <https://www.wto.org/english/thewto_e/minist_e/min01_e/m indecl_trips_e.htm> accessed 17 January 2016.

⁸ As a least developed country (LDC), Cambodia is granted an extension of the transition period up to 1 July 2021 to implement the TRIPS Agreement.

⁹ Owing to the limited space of this Paper, this subject is not discussed in detail. For a detailed explanation and discussion, see UNDP, *Good Practice Guide: Improving Access to Treatment by Utilizing Public Health Flexibilities in the WTO TRIPS Agreement* (UNDP 2010) (the UNDP Good Practice Guide).

A. PUBLIC HEALTH - RELATED TRIPS FLEXIBILITIES

Under the TRIPS Agreement, there are several provisions that relate to TRIPS flexibilities that can be utilized by WTO Members to promote public health. A good practice guide published by UNDP divides these public health-related TRIPS flexibilities into three types: preventive, remedial, and enforcement. The three types of public health-related TRIPS flexibilities are summarized in a table below.

Among these public-health-related TRIPS flexibilities, certain flexibilities were incorporated into the Patent Law of Cambodia. Part III of this Paper will examine and review the Patent Law and identify which flexibilities were incorporated, as well as explain why they were not used to the fullest extent.

B. DOHA DECLARATION AND DECISION ON IP AND PUBLIC HEALTH

The debate on public health and access to medicines was initiated in 2001 in Doha, Qatar to clarify the ambiguities between the need for governments to implement the TRIPS Agreement and to protect the right to health.¹⁰ Developed countries, developing countries and LDCs took part in this discussion concerning IP and access to medicines, which led to the adoption by WTO Members of the 'Doha Declaration on the TRIPS Agreement and Public Health' (the Doha Declaration) in 2001. The Doha Declaration affirms that the TRIPS Agreement 'does not and should not prevent Members from taking measure to protect public health' and that it:

Public Health-Related TRIPS Flexibilities	Examples and Relevant References
<p>Preventative:</p> <p><i>Policy options to ensure that patents do not hinder access to affordable medicines.</i></p> <p><i>Advantages: easier, faster, less politically sensitive compared to some remedial measures.</i></p>	<p>Exclusion from Patentability: exclude new use of known substances, methods and processes (Articles 27.2 and 27.3)</p> <p>Patentability Criteria: develop and apply strict patentability criteria for examination of pharmaceutical patents. Mitigate frivolous patents and "evergreening" opportunities. (Articles 1 and 27.1).</p> <p>Patent Opposition: allow pre-grant and post-grant patent opposition in fast, accessible and cost-efficient manner.</p> <p>Waiver for LDCs: LDCs should utilize the waiver to provide patent protection for pharmaceuticals until 1 January 2016 (<i>now 1 January 2033</i>) (and possibly longer, if extended).</p>
<p>Remedial:</p> <p><i>Preventative flexibilities cannot always be used to meet existing and emerging needs to secure access to affordable medicines. Therefore, series of remedial flexibilities are included in the TRIPS Agreement.</i></p>	<p>Compulsory Licences and Government Use Orders</p> <p>(Article 31 (a)-(j))</p> <p>Compulsory Licences for Export under the WTO 30 August, 2003 Decision.</p> <p>Exceptions: Bolar (early working) exception, research and experimental use exception, individual use (Article 30)</p> <p>Use of National Competition Laws to prevent IPR abuse and provide remedies (Articles 8.2, 31(k) and 40)</p> <p>Parallel Importation (Article 6)</p>
<p>Enforcement:</p> <p><i>Related to obligations under Part III of the TRIPS Agreement, which sets minimum standards for IPR enforcement.</i></p>	<p>No border measures for suspected patent infringement (Article 51)</p> <p>No criminalization of patent infringement (Part III, Section 5)</p>
<p>UNDP, Good Practice Guide: Improving Access to Treatment by Utilizing Public Health Flexibilities in the WTO TRIPS Agreement, 15 (2010)</p>	

¹⁰ See UNDP Good Practice Guide 6-8.

can and should be interpreted and implemented in a manner supportive of WTO Members' right to promote public health and, in particular, to promote access to medicines for all.¹¹

In paragraph 4, the Doha Declaration formally affirms that WTO State Members should have the right 'to use, to the full, the provisions in the TRIPS Agreement, which provide flexibility for this purpose.'¹² The Doha Declaration then spells out in paragraph 5 that, within the context of the TRIPS Agreement, these flexibilities include:

- The right to grant compulsory licences and the freedom to determine the grounds upon which such licences are granted; and
- 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.

The Doha Declaration, however, failed to address an issue under paragraph 6. Recognizing 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.

The Ministers charged the Council for TRIPS to find 'an expeditious solution' to the issue. For about two years, the Council for TRIPS implemented its mandate and finally presented the expeditious solution to WTO Members. In August 2003, a decision on the implementation of Paragraph 6 of the Doha Declaration was adopted by WTO Members, establishing a system under which a country can issue a compulsory licence for the purpose of exporting generic medicines to countries with insufficient or no manufacturing capacity (the August 30 Decision).

The August 30 Decision introduced two important waivers to Article 31 of the TRIPS Agreement. The first waiver concerns the requirement of TRIPS Article 31(f) for predominant domestic use, which provides a mechanism that allows WTO Members to issue compulsory licences for the export of generic

¹¹ Ministerial Declaration on the TRIPS Agreement and Public Health, paragraph 4.

¹² *ibid.*

equivalents of patented medicines to countries with no or insufficient pharmaceutical manufacturing capacity. The second waiver concerns the obligation of importing countries under the requirement of TRIPS Article 31(h). A number of conditions must be satisfied in order to implement the August 30 Decision.¹³

The use and implementation of the August 30 Decision is optional, not mandatory and thus each WTO Member can decide whether or not to use and implement it. Among the WTO Members with express implementing laws or regulations, there are three categories of Members that have implemented the August 30 Decision:

- exclusively as exporters (41 Members);
- exclusively as importers (three Members); or
- both as exporters and importers (seven Members).¹⁴

On 1 November 2011, Cambodia expressly submitted an Instrument of Acceptance of the amendment of the TRIPS Agreement that it will use and implement the August 30 Decision, both as exporter and importer.¹⁵ However, Cambodia has not adopted any domestic law or regulation for such use and implementation. A law on compulsory licensing for public health is being drafted, but this process is lengthy and is proving challenging since the introduction of the first draft by experts and the Ministry of Health, who is in charge of this law. Section III below spells out the details of this draft law, while discussing some of the key challenges facing Cambodia.

III. NATIONAL LEGAL AND POLICY FRAMEWORK FOR IP AND PUBLIC HEALTH

Patents are the most relevant type of IP in the context of public health. In 2003 Cambodia adopted for the first time a Law on Patents, Utility Model Certificates, and Industrial Designs (the Patent Law). The Patent Law is supplemented by two important regulations on patents, utility models and industrial designs, namely the Prakas on Procedures for Granting Patents and Utility Model Certificates (2006) (the Patent Regulation), and the Prakas on Procedures for Registration of Industrial

¹³ For a detailed explanation on these requirements, see Frederick M Abbot and Rudolf V Van Puymbroeck, *Compulsory Licensing for Public Health: A Guide and Model Documents for Implementation of the Doha Declaration Paragraph 6 Decision*, World Bank Working Paper No. 61 (World Bank 2005).

¹⁴ See Roger Kampf, *Special Compulsory Licences for Export of Medicines: Key Features of WTO Members' Implementing Legislation*, Staff Working Paper ERSD-2015-07, 8 (Economic Research and Statistics Division, WTO 2015).

¹⁵ See WTO, WT/Let/833.

Designs (2006). These two regulations provide guidelines both for the Patent Office and inventors, on how to grant patents and utility model certificates and how to register industrial designs. The Patent Law and the two regulations are fundamental legal frameworks for the protection of patents, utility models and industrial designs in Cambodia.

The following sections will review the NIPS, the Patent Law and Patent Regulation in relation to public health.¹⁶

A. NIPS IN THE CONTEXT OF PUBLIC HEALTH

In line with objectives and challenges raised in the Second Health Sector Strategic Plan 2008-2015, the NIPS has identified five areas where the IP system should be managed to ensure that it contributes positively to public health in Cambodia:

- Fostering the growth of the pharmaceutical industry in Cambodia;
- controlling and reducing the price of pharmaceuticals by taking advantage of the flexibilities available under the TRIPS Agreement to access essential medicines;
- providing tools to assist with enforcement action against providers of counterfeit pharmaceuticals;
- facilitating collaboration with outside health organizations to share technologies, treatment methods and pharmaceuticals that otherwise may not be made available without adequate IP protection;
- providing mechanisms for the control and protection of traditional medicines and traditional medicine practices, and opportunities for protection of innovations in this area.¹⁷

In order to support these five areas, five initiatives were adopted in the NIPS in relation to IP and public health for implementation within short-, medium- and long-term timelines.¹⁸ Some of the initiatives have been launched and implemented by the relevant ministries in charge, while others have yet to start or be developed. Hence, an evaluation of what needs to be done and what has not been done by the relevant ministries should be undertaken to identify and share both the

success stories and the challenges facing the relevant ministries in their implementation.

B. PATENT LAWS AND REGULATIONS IN THE CONTEXT OF PUBLIC HEALTH

In addition to the NIPS, Cambodia has the Patent Law, which does not grant patent protection to pharmaceutical products until 1 January 2016. Pharmaceutical products were clearly excluded from the subject matters of patent protection¹⁹ and will be granted accordingly from 1 January 2016.²⁰

Although the Patent Law does not provide patent protection to pharmaceutical products, the Patent Office has, however, accepted patent applications for pharmaceutical products since 2007 under the Patent Regulation.²¹ Thus Cambodia has practiced a mailbox system, although it is not obliged under the TRIPS Agreement to have this system in place. The mailbox would be opened starting in January 2016, at which time Cambodia would need to grant patent protection in accordance with the Patent Law as from the grant of the patent and for the remainder of the patent term, counted from the filing date.²² Following the granting of patent protection, access to generic medicines would be potentially restricted because the medicines are patented.

Even though a patent is granted to pharmaceutical products, there are some situations in which a government agency or a designated third party can exploit the invention without the agreement of the patent holder²³, in particular when the public interest, including national security, nutrition, health or the development of other vital sectors of the national economy so requires; when the exploitation by an owner is anti-competitive;²⁴ when the patented invention is not worked or worked but not sufficiently;²⁵ or when there is an interdependent patent.²⁶ This is called a 'compulsory licensing' or 'a non-voluntary licensing' system. In such situations, however, a compulsory licence must be issued in compliance with the following requirements and conditions:

- Adequate remuneration (Article 47);
- an authorization may be obtained only if efforts have been made to obtain a contractual licence and have failed with exceptions (Article 52);

¹⁶ Owing to space limitation, this Paper will not discuss the laws and regulations on the management of pharmaceutical products, which also have a potential impact on the access to medicines in Cambodia.

¹⁷ *ibid.*, 43.

¹⁸ *ibid.*, 43-48.

¹⁹ The Patent Law, Article 4.

²⁰ The Patent Law, Article 136.

²¹ The Patent Regulation, Rule 45.

²² *ibid.*

²³ The Patent Law, Articles 11 and 12.

²⁴ The Patent Law, Article 47.

²⁵ The Patent Law, Article 56.

²⁶ The Patent Law, Article 59.

- non-exclusive (Article 51);
- limited transfer of the authorization (Article 50);
- predominantly used for the supply of the domestic market (Article 53);
- variation of decision (Article 48);
- termination of decision (Article 49);
- subject to appeal (Article 55).

Under the Patent Law, condition No. 2 above will not apply when the compulsory licence is issued for the purpose of national emergency, extreme urgency and public non-commercial use.²⁷ Conditions No. 4 and No. 5, however, are the same as Article 31 of the TRIPS Agreement and have not been modified since its adoption in 2003, even though these conditions are partially or fully waived by the August 30 Decision of the Council for TRIPS. These conditions will be spelt out in more detail in Part IV.

C. DRAFT LAW ON COMPULSORY LICENSING FOR PUBLIC HEALTH

Since 2004, with assistance and support from development partners such as UNDP, UNAIDS and WHO, the Ministry of Health of Cambodia has started the discussion about IP and public health and the process of drafting the law on compulsory licensing for public health (the CL Law) has already been initiated since that time. Until now, however, the draft CL Law has not yet been adopted. The current version of the draft CL Law has already been discussed and finalized by the technical working group of the Ministry of Health and other relevant ministries. The next step in the process will be the endorsement of the Council of Ministers, the submission to the National Assembly and the Senate, and then the promulgation of the CL Law by the King.

The draft CL Law is a standalone law, separate from the Patent Law. It intends to incorporate flexibilities under the Doha Declaration and the August 30 Decision, in order to promote access to affordable medicines through the use and implementation of the special compulsory licensing system, that is, the import and export of medicines through this system. As long as the CL Law has not been adopted, however, the use and implementation of the August 30 Decision have yet to be realized. Consequently, it will potentially impact the access to medicines for patients in Cambodia.

IV. LESSONS LEARNED AND IMPLICATIONS FOR OTHER COUNTRIES

After reviewing and discussing the international and national legal framework in Part II and Part III, some lessons can be learned from Cambodia's experience, together with implications for other countries when they seek to address the balance between IP and public health. The following sections will spell out those lessons and implications in more detail.

A. NO FULL USES OF PUBLIC HEALTH-RELATED TRIPS FLEXIBILITIES

The Cambodian Patent Law was adopted in 2003 and since then it has never been modified or amended. The drafting of the Patent Law followed a WIPO Model Law called 'Draft Industrial Property Act for [Country] and Commentary on Its Main Provisions'. Consequently, the Patent Law incorporated certain flexibilities and left other flexibilities unstipulated. The following table summarizes what flexibilities were incorporated and which flexibilities were not incorporated by using the three types of flexibilities developed by the UNDP Good Practice Guide.

²⁷ The Patent Law, Article 52, para 2.

Type of Flexibilities	Incorporated	Not Incorporated
Preventative	Waiver for LDCs: Patent protection for pharmaceuticals until 1 January 2016 (Article 136 of the Patent Law).	<p>Exclusion from Patentability: exclude new use of known substances, methods and processes (Articles 27.2 and 27.3)</p> <p>Patentability Criteria: develop and apply strict patentability criteria for examination of pharmaceutical patents. Mitigate frivolous patents and "evergreening" opportunities. (Articles 1 and 27.1).</p> <p>Patent Opposition: allow pre-grant and post-grant patent opposition in fast, accessible and cost-efficient manner.</p> <p>Waiver for LDCs: Cambodia has not yet amended its Patent Law to the exception for patent protection for pharmaceuticals until 1 January 2033 (and possibly longer, if extended).</p>
Remedial	<p>Government Use and Non-Voluntary Licence</p> <p>(Article 47-64 of the Patent Law)</p> <p>International Exhaustion (Article 44(i) of the Patent Law)</p> <p>Exceptions: Research and experimental use exception, individual use (Article (iii)(iv) of the Patent Law)</p>	<p>Compulsory Licences for Import and Export under the August 30 Decision.</p> <p>Exceptions: Bolar (early working) exception (Article 30)</p> <p>Use of National Competition Laws to prevent IPR abuse and provide remedies (Articles 8.2, 31(k) and 40)</p>
Enforcement	No border measures for suspected patent infringement	No criminalization of patent infringement (Part III, Section 5)

As set out in the above table, the Cambodian Patent Law has failed to incorporate fully the key TRIPS public health-related flexibilities. There are three main reasons for this failure: First, the Patent Law followed the WIPO Draft Industrial Property Act, which was developed several years ago and did not contain all of these flexibilities. Second, since its adoption in 2003, the Cambodian Patent Law has never been reviewed or modified to take advantage of these flexibilities, in particular those envisaged in the Doha Declaration and put in place after its adoption, such as the transitional period for pharmaceutical products until 2033 and the special compulsory licensing system under the August 30 Decision. Third and last, the draft CL Law, incorporating the flexibilities under the August 30 Decision, was finalized, but has not been endorsed or adopted.

In addition to the above findings, the Patent Regulation is also problematic since the Patent Office had adopted and implemented the mailbox system since 2007. In light of the recent development with regard to this issue, Cambodia as a LDC is not required to establish

such a mailbox system.²⁸ Therefore, the Cambodian Government needs to address two issues urgently. The first issue concerns the current version of the Patent Regulation, which should be amended to abolish the current mailbox system. The second issue concerns the applications which have been filed with the Patent Office since 2007 and particularly whether those applications should be opened from 1 January 2016 or they should not be opened until the lapse of the new transitional period (2033).

²⁸ See WTO Decision on Obligations under Article 70.8 and Article 70.9 of the TRIPS Agreement with respect to Pharmaceutical Products, dated 30 November 2015, WT/L/971.

B. CHALLENGES OF DRAFTING THE LAW ON COMPULSORY LICENSING FOR PUBLIC HEALTH

In the process of drafting the CL Law, Cambodia has faced many challenges and four of them can be summarized as follows²⁹:

- **Overlapping Jurisdiction:** there has been a lengthy debate over whether or not MIH should be in charge of implementing the Patent Law or MOH in charge of public health should be the institution in charge of issuing compulsory licences for public health.
- **Reasonable Royalty:** the stakeholders had little understanding about the standard reasonable royalty, which continues to be debated, or of other countries' experience.
- **Penalty:** a question has also been raised as to how to stipulate those provisions in the draft CL Law, without limiting the public health protection offered by the compulsory licence.
- **Implementing Regulations:** the draft CL Law sets forth only basic principles and procedures, but does not contain detailed provisions, which need to be provided for in subsequent implementing regulation.

The reasons for these challenges are threefold. First of all, there is a very limited human resource that can understand the intersection of IP and public health. Second, although there are some model provisions and guides available for drafting the compulsory licensing system³⁰, they are purported to be incorporated into the patent law, but not in a standalone law such as in Cambodia. Third, limited human resource and capacity have prevented Cambodia from using and taking advantage of those model provisions and guides, which are available mostly in English. The actual use and implementation of the August 30 Decision will take place within the context of each country's existing legislative and regulatory framework, practice and

²⁹ See Lim Ratanak, Cambodia's Draft Law on Compulsory Licensing and Public Health, Presented at the Workshop on Trade and Access to Medicines in Cambodia, 11-12 November 2013, Siem Reap, Cambodia.

³⁰ Those model provisions and guides include Frederick M Abbot and Rudolf V Van Puymbroeck, *Compulsory Licensing for Public Health: A Guide and Model Documents for Implementation of the Doha Declaration Paragraph 6 Decision*, World Bank Working Paper No. 61 (World Bank 2005), and Correa M Carlos, *Compulsory Licensing: How to Gain Access to Patented Technology*, in *Intellectual Property Management in Health and Agricultural Innovation: A Handbook of Best Practices* (eds A Krattiger, RT Mahoney, L Nelsen, et al), available online at <<http://www.ipHandbook.org>>

jurisprudence. Therefore, the Government of Cambodia should work closely with its own experts to draft and adopt the CL Law appropriate for Cambodia's unique situation.

V. CONCLUSION

Cambodia is a LDC Member of the WTO since October 2004. It has adopted all key laws and regulations related to IP rights, and at the same time it has made efforts to introduce new laws and policies to address public health issues. The opportunities and challenges facing Cambodia are interesting and are helpful lessons which should be shared with other policy makers and researchers from other countries or regions, in particular its experience and lessons on how the existing laws and policies should be reviewed and revised within the national and international context to balance public health interests and the interests protected by IP laws and policies.

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