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What Can Cambodia Learn from Thailand and India as It Prepares to Graduate from Least Developed Country Status?

Brigitte Tenni, Deborah Gleeson, Joel Lexchin,
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WHAT CAN CAMBODIA LEARN FROM THAILAND AND INDIA AS IT PREPARES TO GRADUATE FROM LEAST DEVELOPED COUNTRY STATUS?

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SOUTH CENTRE

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ABSTRACT

Cambodia is expected to graduate from Least Developed Country status soon, at which time it will be required to make patents available for pharmaceutical products and processes to meet its obligations under the Agreement on Trade Related Aspects of Intellectual Property Rights (TRIPS). Given its impending transition from LDC status, there is a need to balance Cambodia's intellectual property (IP) policies and regulations with public health priorities to ensure access to affordable life-saving medicines. This will be critical to achieving universal health coverage, one of the United Nations' Sustainable Development Goals. This paper examines Cambodia's IP laws and regulations to identify provisions that could reduce access to affordable generic medicines when it starts granting patents for pharmaceuticals. It systematically compares Cambodia's IP laws and regulations with those of Thailand and India – two developing countries that have had some successes in preserving access to medicines despite the introduction of pharmaceutical patents. It identifies lessons for Cambodia from the experiences of Thailand and India in implementing TRIPS and using TRIPS flexibilities such as compulsory licensing to ensure access to a sustainable supply of affordable generic medicines. Key recommendations for reform for Cambodia include strengthening the use of preventive and remedial TRIPS flexibilities and removing criminal sanctions for patent infringements. Cambodia should reject any TRIPS-plus provisions in its patent legislation and avoid membership in bilateral or plurilateral trade agreements that include TRIPS-plus provisions as well as signing patent treaties and memorandums of understanding that may facilitate the granting of unwarranted patents.

Se espera que Camboya deje pronto de ser un país menos adelantado, momento en el que deberá conceder patentes para productos y procesos farmacéuticos a fin de cumplir sus obligaciones en virtud del Acuerdo sobre los Aspectos de los Derechos de Propiedad Intelectual relacionados con el Comercio (ADPIC). Dada su inminente transición del estatus de PMA, es necesario equilibrar las políticas y normativas de propiedad intelectual (PI) de Camboya con las prioridades de salud pública para garantizar el acceso a medicamentos asequibles que salvan vidas. Esto será fundamental para lograr la cobertura sanitaria universal, uno de los Objetivos de Desarrollo Sostenible de las Naciones Unidas. Este documento examina las leyes y reglamentos de Camboya en materia de PI para identificar las disposiciones que podrían reducir el acceso a medicamentos genéricos asequibles cuando empiece a conceder patentes para productos farmacéuticos. Compara sistemáticamente las leyes y normativas de Camboya en materia de PI con las de Tailandia y la India, dos países en desarrollo que han logrado hasta cierto punto preservar el acceso a los medicamentos a pesar de la introducción de patentes farmacéuticas. Identifica las lecciones que Camboya puede extraer de las experiencias de Tailandia e India en la aplicación del ADPIC y en el uso de las flexibilidades del ADPIC tales como las licencias obligatorias, para garantizar el acceso a un suministro sostenible de medicamentos genéricos asequibles. Las principales recomendaciones de reforma para Camboya incluyen reforzar el uso de las flexibilidades preventivas y correctivas del ADPIC y eliminar las sanciones penales por infracción de patentes. Camboya debe rechazar cualquier disposición ADPIC plus en su legislación sobre patentes y evitar la adhesión a acuerdos comerciales bilaterales o plurilaterales que incluyan disposiciones ADPIC plus, así como evitar firmar tratados sobre patentes y memorandos de entendimiento que puedan facilitar la concesión injustificada de patentes.

Le Cambodge devrait bientôt quitter le statut de pays moins avancé, et sera alors tenu de délivrer des brevets pour les produits et procédés pharmaceutiques afin de respecter les

obligations qui lui incombent en vertu de l'accord sur les aspects des droits de propriété intellectuelle qui touchent au commerce (ADPIC). Compte tenu de sa transition imminente du statut de PMA, le Cambodge doit équilibrer ses politiques et réglementations en matière de propriété intellectuelle avec les priorités de santé publique afin de garantir l'accès à des médicaments vitaux à un prix abordable. Cela sera essentiel pour atteindre la couverture sanitaire universelle, l'un des objectifs de développement durable des Nations unies. Le présent document examine les lois et réglementations cambodgiennes en matière de propriété intellectuelle afin d'identifier les dispositions qui pourraient entraver l'accès à des médicaments génériques abordables lorsque le Cambodge commencera à délivrer des brevets pour des produits pharmaceutiques. Il compare systématiquement les lois et réglementations cambodgiennes en matière de propriété intellectuelle avec celles de la Thaïlande et de l'Inde, deux pays en développement qui ont réussi à préserver l'accès aux médicaments malgré l'introduction de brevets pharmaceutiques. Il identifie les leçons que le Cambodge peut tirer de l'expérience de la Thaïlande et de l'Inde dans la mise en œuvre de l'accord sur les ADPIC et dans l'utilisation des flexibilités de l'accord sur les ADPIC, telles que les licences obligatoires, afin de garantir l'accès à un approvisionnement durable en médicaments génériques abordables. Les principales recommandations de réforme pour le Cambodge comprennent le renforcement de l'utilisation des flexibilités préventives et correctives de l'ADPIC et la suppression des sanctions pénales pour les violations de brevets. Le Cambodge devrait rejeter toute disposition ADPIC-plus dans sa législation sur les brevets et éviter d'adhérer à des accords commerciaux bilatéraux ou plurilatéraux comprenant des dispositions ADPIC-plus, ainsi qu'éviter de signer des traités sur les brevets et des mémorandums d'accord susceptibles de faciliter l'octroi de brevets injustifiés.

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1. INTRODUCTION

Cambodia is a South-East Asian nation with a population of over 17 million people (The World Bank 2021b). Rapid economic growth in recent years has moved Cambodia into lower middle-income country status¹ as defined by the World Bank (The World Bank 2021a).

Cambodia has also seen a marked reduction in the percentage of people living in poverty;² from 50 per cent in 1992 to the current 13 per cent (Asian Development Bank 2021). The majority of the country's poor live in rural areas. The United Nations classify Cambodia as a least developed country (LDC). Cambodia met all three criteria for LDC graduation at the most recent review in 2021 (United Nations 2021) and is expected to graduate from LDC status in the coming years.

Despite this economic growth, almost half of Cambodia's population is extremely vulnerable to negative economic shocks that could force them back into poverty (Ir et al. 2019). Cambodia has a very high rate of out-of-pocket (OOP) healthcare expenditure and OOP is by far the largest source of funding for the health system, constituting around 60 per cent of total health expenditure (World Health Organization 2019). A recent study found that 28 per cent of households borrowed to pay for healthcare, with 55 per cent of these loans subjected to interest (Ir et al. 2019). Cambodia also has very high rates of OOP for pharmaceuticals. Direct OOP accounted for 77 per cent of total spending on pharmaceuticals (Bureau of Health Economics and Financing of the Department of Planning and Health Information. Ministry of Health 2016). This indicates that the Cambodian people bear the brunt of high medicine prices and spending on pharmaceuticals can constitute a major financial barrier to access and cause catastrophic expenditure. OOP payments for medicines disproportionately impact the poorest. A study comparing the universal health coverage among 52 countries found Cambodia to have one of the highest disparities between the national average universal health service coverage, and estimated service coverage for the poorest wealth quintile; 55 per cent versus 28 per cent (Hogan et al. 2018).

Cambodia became the 148th member of the World Trade Organization (WTO) on 13 October 2004. Together with Nepal, it was the first least developed country (LDC) to accede to the WTO.³ As a WTO Member State, Cambodia must abide by WTO's Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS as well as by the commitments made in the process of accession to the WTO.⁴ This multilateral agreement on intellectual property (IP) binds WTO Members to minimum standards of IP protection (World Trade Organization 2021a, Apr. 15, 1994). The TRIPS Agreement obliges Member States to make patents available for pharmaceutical products or processes that meet the standard criteria for patentability: novelty, an inventive step, and industrial applicability. If granted, patent terms must provide at least 20 years protection from the date of filing the patent application (World Trade Organization Apr. 15, 1994). As a LDC, Cambodia is not required to grant patents for pharmaceuticals until 2033 or until it graduates from LDC status (WTO OMC September 2003). TRIPS Article 66.1 includes a LDC pharmaceutical specific transition period extension in recognition of LDC's specific economic, financial, and administrative challenges. This LDC

¹ This is a World Bank classification that assigns the world's economies to four income groups—low, lower-middle, upper-middle, and high-income countries. The classifications are updated each year on July 1 and are based on GNI per capita in current USD of the previous year.

² The international poverty line is currently defined at \$US2.15 or below.

³ The WTO uses The United Nations country economic classification system and classifies Cambodia as a least developed country (LDC). This is different to the World Bank classifications which lists Cambodia as a LMIC.

⁴ See, Frederik Abbott and Carlos Correa, World Trade Organization Accession Agreements: Intellectual Property Issues, QUNO, May 2007, available from <https://quno.org/sites/default/files/resources/QUNO%2BWTO%2Baccession%2BIP.pdf>.

transition period for pharmaceuticals has been extended twice (World Trade Organization 2021c).

The Declaration on the TRIPS Agreement and Public Health (the Doha Declaration) was adopted on 14 November 2001 with the aim of promoting an interpretation of the TRIPS Agreement in a manner that is supportive of a WTO Member's right to protect public health and promote access to medicines for all. The Doha Declaration reaffirmed WTO members' right to make use of public health related flexibilities of the TRIPS Agreement (World Trade Organization Adopted on 14 November 2001).

Cambodia's Patent law of 2003, "The Law on Patents, Utility Model Certificates and Industrial Designs" (Kingdom of Cambodia 22 January 2003) is supplemented by the Prakas on the Procedures for Granting Patents and Utility Model Certificates (2006) (Kingdom of Cambodia 2007), the Prakas on Procedures for Registration of Industrial Designs (2006) (Kingdom of Cambodia 2006) and the Prakas on Management and Procedures for Granting Patents and Utility Model Certificates (2019) (Kingdom of Cambodia 2019).⁵ Cambodia only recently introduced a "Law on compulsory licensing for public health" (Kingdom of Cambodia 2018), however it has not fully incorporated other public health-related TRIPS flexibilities into legislation and its patent-related legislation contains some TRIPS-plus provisions, i.e., provisions that go beyond what is required by TRIPS. This is problematic given Cambodia may soon be required to enforce patent law and grant patents for pharmaceuticals.

Along with these TRIPS-plus provisions, Cambodia has acceded to multiple patent treaties designed to expedite the granting of patents (Phin Savath, 2017). Cambodia also operates a mailbox system for accepting pharmaceutical patent applications. Thus, Cambodian legislation authorises the filing of patent applications for pharmaceutical products despite the fact TRIPS does not obligate LDCs to provide patent protection or a mailbox system for accepting them (European Patent Office 2018) and it is not obliged to accept such patent applications until 2033 or until it graduates from LDC status (The World Trade Organization 2021).⁶ The mailbox system is a way to file and store patent applications for examination at a later date. These applications will not be examined as to their admissibility until the end of the LDC transitional period. In accordance with Rule 48 of the 2019 Prakas, the mailbox will start opening applications after the expiry of the LDC transitional period (Kingdom of Cambodia 2019).

Thailand and India are often lauded for their interpretation and implementation of TRIPS in a manner that supports their right to protect public health and to promote access to medicines for all, in keeping with the central tenet of the Doha Declaration. They, therefore, provide practical and valuable lessons for Cambodia in applying TRIPS for greatest public benefit.

India has been a Member State of the WTO since its inception in 1995 (World Trade Organization 2021b). The Indian patent system inherited from the British was amended in 1970 to limit the grant of patents to "process" patents only for pharmaceuticals, i.e., patents that protected the process by which medicines were made. (Product patents, which are much more robust, protect the actual medication.) To be TRIPS compliant India amended the Indian Patents Act 1970 (IPA) in 1999, 2002 and in 2005 (Government of India 1970). Article 65.4 of the TRIPS agreement granted a ten-year transition period in which to introduce necessary amendments to "developing countries" such as India, that didn't provide product patent protection for pharmaceuticals (World Trade Organization Apr. 15, 1994).

⁵ A "Prakas" is an official ministerial proclamation, similar to a bylaw or regulation that supplements provisions under a statutory law.

⁶ It is worth noting that Cambodia was bound to accept data exclusivity, a clear TRIPS-plus protection, in the process of accession to the WTO [Note of the Editor].

During this transition period, Article 70.8 required India to set up a “mailbox” system for accepting pharmaceutical product patent applications and to assign them a filing date. Companies could file patent applications during the transition period that would be processed when the mailbox was “opened” in 2005 and be granted a patent if criteria were met. In line with the Doha Declaration, India has attempted to balance the requirements of TRIPS whilst preserving and prioritising access to affordable medicines. It has enacted amendments that leverage the flexibility provided by the TRIPS Agreement. This includes provisions in the IPA for pre and post grant opposition, compulsory licences, and standards of patentability, that guard against “evergreening” which extends patent terms by making minor modifications to an existing product (Unni 2012). Examples of these provisions are explored in the literature review section below.

Thailand has been a WTO Member State since 1995 (World Trade Organization 2021d). Thailand passed the Patent Act B.E. 2522 in 1979 (THAILAND Patent Act B.E. 2522 (1979) As Amended by the Patent Act (No. 2) B.E 2535 (1992) and the Patent Act (No. 3) B.E. 2542 (1999)). This Act was drafted following the Paris Convention for the Protection of Industrial Property, allowing foreigners to have national treatment and has been amended twice. First in 1992, under pressure from the USA to increase patent protection for US pharmaceutical companies (Puasiri 2013). This amendment included patents for pharmaceutical products, increased the patent protection period from 15 to 20 years and added an opposition procedure. The second amendment occurred in 1999 to comply with the TRIPS Agreement. It narrowed down the grounds for compulsory licences and abolished The Drug Board, a government agency set up in 1992 to control drug prices and prevent pharmaceutical industry monopolies. A third amendment has been proposed and debated for several years but is yet to be passed by the parliament (Vachanavuttivong and Siriwat 17 December 2020). The proposed changes include the addition of surgical methods to the list of non-patentable subject matter and allow for compulsory licenses to export medicines to countries with insufficient or no pharmaceutical manufacturing capacity (Vachanavuttivong and Siriwat 17 December 2020).

Thailand has a rich history of access to medicines activism. People living with HIV (PLHIV) groups and other stakeholders have advocated strongly over many years to be able to access affordable medicines. Many access to medicines campaigns have targeted IP barriers to affordable medicines and advocated for the implementation of TRIPS flexibilities such as compulsory licencing and pre- and post-grant patent opposition (APN+ 2009). Some examples of these are explored in the literature review.

Our study aims to:

- examine Cambodia’s patent law and regulations to identify provisions that could reduce access to affordable generic medicines in Cambodia when it starts to grant patents for pharmaceuticals,
- systematically compare Cambodia’s patent law and regulations with those of Thailand and India to identify changes that could be made to improve access to medicines in Cambodia after full implementation of TRIPS, and
- identify lessons for Cambodia from the experiences of Thailand and India in implementing TRIPS and using TRIPS flexibilities such as compulsory licensing to ensure access to a sustainable supply of affordable generic medicines and in how to avoid signing onto TRIPS-plus provisions in bilateral and plurilateral trade agreements.

2. METHODS

The database of the World Intellectual Property Organization (WIPO Lex) was searched for the national IP laws and regulations of Cambodia, Thailand and India. WIPO Lex lists all laws and regulations related to IP in a given country (World Intellectual Property Organization 2021b). The texts of the identified laws and regulations were scanned and included if they related to the governance or regulation of patents for pharmaceuticals. The included laws and regulations were then examined to identify key TRIPS-plus provisions and to determine whether TRIPS flexibilities are utilised.

A table was designed to systematically compare Cambodia's IP laws and regulations (in particular TRIPS-plus provisions and flexibilities) with those of Thailand and India to highlight major differences and potential policy-related barriers to access to medicines when Cambodia introduces patents for pharmaceutical products and processes. The framework used to build the table was adapted from The United Nations Development Programme publication, "Good Practice Guide: Improving Access to Treatment by Utilizing Public Health Flexibilities in the WTO TRIPS Agreement" (United Nations Development Programme 2010) and the WTO publication, "A Conceptual Framework for Designing and Implementing Laws and Policies to Promote Access to Medicines in Cambodia"(Phin 2015). This framework separates key TRIPS articles into preventive, remedial and enforcement categories.

A targeted literature review was undertaken to explore the ways in which Thailand and India have implemented TRIPS and used TRIPS flexibilities such as compulsory licensing to ensure access to a sustainable supply of affordable generic medicines.

3. RESULTS

Comparison of Patent Laws and Regulations

The main legislation governing the patenting of pharmaceuticals in Cambodia, India and Thailand are The Law on Patents, Utility Model Certificates and Industrial Designs of 2003, The Indian Patents Act 1970, and the Patent Act B.E. 2522 of 1979, respectively. Table 1 below separates key TRIPS flexibilities into three categories (preventive,⁷ remedial,⁸ and enforcement⁹) and presents an analysis of whether each country has incorporated specific TRIPS flexibilities in its national law.

Table 1: Comparison of the Laws and Policies That Govern Patents			
TRIPS FLEXIBILITIES	Cambodia	India	Thailand
Preventive			
Exclusion from Patentability: Exclude new use of known substances, methods and processes (TRIPS Articles 27.2 and 27.3)	Not fully incorporated. Citation: The Law on Patents, Utility Model Certificates and Industrial Design 2003. Article 4: The following inventions, shall be excluded. Note: does not exclude new use of known substances, methods and processes but does exclude methods for treatment of the human or animal body by surgery or therapy, as well as diagnostic methods practiced on the human or animal body.	Incorporated. Citation: IPA 1970. Chapter II Inventions not Patentable, Section 3 What are not inventions.	Not fully incorporated. Citation: Patent Act B.E. 2522. Section 9.4. Note: Does not specifically exclude new uses of known substances methods and processes but does exclude methods of diagnosis, treatment or cure of human and animal diseases.
Patentability Criteria: Develop and apply strict patentability criteria for examination of pharmaceutical patents. Mitigate frivolous patents and “evergreening” opportunities. (TRIPS Articles 1 and 27.1)	Not fully incorporated. Citation: The Law on Patents, Utility Model Certificates and Industrial Designs 2003. Article 3: definition of invention, Article 5: new, involve an inventive step and industrially applicable, Article 4 and 9. Note: Doesn’t specifically exclude frivolous patents and evergreening.	Incorporated. Citation: IPA 1970. Chapter II Inventions not Patentable Section 3 (d). What are not inventions	Not fully incorporated. Citation: Patent Act B.E. 2522. Chapter II Patents for Inventions. Part I Application for Patents Sections 5-9. Note: Doesn’t specifically exclude frivolous patents and evergreening.

⁷ Policy options to ensure that patents do not hinder access to affordable medicines.

⁸ Preventative flexibilities cannot always be used to meet existing and emerging needs to secure access to affordable medicines. Therefore, a series of remedial flexibilities are included in the TRIPS Agreement.

⁹ Related to obligations under Part III of the TRIPS Agreement, which sets minimum standards for IP Rights enforcement.

Patent Opposition: Allow pre-grant and post-grant patent opposition in fast, accessible, and cost-efficient manner.	Not fully incorporated. Citation: Pre-grant opposition: 2019 Prakas Article 27 (8). Post-grant invalidation: The Law on Patents, Utility Model Certificates, and Industrial Designs 2003. Chapter 2, Section 13. Note: post-grant invalidation only through judicial court procedure.	Incorporated. Citation: IPA 1970. Chapter V Opposition. Proceedings to Grant of Patents Section 25. Opposition to the patent.	Not fully incorporated. Citation: Patent Act B.E.2522. Sections 31 pre-grant opposition. Section 54 post grant opposition. Note: post-grant opposition only through judicial court procedure.
Waiver for LDCs: LDCs should utilize the waiver to provide patent protection for pharmaceuticals until 2033	Incorporated. Citation: Law on Patent, Utility Model Certificates, and Industrial Design 2003. Amendment (2017) Article 136\.	Not applicable – India is not an LDC.	Not applicable – Thailand is not an LDC.
Remedial			
Compulsory Licenses and Government Use Orders (TRIPS Article 31 (a)—(j)) Compulsory Licenses for Export under the WTO 30 August 2003 Decision and Doha Declaration	Incorporated. Citation: Law On Compulsory Licensing for Public Health 2018. Note: includes compulsory licences for export.	Incorporated. Citation: IPA 1970. Sections 84-103.	Not fully incorporated. Citation: Patent Act B.E. 2522. Sections 45-55. Note: Does not include compulsory licences for export.
Exceptions: Bolar (early working) exception, research and experimental use exception, individual use (TRIPS Article 30)	Not fully incorporated. Citation: The Law on Patents, Utility Model Certificates, and Industrial Designs 2003. Article 42 (iii) (research and experience purpose) and Section 11 and Section 12 government use and non-commercial use. Note: No IP laws or regulations allow bolar/early working exemption.	Incorporated. Citation: IPA 1970. Section 107A.	Incorporated. Citation: Patent Act B.E. 2522. Section 36.
Use of National Competition Laws to prevent IPR abuse and provide remedies (TRIPS Articles 8.2, 31(k) and 40)	Incorporated. Citation: Law Concerning Marks, Trade Names and Acts of Unfair Competition 2002. Article 1 and 22.	Incorporated. Citation: IPA 1970. Section 83 (f) and (g).	Incorporated. Citation: Trade Competition Act B.E. 2560 (2017).
Parallel Importation (TRIPS Article 6) and Doha Declaration	Not fully incorporated. Citation: The Law on Patents, Utility Model Certificates and Industrial Designs 2003. Article 44 (i) International	Incorporated. Citation: IPA 1970. amendment of 2005 Section 107A(b).	Incorporated. Citation: Patent Act B.E. 2522. section 36(7).

	Exhaustion. Law Concerning Marks, Trade Names and Acts of Unfair Competition article 11c includes national exhaustion doctrine. Note: conflicting laws complicate legality of parallel importation.		
Enforcement			
No border measures for suspected patent infringement (TRIPS Article 51) ¹⁰	Incorporated. Note: No border measures listed in any IP laws or regulations in relation to pharmaceutical patents.	Incorporated. Note: No border measures listed in any IP laws or regulations in relation to pharmaceutical patents.	Incorporated. Note: No border measures listed in any IP laws or regulations in relation to pharmaceutical patents.
No criminalization of patent infringement (Part III, Section 5)	Not incorporated. Citation: The Law on Patents, Utility Model Certificates and Industrial Designs 2003. Chapter VII: Offenses Article 132-135.	Incorporated. Note: No criminalisation of patent infringement listed in any IP laws or regulations.	Not incorporated. Citation: Patent Act B.E. 2522. Chapter VI Offences and Penalties Section 82-88.

Importantly, Cambodia has incorporated the TRIPS transition period for LDCs relating to pharmaceutical products in article 136¹¹ of The Law on Patents, Utility Model Certificates and Industrial Designs which excludes pharmaceuticals from patent protection until 2033 or until it ceases to be an LDC. This law also incorporates some of the TRIPS flexibilities outlined in Table 1 including allowing for parallel importation and omitting border measures for patent infringement. Although it does contain some exclusions to patentability such as “methods for treatment of the human or animal body by surgery or therapy, as well as diagnostic methods practiced on the human or animal body” it doesn’t specifically exclude patents for new use of known substances, methods and processes nor does it specifically exclude opportunities for frivolous patents and evergreening. Cambodian Patent Law criminalises the infringement of patents and the only opportunity for pre-grant opposition is in the 2019 Prakas. The Cambodian Patent Law does not provide an opportunity for post-grant opposition and any request for revocation or validation must be filed to the competent court. It includes exemptions to patent rights for research purposes but does not allow exemptions for Bolar/early working that enables generic companies to request and obtain marketing approval before the time of patent expiry. The Competition law provides recourse for IPR abuse, and the 2018 Law on Compulsory Licensing for Public Health allows for compulsory licenses for production, exportation, and importation.

As evidenced in Table 1, India has incorporated all key TRIPS flexibilities outlined in the table in the IPA 1970 and its amendments of 1999, 2002 and 2005. Thailand’s Patent Act B.E. 2522 and the amendments of 1992 and 1999 utilises many of the TRIPS flexibilities outlined in Table 1 however some provisions lack clarity and could be strengthened, especially patentability requirements and exclusions from patentability, to ensure only high-quality patents are

¹⁰ This is a search of IP laws and regulations only. It is possible that border measures could be found in customs statutes.

¹¹ Article 136.-The pharmaceutical products mentioned in the Article 4 of this Law shall be excluded from patent protection until January 01, 2033, according to the Declaration on Agreement on Trade-Related Aspects of Intellectual Property Rights and Public Health of the Ministerial Conference of World Trade Organization dated 14 November 2001 in Doha of Qatar.

granted. Thailand is yet to incorporate provisions enabling compulsory licencing for export and only incorporates provisions for post grant opposition via a judicial process. Additionally, the Thai Patent Act B.E. 2522 Chapter VI Offences and Penalties Section 82-88 allows for the criminalisation of patent infringement.¹²

¹² Section 85. Any person who commits any act under section 36 or section 63 without the authorisation of the owner of the patent shall be liable to imprisonment for a term not exceeding two years or to a fine not exceeding four hundred thousand baht, or to both. Section 86. Any person who commits any act under section 65decies in conjunction with section 36 without the authorisation of the owner of the patent shall be liable to imprisonment for a term not exceeding one year or to a fine not exceeding two hundred thousand baht, or to both Section 36. Only the owner of the patent shall have the following rights: (1) in the case where the patent has been granted in respect of a product, the right to produce, use, sell, have in the possession for sale, offer for sale or import the patented product into the Kingdom; (2) in the case where the patent has been granted in respect of a process, the right to use the patented process, produce, use, sell, have in the possession for sale, offer for sale or import the product produced by means of the patented process into the Kingdom;

4. IMPLEMENTATION OF TRIPS FLEXIBILITIES BY INDIA AND THAILAND

In this section of the paper, we examine the experiences of India and Thailand in implementing preventive, remedial and enforcement related TRIPS flexibilities.

Standards of Patentability

India was granted a 10-year transition period, expiring on 1 January 2005, to update its Patent Act to be compliant with the TRIPS agreement. This included providing patent protection for pharmaceutical products for the first time. To minimise the impact of providing product patents and to balance the national interest with its international obligations, India drafted its Patent Act to ensure only justifiable and high-quality patents were granted (Kumar, Shukla, and Sangal June 15, 2009). This was a unique and bold approach that provides a valuable lesson to other countries introducing IP laws.

The cornerstone of the patent law was section 3(d) which narrowed the scope of patentability to prevent evergreening (Government of India 1970). Section 3(d) states:

3(d) the mere discovery of a new form of a known substance which does not result in the enhancement of the known efficacy of that substance or the mere discovery of any new property or new use for a known substance or of the mere use of a known process, machine or apparatus unless such known process results in a new product or employs at least one new reactant.

Explanation.—For the purposes of this clause, salts, esters, ethers, polymorphs, metabolites, pure form, particle size, isomers, mixtures of isomers, complexes, combinations and other derivatives of known substance shall be considered to be the same substance, unless they differ significantly in properties with regard to efficacy (Government of India 1970)

Utilising section 3(d), the Indian Patent Office has denied patents for drugs previously granted patents in other countries on the basis that they are modifications or extensions of known substances. This includes Pfizer's Caduet (cholesterol and hypertension), GlaxoSmithKline's Avandia (diabetes), Gilead Science's Tamiflu (bird flu) and Hepsera (Hepatitis B) (Kumar, Shukla, and Sangal June 15, 2009). The most well-known demonstration of India's opposition to evergreening is the Novartis – Glivec case.

Pre-Grant Opposition

A patent opposition procedure was introduced in Thailand in 1979 and allows any interested person to oppose the registration of a patent within 90 days after the publication date of a patent application (Thai Patent Act B.E. 2522 As Amended by the Patent Act (No.2) B.E 2535 And the Patent Act (No.3) B.E. 2542). This is usually on the basis that the application is not new or inventive and therefore does not meet Thailand's patentability criteria. Pre-grant opposition has been used to great effect in Thailand and has helped prevent low-quality patents being granted (Puasiri 2013). The Government Pharmaceutical Organization (GPO), a state-owned enterprise, has been successful in opposing many poor-quality grants mostly on the grounds that they did not include an inventive step. This includes patent applications by Novartis for insulin sensitivity enhancers for the prophylaxis and treatment of diabetes and by InterMune Inc. for a chronic hepatitis C treatment method for patients who had previously failed antiviral therapy (Puasiri 2013). India too, has made good use of pre-grant opposition provisions. Under IPA, a pre-grant opposition may be filed by "any person". PLHIV networks

have been successful in filing pre-grant opposition to numerous ARV medications which has led to patent applications being rejected and withdrawn (APN+ 2009). This demonstrates that pre-grant opposition can be effective in preventing poor quality patents even when an application is upheld. The pre-grant opposition, and the publicity and advocacy that it attracts can lead to pharmaceutical companies abandoning or withdrawing patent applications.

Post-Grant Opposition

India's IPA allows for post-grant opposition and revocation of an existing patent in Section 25 (2) and Section 64 respectively (Government of India 1970). Post-grant opposition can be filed at any time after the grant of patent and up to one year from the date of grant publication, whereas patent revocation under Section 64 can be filed at any time after the grant of the patent (Rathod 2022). In 2012, The Sankalp Trust, a Mumbai based NGO, successfully challenged the patent granted to Roche for Pegasys, a medicine used to treat hepatitis C, on the grounds that it was "obvious" (Rathod 2022). In doing so, they also challenged what constitutes an "interested party" in order to be able to bring the case to court. The patent granted to Roche in 2006 was the first pharmaceutical product patent granted in India under the new TRIPS-mandated product patent regime for medicines and the first post-grant opposition case (Kay 2012). As a result of the intervention, a biosimilar was able to be produced locally for 20 per cent of the cost of Roche's product. Unlike first- and second-line antiretroviral treatment for HIV, which is available to all people infected with HIV who need it, this hepatitis C treatment was previously unavailable to government hospitals due to cost. This patent revocation enabled many more of the estimated 10 million people living with hepatitis C in India to access treatment (Kay 2012).

Section 54 of the Thai Patent Act allows for challenges to the validity of a granted patent (Thai Patent Act B.E. 2522 As Amended by the Patent Act (No.2) B.E 2535 And the Patent Act (No.3) B.E. 2542). However, this is only via a judicial process and can't be revoked by the Department of Intellectual Property (DIP). One of the most recognised cases of patent opposition in Thailand was the 1999 case against the DIP in relation to the Bristol-Myers Squibb (BMS) patent for the antiretroviral drug, didanosine (ddl). Two PLHIV were plaintiffs in the case, marking the first time that an individual or consumer was deemed an "interested party" in a case. In allowing the plaintiffs to challenge the patent, the judge quoted the Doha Declaration and deemed "those in need of medicines are interested parties to the granting of a patent" (Patent Opposition Database). The patent was challenged on several grounds including that it did not contain an inventive step (Wisartsakul July 2004). In 2003, after several adverse rulings, BMS voluntarily terminated its claim on the ddl patent ensuring GPO could manufacture an affordable generic version (Patent Opposition Database).

Compulsory Licencing

The Thai Patent Act and the IPA both have a provision for compulsory licencing and both countries have issued compulsory licences in order to access more affordable generic medications. The IPA includes provision for compulsory licencing for export (Government of India 1970).

Thailand has issued seven compulsory licences in total under Section 51 of the Patent Act 1979, which authorises the government use of patents "to prevent or relieve a severe shortage of food, pharmaceuticals or other consumption goods, or for other public interests, any ministry, bureau, department of the government may, by themselves or through others, exploit any of the rights conferred by a patent" (Thai Patent Act B.E. 2522 (A.D. 1979) 1979). It was the first time a developing country had issued a compulsory licence for a drug other than an ARV. The seven compulsory licences were estimated to save the government budget

approximately \$370 million over 5 years and allowed access for an additional 84,158 patients (Mohara et al. 2012; Yamabhai et al. 2009, 2011).

Sections 84-92 of the IPA provides for the grant of compulsory licences without a prior attempt to obtain a voluntary licence from the patentee on reasonable terms and conditions in case of anti-competitive practices adopted by the patentee as well as the right to export any products produced under such licences (Government of India 1970).

India issued its first and only compulsory licence in March 2012 for Bayer's kidney and liver cancer drug, sorafenib tosylate (Nexavar). India's sole compulsory licence has possibly had a wider and more long-term impact than just on the drug it was issued for. An Indian modelling study found that compulsory licencing in India can increase consumer welfare and surmised that India had been offered preferential pricing by pharmaceutical companies since the introduction of the compulsory licence provision to prevent a compulsory licence being granted for their products (Chatterjee, Kubo, and Pingali 2015).

Exemptions: Bolar and Research and Experimental Use

India's Bolar exception legislation is very important to India as a global supplier of affordable generic and biosimilars as it has been purported to create the conditions that support the development and expansion of the generic and biosimilar industry (Munoz Tellez 2022). Section 107 B of the IPA outlines the Bolar exception which extends to acts such as the manufacture of a patented protected product, the export of an active pharmaceutical ingredient (API) or the conduct of clinical trials to support regulatory approvals in India and other countries (Government of India 1970). This legislation has proven useful for compulsory licencing purposes. Section 107B allowed Natco, a generic pharmaceutical company, to export 1 kg of API for Sorafenib Tosylate to China for the conduct of clinical studies and trials for regulatory purposes following Natco's successful request for a compulsory licence (Munoz Tellez 2022).

5. DISCUSSION

Cambodia

Cambodia is currently missing several key preventive, remedial and enforcement TRIPS flexibilities in its patent law and regulations. Their absence could lead to low quality patents being granted and few possibilities to challenge them. As Cambodia makes use of the LDC waiver it has not yet exercised any other TRIPS flexibilities, however the Law on Patents, Utility Model Certificates and Industrial Designs is likely to be tested in the coming years when Cambodia graduates from LDC status.

Preventive flexibilities

Article 4 of the Law on the Patents, Utility Model Certificates and Industrial Designs provides a list of exclusions from patent protection including but not limited to methods for treatment of the human or animal body by surgery or therapy, diagnostic methods practiced on the human or animal bodies; plants and animals other than micro-organisms, biological processes for the production of plants or animals and importantly, pharmaceutical patents (Kingdom of Cambodia 22 January 2003). The Law on Patents, Utility Model Certificates and Industrial Designs does not specifically exclude patents for new uses of known substances, methods and processes. It therefore leaves open the opportunity for secondary patenting and granting poor quality patents.

Critically, on the positive side, it has made full use of the LDC waiver to avoid granting patents for pharmaceutical products and processes. However, it operates a mailbox system which allows patent applications to be filed and opened when the transition period expires. This is not required by TRIPS (World Trade Organization Apr. 15, 1994) and will undoubtedly lead to patents being granted (from the filing date) that would otherwise not have been granted if the companies had to wait until the end of the TRIPS waiver period to submit an application.

The Cambodian Law on Patents has provision for pre-grant opposition but like Thailand, has no provision for an administrative post-grant opposition process. Any challenges to existing patents must be filed in court. This is a more onerous and lengthy process than filing a post grant opposition procedure at the patent office and is out of step with patent acts in developed countries such as Japan and US. This limitation could deter interested parties from challenging low-quality patents and lengthen the time taken to revoke a patent granted in error.

Remedial flexibilities

The adoption of the Law on Compulsory Licencing for Public Health (Kingdom of Cambodia 2018) has been a positive development and a critical addition to the IP regime. Importantly this law includes compulsory licenses for export which is affirmed under the WTO 30 August 2003 Decision and Doha Declaration. This law, however, currently lacks the regulations necessary for implementation. The drafting of such regulations will take time and provides an opportunity for government and relevant stakeholders to become more educated about the importance of these laws.

The Law on Patents allows for exemptions for research purposes but has no provision for bolar/early working exemption. This exemption allows for the development, testing, and experimental work necessary to obtain regulatory approvals to occur while the patent is still valid. This enables generics to be ready to enter the market upon patent expiry of the originator medicine. Without a bolar provision, generic firms are unable to prepare for regulatory

approval until after patent expiry. This can take two or more years and extend the effective monopoly period for originator medicines (Munoz Tellez 2022).

Cambodia has some conflicting laws and policies in relation to parallel importation. The Law on Patents Article 44 includes the international exhaustion of patent rights which allows for the importation of a patented product sold in a foreign country (Kingdom of Cambodia 22 January 2003). Trademark law however, adopts a national exhaustion doctrine that prohibits parallel imports of trade marked products (Kingdom of Cambodia 2002). This could potentially hinder Cambodia's ability to import cheaper patented products from foreign markets. This will become a more pertinent issue when Cambodia graduates from LDC status and is obligated to grant patents. To facilitate parallel importation, Cambodia will need to amend its Trademark Law from a principle of national exhaustion of trademark rights currently adopted by article 11.c, to a principle of international exhaustion of trademark rights.

Enforcement

Infringement of The Law on Patents attracts criminal penalties of up to five years imprisonment and can result in the seizure and destruction of the infringing goods (Kingdom of Cambodia 22 January 2003). The TRIPS Agreement limits criminalisation offenses to commercial level wilful trademark counterfeiting and copyright piracy (World Trade Organization Apr. 15, 1994). Criminalising patent infringement can deter generic companies from entering the market thereby restricting access to affordable generic medicines. Legitimate international trade in generic medicines can be compromised by overzealous seizures and the destruction of suspected infringing goods by customs officials (United Nations Development Programme 2010).

In addition to the above, Cambodia has signed on to a raft of MoUs and patent treaties designed to expedite and facilitate the granting of patents. These include the Joint Statement of Intent between the Ministry of Industry and Handicrafts (MIH) and the Japan Patent Office (JPO) (Japan Patent Office (JPO) and the Ministry of Industry and Handicrafts (MIH) Cambodia 2016), the Memorandum of Understanding (MOU) with the Intellectual Property Office of Singapore (IPOS) (Intellectual Property Office of Singapore (IPOS) and Cambodia's Ministry of Industry and Handicraft (MIH) 2015), the Patent Cooperation Treaty (PCT) (World Intellectual Property Organization 2021a), the Patent Validation Agreement between Cambodia and the European Patent Organization (EPO) (OEI), the MoU with China (OEI, OEI), the MoU with South Korea (OEI) and the Worksharing agreement with the United States Patent and Trademark Office (USPTO) (OEI). These agreements have no impact while the TRIPS LDC waiver is in play. However, once Cambodia starts to patent protection for pharmaceuticals, they will invariably accelerate and increase the number of patents being granted.

Cambodia has created a National Committee for Intellectual Property Rights (NCIPR) to coordinate all agencies involved in IP protection. The NCIPR has been promoting a holistic and comprehensive approach to IP governance in Cambodia. However, the patent office lacks the institutional, human, IT, and financial resources to fulfil its mandate (Royal Government of Cambodia 2014). Limited patent examination capacity can lead to over reliance on foreign patent offices to assess patent applications, potentially leading to poor quality patents being granted.

Cambodia has so far only signed bilateral trade agreements with China (Ayman Falak Medina September 2021) and South Korea (Chea Vanyuth October 2021) and seven agreements as part of ASEAN (WTO OMC 2021). None of these contain TRIPS-plus measures. Cambodia has also signed onto the Regional Comprehensive Economic Partnership (RCEP) which includes an IP chapter with TRIPS-plus provisions relating to the enforcement of IP rights (Regional Comprehensive Economic Partnership 15 November 2020). Cambodia will need to

be mindful of and resist signing onto future trade agreements or investment treaties that contain TRIPS-plus provisions.

Lessons from India

India faced significant domestic opposition to the implementation of TRIPS. Many stakeholder and interest groups expressed concern that patents would negatively impact India's well established and thriving generic pharmaceutical industry (APN+ 2009). As a "developing country" that did not have existing patent protection for pharmaceuticals, India was entitled to a ten-year transition period to update its patent law to become TRIPS compliant (World Trade Organization Apr. 15, 1994). It made full use of these ten years to amend its patent law three times in order to design a regime that maximised TRIPS flexibilities. A central tenet of this strategy was the inclusion of the unprecedented 3(d) clause to ensure that only high-quality pharmaceutical inventions were granted patents. Additionally, it retained robust compulsory licencing provisions to ensure that generic manufacturers could continue supplying medications at affordable prices and provisions for parallel imports and the Bolar exemption were expanded to prioritise public health objectives (Basheer 2018). This leadership on and adherence to the Doha Declaration's affirmation 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" (World Trade Organization Adopted on 14 November 2001) provides many lessons for other countries for whom LDC graduation is imminent, such as Cambodia.

Lessons from Thailand

Thailand also has a reputation for balancing IP rights and public health. It has implemented many of the TRIPS flexibilities outlined in Table 1, however some provisions lack clarity and could be strengthened, especially patentability standards and exclusions from patentability, to ensure only high quality patents are granted. Thailand's DIP published a new edition of the Guidelines for Examining Patent and Petty Patent Applications in 2019 (Department of Intellectual Property 2019) which generally does not allow for the granting of evergreening patents.

TRIPS-Plus FTAs

Thailand and India have both faced, and resisted pressure, to sign on to TRIPS-plus provisions embedded in bilateral and plurilateral trade agreements. These proposed trade agreements have been met with fierce opposition in both countries from various stakeholders including access to medicine activists and patient representative groups, in particular PLHIV networks and some HIV NGOs (APN+ 2009).

India – EU FTA

Negotiations for a European Union-India FTA began in 2007 but stalled in 2013 after 16 rounds of talks. Intellectual property was just one of several points of difference (Gopalakrishnan 2013). The EU proposed various TRIPS-plus measures including border measures, patent term extension, data exclusivity and an obligation to comply with certain provisions of several IP treaties (Correa 2009). There was considerable concern about the impact on the developmental needs of India and its ability to access affordable generics. MSF launched the "Europe, Hands Off Our Medicine" in response to the EU demands (MSF 2012). India has largely pushed back on these proposed TRIPS-plus provisions (IOBI), however talks have

recently resumed. The text proposed by the EU includes an IP chapter with the
aforementioned TRIPS-plus measures (OBJ).

6. CONCLUSION AND RECOMMENDATIONS

Cambodia will soon graduate from LDC status and must then grant patents for pharmaceutical products and processes. Accessing an affordable and sustainable supply of generic medications will require a reform of its IP regulatory system including its Patent Law to ensure it maximises the flexibilities afforded it in the TRIPS Agreement and omits TRIPS-plus measures. India's experience of implementing TRIPS offers a practical and valuable lesson in applying TRIPS for the greatest public benefit. Thailand, although it has not utilised TRIPS flexibilities as extensively as India, also offers valuable lessons in adapting and interpreting IP law to ensure sustainable access to generic medicines. Both countries have also shown leadership in implementing TRIPS flexibilities, despite considerable pressure not to and in some cases retaliatory or punitive responses from pharmaceutical companies and foreign governments.

Key recommendations for reform for Cambodia include strengthening the use of preventive TRIPS flexibilities. These include removing the mailbox facility from the LDC TRIPS waiver transition period and including the provision for pre-grant opposition in its Patent Law and not just the Prakas as well as the provision for post-grant opposition in addition to the existing invalidity procedure. Additionally, Cambodia should develop and apply strict patentability criteria for the examination of pharmaceutical patents to mitigate frivolous patents and "evergreening" opportunities and consider adapting a variation of India's 3(d) patent law to ensure only high-quality patents are granted. Cambodia should consider emulating India's threshold for an inventive step by raising the threshold to include the need for technical advancement as compared to the existing knowledge, or economic significance or both.

Cambodia could strengthen the use of remedial flexibilities by including an early working/Bolar provision as an exemption to patent rights and modify enforcement provisions by removing criminal sanctions for patent infringements. It should take steps to harmonise its laws in relation to parallel importation by amending its Trademark Law to adopt an international exhaustion doctrine. Cambodia should reject any TRIPS-plus provisions in its patent legislation and avoid signing bilateral or plurilateral trade agreements that include TRIPS-plus provisions such as data exclusivity, patent protection for biologics and patent term extensions. Additionally, it should avoid membership in patent treaties and MoUs designed to facilitate the granting of patents.

Cambodia should continue to strengthen the capacity of the intellectual property offices, in particular the patent office to adequately examine and assess patent applications in order to avoid over reliance on external patent offices, to facilitate the use of preventative TRIPS flexibilities and to reject low quality patent applications.

If Cambodia fails to pre-emptively take advantage of the TRIPS flexibilities and does not learn from the examples of India and Thailand, it may find itself paying high prices for medicines once it graduates from LDC status and is obliged to grant patents for pharmaceutical products and processes. The Indian Patent Act provides an exemplary model of how a country can become TRIPS compliant while minimising the impact on access to medicines. Despite some shortcomings in its Patent Act, Thailand has also shown great leadership in implementing key TRIPS flexibilities such as compulsory licencing and pre- and post-grant opposition, to facilitate greater access to affordable medicines for its citizens.

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