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Lessons from India and Thailand for Cambodia's future implementation of the TRIPS Agreement for pharmaceutical patents

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Abstract

Cambodia is expected to graduate from least developed country (LDC) status in the near future, 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 which could reduce access to affordable generic medicines when it starts to grant patents for pharmaceuticals. It systematically compares Cambodia's IP laws and regulations applicable to patents with those of Thailand and India—two developing countries which 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. 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, especially in relation to compulsory licencing. 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, avoid membership of bilateral or plurilateral trade agreements that include TRIPS-plus provisions and avoid signing patent treaties and agreements designed to facilitate the granting of patents.

KEYWORDS

access to medicines, Agreement on Trade Related Aspects of Intellectual Property Rights, intellectual property, least developed country, TRIPS flexibilities, TRIPS-plus

1 | INTRODUCTION

In recent years, Cambodia has experienced rapid economic growth and made huge progress in reducing the number of people living in poverty.[1] Although currently classified as a least developed country (LDC) by the United Nation (UN), Cambodia is poised to graduate from LDC status in the coming years.[2] This graduation presents both opportunities and challenges. One of the most pressing challenges is access to affordable generic medication. As a member of the World Trade Organization (WTO), the loss of LDC status obliges Cambodia to grant patents for medicines that meet standard criteria.[3] At the same time, Cambodia has committed to universal health coverage and explicitly recognises that access to affordable medicines is a precondition to achieving this goal.[4]

This paper examines Cambodia's IP laws and regulations to identify provisions which could reduce access to affordable generic medicines when it starts to grant patents for pharmaceuticals. It systematically compares Cambodia's IP laws and regulations applicable to patents with those of Thailand and India and makes recommendations to reform Cambodia's IP legislation to ensure it maximises the flexibilities afforded it in the Trade Related Aspects of Intellectual Property Rights (TRIPS) Agreement and omits TRIPS-plus measures.

Section 2 of this paper outlines Cambodia's economic situation, its obligations with regard to membership of the WTO and its current patent law as it applies to pharmaceuticals. Section 3 introduces Cambodia's membership of WTO, its TRIPS obligations, its laws and regulations that govern the granting of patents and its commitments to Universal Health Coverage. This is followed by an analysis of India's and Thailand's IP systems. Section 4 outlines Cambodia's commitments to Universal Health Coverage. The aims of the study are detailed in Section 5 and the methods are described in Section 6. Section 7 results are divided into TRIPS flexibilities in the laws and regulations of Cambodia, India and Thailand and a targeted literature search that provides examples of the implementation of

TRIPS flexibilities in Thailand and India. The discussion in Section 8 is divided into an analysis of the results in relation to the Indian and Thai context. This is followed by an exploration of TRIPS-plus FTAs and the barriers they pose for the implementation of TRIPS flexibilities including examples of the TRIPS-plus FTAs that India and Thailand have negotiated. Section 9 describes the study limitations. The conclusions and recommendations for IP legal reform in Cambodia are outlined in Section 10.

2 | CAMBODIA'S ECONOMIC SITUATION

Cambodia is a South-East Asian nation of over 17 million people.[5] Rapid economic growth in recent years has moved Cambodia into lower middle-income country status[6] as defined by the World Bank.[7] Cambodia has also seen a marked reduction in the percentage of people living in poverty;[8] from 50% in 1992 to the current 13%.[9] A large majority of the country's poor live in rural areas.

Despite this economic growth, almost half of Cambodia's population is extremely vulnerable to negative economic shocks that could force them back into poverty.[10] 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% of total health expenditure.[11] A recent study found that 28% of households borrowed to pay for healthcare, with 55% of these loans subjected to interest payments.[12] Cambodia also has very high rates of OOP for pharmaceuticals. Direct OOP accounted for 77% of total spending on pharmaceuticals.[13] This level of spending 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 low- and middle-income 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% versus 28%, respectively.[14]

3 | WTO MEMBERSHIP AND PATENT LAWS OF CAMBODIA, THAILAND AND INDIA

This section outlines Cambodia, India and Thailand's membership of the WTO and their laws and regulations that govern the granting of patents.

3.1 | Cambodia and WTO

Cambodia became the 148th member of the WTO on 13 October 2004. Together with Nepal, it was the first LDC to accede to the WTO.[15] As a WTO Member State, Cambodia must abide by WTO's Agreement on TRIPS which came into effect on 1 January 1995. This multilateral agreement on intellectual property (IP) binds WTO Members to minimum standards of IP protection.[16] 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.[17] As a LDC, Cambodia is not required to grant patents for pharmaceuticals until 2033 or until it graduates from LDC status.[18] TRIPS Article 66.1 includes an LDC pharmaceutical-specific transition period extension in recognition of LDC's specific economic, financial and administrative challenges. This LDC transition period has been extended twice.[19] Cambodia met all three criteria for LDC graduation at the most recent review in 2021[20] and is expected to graduate from LDC status in the coming years.

The Declaration on the Agreement on TRIPS 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.[21]

3.2 | Cambodia's Patent Laws

Cambodia's Patent law of 2003, 'The Law on Patents, Utility Model Certificates and Industrial Designs'[22] is based on the World Intellectual Property Organization's (WIPO) Draft Industrial Property Act[23] and is supplemented by its implementing regulations, the Prakas on the Procedures for Granting Patents and Utility Model Certificates (2006)[24] and the Prakas on Management and Procedures for Granting Patents and Utility Model Certificates.[25,26] Cambodia only recently introduced a 'Law on compulsory licensing for public health',[27] however, it has not fully incorporated other public health-related TRIPS flexibilities into legislation and its patent-related legislation contains some TRIPS-plus provisions, that is, IP provisions that go beyond what is required by TRIPS. This is problematic given that 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,[28] including operating a mailbox system. Cambodian legislation authorises the filing of patent product applications despite the fact that TRIPS does not obligate LDCs to provide patent protection or a mailbox system for accepting patent applications[29] and it is not obliged to accept patent applications until 2033 or until it graduates from LDC status.[30] The mailbox system is a way to file and store patent applications for examination at a later time period. These applications will not be examined as to their patentability 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.[31]

3.3 | India and Thailand's Patent Laws

Thailand and India were chosen as models that may hold lessons for Cambodia as it transitions from LDC status for several reasons. India, in particular, has designed its patent law to be both TRIPS-compliant and to maximise access to affordable generic medicines. Both India and Thailand 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. Thailand and India both have 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.[32] Additionally, there is extensive English language documentation about the actions of both countries regarding pharmaceutical IP. Some examples of the implementation of these flexibilities are explored in the literature review in Section 6.3.

3.3.1 | India

India has been a Member State of the WTO since its inception in 1995.[33] The Indian patent system was inherited from the British and was amended in 1970 to limit the grant of patents to 'process' patents only for pharmaceuticals, that is, 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.[34] Article 65.4 of the TRIPS agreement granted a 10-year transition period in which to introduce necessary amendments to 'developing countries' such as India, that didn't provide existing product patent protection when TRIPS came into force.[35]

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. When India opened its mailbox in 2005, there were over 10,000 patent applications on medicines alone. Section 11A(7) of the IPA was designed to mitigate the impact of the large volume of mailbox applications. Under this provision, patent rights for mailbox applications would start only from the patent grant date. If a patented product was already in use or if there was significant investment in the production and marketing of a product before 2005, production could continue subject to 'a reasonable royalty'.[36]

With respect to 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 somewhat controversially, standards of patentability, that guard against 'evergreening' which is the filing of multiple, often successive patent applications on therapeutically minor or insignificant variations or indications of the same compound.[37] Examples of these provisions are explored in the literature review section below.

3.3.2 | Thailand

Thailand has been a WTO Member State since 1995.[38] Thailand passed the Patent Act B.E. 2522 in 1979.[39] This Act was drafted following the Paris Convention of 1963, allowing foreigners to have national treatment and has been amended twice; first in 1992, under pressure from the United States to increase patent protection for US pharmaceutical companies.[40] 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 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 parliament, as of August 2022.[41] The proposed changes include the addition of surgical methods to the list of nonpatentable subject matter and allow for compulsory licenses to export medicines to countries with insufficient or no pharmaceutical manufacturing capacity.[42]

4 | CAMBODIA'S UNIVERSAL HEALTH COVERAGE COMMITMENTS

Cambodia has committed to universal health coverage and explicitly recognises that access to affordable medicines is a precondition to achieving this goal. This is stipulated in the Third National Health Strategic Plan 2016–2020 (HSP3)[43] which aligns with the National Strategic Development Plan 2019–2023[44] to ensure Universal Health Coverage. In addition, along with 191 other countries, Cambodia signed up to the sustainable development goals (SDGs) in 2015 which include specific reference to universal health coverage in article 3.8 and the TRIPS agreement in article 3.9.[45] IP restrictions that may accompany graduation from LDC status will impede access and jeopardise this commitment.

5 | STUDY AIMS

Our study aims to examine Cambodia's IP laws and regulations to identify provisions relevant to patents which could reduce access to affordable generic medicines in Cambodia when it starts to grant patents for pharmaceuticals. It systematically compares Cambodia's IP laws and regulations with those of Thailand and India to identify changes that could be made to improve access to medicines in Cambodia after implementation of TRIPS. Lastly, 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 and in how to avoid signing onto TRIPS-plus provisions in bilateral and plurilateral trade agreements.

6 | METHODS

The database of the WIPO Lex was searched for the IP laws and regulations of Cambodia, Thailand and India relevant to patents for pharmaceuticals. WIPO Lex lists all laws and regulations related to IP in a given country.[46]

The WIPO Lex scan included the terms:

- Competition/enforcement of IP and related laws/patents (inventions)
- Main IP laws/IP-related laws/implementing rules and regulations

for each of Cambodia, India and Thailand. All identified texts were then examined and excluded if they were not related to the regulation of patents for pharmaceutical or TRIPS flexibilities relevant to pharmaceuticals or if they had been superseded. Additional legal documents previously identified by the authors as being relevant, but not catalogued in WIPO Lex, were then added.

A table was designed to systematically compare Cambodia's IP laws and regulations (in particular, TRIPS 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'[47] and the WTO publication, 'A Conceptual Framework for Designing and Implementing Laws and Policies to Promote Access to Medicines in Cambodia'.[48] 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. Google Scholar was searched for key terms focused on TRIPS flexibilities, combining 'India' and 'Thailand' with (as appropriate for each country) 'Section 3(d)', 'standards of patentability' 'pregrant opposition', 'patent opposition', 'post-grant opposition', 'patent revocation', 'Compulsory licens*' 'Bolar exception'. The most relevant articles retrieved, as judged by the authors based on their extensive expertise in this area, were used to construct a narrative account of the implementation of TRIPS flexibilities in each country. Only literature that featured an example of Thailand's and/or India's use of TRIPS flexibilities were included. Attempts were made to include examples from both Thailand and India to demonstrate the use of Preventative, Remedial and Enforcement flexibilities. Some of the flexibility categories, such as 'Standards of Patentability' and 'Exemptions: Bolar and research and experimental use', elicited literature from India only and hence no Thailand example was featured. Similarly, there were no suitable examples from Thailand or India in relation to TRIPS enforcement.

7 | RESULTS

7.1 | Identification of IP laws and regulations

The main legislation governing the patenting of pharmaceuticals in Cambodia, India and Thailand is The Law on Patents, Utility Model Certificates and Industrial Designs of 2003 and its amendment of 2017, the Indian Patents Act 1970, and the Patent Act B.E. 2522 of 1979, respectively. Table 1 outlines the results of the WIPO Lex scan showing a summary of the process by which relevant legal texts were identified for inclusion and provides the final list of laws and regulations relevant to the governance or regulation of patents for pharmaceuticals included in the study. Full details of the screening process are provided in separate country flowcharts in Supplementary Files 1–3.

7.2 | Comparison of the laws and policies that govern IP.

Table 2 below separates key TRIPS flexibilities into three categories (preventative,[49] remedial[50] and enforcement[51]) and presents an analysis of whether each country has incorporated specific TRIPS flexibilities in its national law. For each flexibility, the table first presents whether the flexibility is incorporated in the law. This is followed by the citation and then some clarifying notes where necessary.

As evidenced in Table 2, 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 utilise many of the TRIPS flexibilities outlined in Table 2 however, some provisions lack clarity and could be strengthened, especially patent standards and exclusions from patentability, to ensure only high-quality patents are granted. Thailand is yet to incorporate provisions enabling compulsory licencing for export and only incorporates provision for postgrant opposition via a judicial process through the courts. Patent Act B.E. 2522 Section 31 allows any third party to submit a pre-grant opposition within 90 days following the publication of the patent application. Additionally, the Thai Patent Act B.E. 2522 Chapter VI Offences and Penalties Section 82–88 allows for the criminalisation of patent infringement.[52] Thailand's Trade Competition Act B.E. 2560 (2017) addresses the abuse of market power and unfair trade practices.[53]

Importantly, Cambodia has incorporated the TRIPS waiver for LDCs in article 136[54] 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 2 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 does not 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. Article 27 (8) of this Prakas allows for a third party to file a pregrant opposition within 3 months from the date of publication. 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[55] but does not allow exemptions for Bolar/early working that enables generic companies to enter the market at the time of patent expiry. The Competition law provides recourse for IPR abuse,[56] and the 2018 Law on Compulsory Licensing for Public Health allows for compulsory licenses for production, exportation and importation.[57]

TABLE 1 WIPO Lex scan of IP laws and regulations.

Results of WIPO Lex scan that included the terms: – Competition/enforcement of IP and related laws/patents (inventions) – Main IP laws/IP-related laws/implementing rules and regulations			
	Cambodia	**India**	**Thailand**
Number of texts scanned for relevance and currency	16 texts	32 texts	22 texts
Number of texts excluded as not related to regulation of patents for pharmaceutical or TRIPS flexibilities	−9 texts	−27 texts	−11 texts
Number of texts excluded due to currency	−0 texts	−0 texts	−1 text
Relevant identified texts added	+0 texts	+0 texts	+1 text
Laws and regulations included	7 texts • Prakas on Management and Procedures for the Grant of Patent and Utility Model Certificate (2019) • Law on Compulsory Licensing for Public Health (2018) • Law on Amendments to the Law on Patents, Utility Models and Industrial Designs (2017) • Law on Patents, Utility Models and Industrial Designs (2003) • Law Concerning Marks, Trade Names and Acts of Unfair Competition (2002) • Sub-Decree on the Implementation of the Law Concerning Mark, Trade Names and Acts of Unfair Competition of the Kingdom of Cambodia • Prakas on the Procedures for Granting Patents and Utility Model Certificates (2006)	5 texts • The Patents Act, 1970 (Act No. 39 of 1970, as amended up to the Patents (Amendment) Act, 2005) • The Patents Rules, 2003 (as amended up to Patents (Amendment) Rules, 2017) • Patents (Amendment) Rules, 2006 • Patents (Amendment) Rules, 2005 • Patents Rules, 1972	11 texts • Patent Act B.E. 2522 (1979) • Trade Competition Act B.E. 2560 (2017) • Trade Secrets Act B.E. 2545 (2002) (as amended by Trade Secrets Act (No. 2) B.E. 2558 (2015))[a] • Ministerial Regulations No. 21 of 1999 (B.E. 2542) • Ministerial Regulations No. 22 of 1999 (B.E. 2542) • Ministerial Regulations No. 23 of 1999 (B.E. 2542) issued under the Patent Act • Ministerial Regulations No. 24 of 1999 (B.E. 2542) • Ministerial Regulations No. 25 of 1999 (B.E. 2542) • Ministerial Regulations No. 26 of 1999 (BE. 2542) • Ministerial Regulations No. 27 of 1999 (B.E. 2542)

(Continues)

TABLE 1 (Continued)

Results of WIPO Lex scan that included the terms: – Competition/enforcement of IP and related laws/patents (inventions) – Main IP laws/IP-related laws/implementing rules and regulations		
Cambodia	**India**	**Thailand**
		• Ministerial Regulations No. 10 B.E. 2529 (1986)

[a]Trade Secrets Act B.E. 2545 (2002) (as amended by Trade Secrets Act (No. 2) B.E. 2558 (2015) includes provision for data protection against unfair commercial use which a TRIPS requirement (Article 39.3) for new chemical entities.

7.3 | Results of the targeted literature review—Implementation of TRIPS flexibilities by India and Thailand

In this section of the paper, we examine India and Thailand's experience of implementing preventative, remedial and enforcement TRIPS flexibilities.

7.3.1 | Standards of patentability

India was granted a 10-year transition period, expiring on 1 January 2005, in which to update its Patent Act to be TRIPS compliant. 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.[58] 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.[59] 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[60]

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 use includes Pfizer's patent application for amlodipine/atorvastatin (cardiac), GlaxoSmithKline's application for rosiglitazone (diabetes) and Gilead Science's applications for osaltemivir (bird flu) and adefovir (hepatitis B).[61] The most well-known demonstration of India's opposition to evergreening is the Novartis-imatinib (Glivec) case.

The pharmaceutical company Novartis filed a mailbox patent application for a specific crystalline form (β-crystal form) of imatinib mesylate, marketed by Novartis as Glivec/Gleevec for the treatment of chronic myeloid leukaemia.[62] This application was opened in 2005 and subsequently opposed by several generic drug companies

TABLE 2 Comparison of the laws and policies that govern IP

TRIPS flexibilities	Cambodia	India	Thailand
Preventative			
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 What are not inventions (d).	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.
Patent opposition: Allow pre-grant and postgrant 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: postgrant 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 pregrant opposition. Section 54 postgrant 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 not a LDC.	Not applicable – Thailand not a LDC.

(Continues)

TABLE 2 (Continued)

TRIPS flexibilities	Cambodia	India	Thailand
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 noncommercial use. Note: No IP laws or regulations allow bolar/ early working exemption.	Incorporated. Citation: IPA 1970. Section 107 A.	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 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.	Incorporated. Citation: IPA 1970. amendment of 2005 Section 107 A(b).	Incorporated. Citation: Patent Act B.E. 2522. section 36(7).
Enforcement			
No border measures for suspected patent infringement (TRIPS Article 51)	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	Incorporated. Note: No border measures listed in any IP laws or regulations in relation to

TABLE 2 (Continued)

TRIPS flexibilities	Cambodia	India	Thailand
		relation to pharmaceutical patents.	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.

and the Cancer Patients' Aid Association under Section 3(d)[63] on the grounds that it lacked novelty and did not significantly enhanced 'efficacy'. It was rejected by the Indian Patent Office on the grounds that this form was not a new substance, was already known and did not show enhanced therapeutic efficacy. Novartis appealed this decision and maintained that Section 3(d) was unconstitutional and a violation of India's obligations under TRIPS. The case was referred to the newly constituted Intellectual Property Appellate Board (IPAB), a specialist tribunal tasked with adjudicating IP disputes.[64] IPBAB also found that the application did not meet 3(d)'s standards of increased efficacy.[65] Novartis' claim that Section 3(d) was unconstitutional and did not comply with the TRIPS Agreement was rejected by the High Court of Madras. The Court upheld the validity of India's 2005 Patents Amendment Act and ruled that the court was an inappropriate forum to assess compliance with the TRIPS Agreement.[66] Novartis then appealed to the Supreme Court which concurred with the Patent Office and IPAB and upheld the strict interpretation and application of Section 3(d) and concluded that Novartis' purported invention did not meet the patentability criteria or indeed of invention under the Indian Patents Act.[67] This court battle continued over 7 years and attracted international interest as the outcome had the potential to set a precedent for future evergreening applications. Given the size of India's pharmaceutical sector, especially its generic component, an adverse decision could have affected generic medicine supply globally. Médecins Sans Frontières (MSF) launched their Drop the Case campaign in response to Novartis' appeals. This garnered global media attention and almost half a million signatures calling on the company to drop its appeal.[68] A recent study has found a sharp increase in the use of Section 3(d) over time, mainly by third parties to oppose patent applications.[69] It is often used in conjunction with other objections to patentability. Despite its intent to address evergreening applications, it is being increasing used to oppose primary patent applications.[70]

7.3.2 | Pregrant 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.[71] This is usually on the basis that the application is not new or inventive and therefore does not meet Thailand's patentability criteria. Despite the limited time allowed to submit a pre-grant opposition, it has been used to great effect in Thailand and has helped prevent low-quality patents being granted.[72] 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.[73] India too, has made good use of pregrant oppositions 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.[74] This

demonstrates that pre-grant opposition can be effective in preventing poor quality patents even when an application is upheld. The pregrant opposition, and the publicity and advocacy that it attracts can lead to pharmaceutical companies abandoning or withdrawing patent applications. This is what happened when both Thai and Indian advocacy groups filed pregrant oppositions for the GlaxoSmithKline (GSK) produced, fixed-dose combination of zidovudine/lamivudine (AZT/3TC) marketed as 'Combid' or 'Combivir' in their respective countries.[75] Thai groups began their campaign against GSK's patent application for the AZT/3TC combination as early as 2000. Indian groups filed pregrant oppositions to GSK's patent application when India changed its patent law to become TRIPS-compliant in 2005.[76] There was particular concern about the impact on generic availability globally if India granted the patent, given India supplies much of the world's generic ARVs. Pregrant opposition for this drug became a focus of joint advocacy by law and pharmaceutical academics, civil society, patient groups and access to medicines activists. Coordinated joint advocacy actions were held in India and Thailand and received international media coverage and support.[77] These joint actions prompted an immediate response from GSK which issued a press release on 10 August 2006 stating that it had withdrawn or was in the process of withdrawing the patent application for Combivir in all countries where it had been filed.[78]

7.3.3 | Postgrant opposition

India's IPA allows for postgrant opposition and revocation of an existing patent in Section 25 (2) and Section 64, respectively.[79] Postgrant opposition can be filed at any time after the grant of the patent and up to 1 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.[80] In 2012, The Sankalp Trust, a Mumbai based NGO, successfully challenged the patent granted to Roche for peginterferon alfa-2a (Pegasys), a medicine used to treat hepatitis C, on the grounds that it was 'obvious'.[81] In doing so, they also challenged what constitutes an 'interested party' 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 postgrant opposition case.[82] As a result of the intervention, a biosimilar was able to be produced locally for 20% 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.[83]

Section 54 of the Thai Patent Act allows for challenges to the validity of a granted patent.[84] However, this is only via a judicial process and patents cannot 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 (ddI). 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'.[85] The patent was challenged on several grounds including that it did not contain an inventive step.[86] In 2003, after several adverse rulings, BMS voluntarily terminated its claim on the ddI patent, ensuring GPO could manufacture an affordable generic version.[87]

7.3.4 | Compulsory licencing

The Thai Patent Act and the IPA both have a provision for compulsory licencing and both countries have issued compulsory licences to access more affordable generic medications. The IPA includes a provision for compulsory licencing for export.[88]

Together with Ecuador, Thailand has made the most frequent use of compulsory licencing of any WTO Member.[89] 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'.[90] After nearly a decade of lobbying by PLHIV and HIV stakeholders[91] the Thai government finally issued a compulsory licence for the ARV drug, efavirenz (Sustiva), in November 2006. This was closely followed by compulsory licences in January 2007 for the second-line ARV combination of lopinavir/ritonavir (LPV/r)[92] produced by Abbott and marketed as Kaletra and clopidogrel (Plavix, an antiplatelet agent used in the treatment of coronary artery disease).[93] The latter was under patent by Sanofi-Aventis, a French pharmaceutical company. This was the first time a developing country had issued a compulsory licence for a drug other than an ARV. Four additional licenses were granted in January 2008 for the cancer drugs letrozole (Femara)[94] docetaxel (Taxotere)[95] erlotinib (Tarceva)[96] and imatinib (Glivex/Gleevec)[97] for the treatment of breast and lung cancers, gastrointestinal stromal tumours and leukaemia, respectively.

Thailand's Minister of Health came under increasing pressure from the Thai Pharmaceutical Research and Manufacturers' Association (PReMA) and the US embassy to withdraw the licences.[98] The World Bank had previously recommended Thailand consider the use of compulsory licences to procure less expensive generic medicines to address excessive costs associated with providing second and third-line ARV treatment.[99] It was estimated that the compulsory licence for lopinavir/ritonavir (Kaletra) alone saved Thailand as much as US$24 million a year. The seven compulsory licences were estimated to have saved the government budget approximately $370 million over 5 years and allowed access to treatment for an additional 84,158 patients.[100]

India issued its first and only compulsory licence in March 2012 for Bayer's kidney and liver cancer drug, sorafenib tosylate (Nexavar) at the request of Natco, a local generic firm. Natco was then able to legally manufacture a generic version for $175 per month, 97% less than the cost of Nexavar, the branded version of sorafenib.[101] India's sole compulsory licence has possibly had a wider and more long-term impact than just on the drug it was issued for. Section 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 anticompetitive practices adopted by the patentee as well as the right to export any products produced under such licences.[102] 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.[103]

7.3.5 | 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 country's generic and biosimilar industry.[104] Section 107 B of the IPA outlines the Bolar exception which extends to acts such as the manufacture of a patent 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.[105] This legislation has proven useful for compulsory licencing purposes. Section 107B allowed Natco 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.[106]

8 | DISCUSSION

The discussion begins with an analysis of the results in relation to the Indian and Thai context. This is followed by an exploration of the barriers TRIPS-plus FTAs pose for the implementation of TRIPS flexibilities and an examination of a TRIPS-plus FTA relevant to India and Thailand. It then discusses the results in relation to the Cambodian context.

8.1 | 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.[107] As a 'developing country' that did not have existing patent protection for pharmaceuticals, India was entitled to a 10-year transition period in which to update its patent law to become TRIPS compliant.[108] It made full use of these 10 years to amend its patent law three times 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.[109] 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'[110] provides many lessons for other countries for whom LDC graduation is imminent, such as Cambodia. Despite India's commitment to implementing TRIPS in a manner that supports public health, studies have shown that the introduction of pharmaceutical patents in India can lead to increases in the price of drugs,[111] large losses in consumer welfare and welfare losses for the Indian economy.[112]

8.2 | 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 and in 2019 its DIP published a new edition of the Guidelines for Examining Patent and Petty Patent Applications in 2019[113] which generally does not allow for the granting of evergreening patents. However, some preventative flexibilities lack clarity and could be strengthened, especially patent standards and exclusions from patentability, to ensure only high quality patents are granted.

8.3 | 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 provisions can undermine efforts to incorporate and implement TRIPS flexibilities for greater access to affordable generic medicines. Thailand's and India's experience of these trade-related TRIPS-plus proposals and negotiations provide a salient lesson for Cambodia that may also be faced with similar agreements in the future and warrants some discussion and analysis.

TRIPS-plus trade agreements have been met with fierce opposition in both Thailand and India from various stakeholders including access to medicine activists and patient representative groups, in particular PLHIV networks and some HIV NGOs.[114]

8.3.1 | Thailand TRIPS-plus FTAs

Thailand began negotiations with the United States on a bilateral trade agreement in June 2004. The IP chapter of the draft agreement was leaked to the press and proposed to extend the patent life of a drug to accommodate 'unreasonable' delays in the granting of a patent; allow the patenting of therapeutic and diagnostic procedures; extend the responsibilities of the Thai FDA to include acting as a patent watchdog;

enforce a data-exclusivity period of 5 years; restrict the grounds for compulsory licensing and parallel imports; prohibit the revocation of patents; enforce accession to patent cooperation treaties; and prohibit pregrant opposition to patents.[115] Modelling studies found that TRIPS-plus provisions in the proposed Thailand–United States FTA would have resulted in consumer welfare[116] losses,[117] an increase in drug expenditure and a delay in the market entry of generics.[118] Negotiations were suspended in 2006 when Prime Minister, Thaksin Shinawatra was deposed by a coup d'etat.

Thailand has recently expressed interest in join the Comprehensive and Progressive Agreement for Trans-Pacific Partnership (CPTPP) although a definitive decision has not yet been made.[119] This multilateral trade agreement between Australia, Brunei Darussalam, Canada, Chile, Japan, Malaysia, Mexico, Peru, New Zealand, Singapore and Vietnam was signed on 8 March 2018 in Santiago, Chile.[120] The CPTPP IP chapter includes provision for patent linkage which links marketing approval for generics to the patent status of a drug. Studies have shown patent linkage can provide additional protection from generic competition.[121] The Trump Administration withdrew the United States from the original incarnation of this agreement, the Trans-Pacific Partnership Agreement (TPP). After the USA withdrawal, several provisions were suspended including key TRIPS-plus settings which could be reintroduced by agreement amongst the parties if the Biden Administration decides to rejoin. Patent linkage is not one of the suspended provisions[122] and would require Thailand to update its Patent Law if they were to join the CPTPP. The TRIPS-plus suspended clauses include:

- Patents be made available for either new uses of known product, new methods of using a known product or new processes of using a known product;
- Patents be available for inventions derived from plants;
- Patent term extensions;
- Data exclusivity;
- Five years of test data protection for biologics.[123]

8.3.2 | India TRIPS-plus FTAs—EU FTA

Negotiations for a European Union–India FTA began in 2007 but stalled in 2013 after 16 rounds of talks. IP was just one of several points of difference.[124] 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.[125] 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' campaign in response to the EU demands.[126] India has largely pushed back on these proposed TRIPS-plus provisions,[127] however, talks have recently resumed. The text proposed by the EU includes an IP chapter with the aforementioned TRIPS-plus measures.[128]

8.3.3 | Regional Comprehensive Economic Partnership (RCEP)

Negotiations on the RCEP initially included all 10 ASEAN nations (Brunei, Cambodia, Indonesia, Laos, Malaysia, Myanmar, Philippines, Singapore, Thailand and Vietnam) and those nations with existing trade agreements with ASEAN: Australia, China, India, Japan, New Zealand and the Republic of Korea.[129] In November 2019, India withdrew, citing dissatisfaction with elements of the RCEP and has since indicated it would not sign the Agreement at this time.[130] It was signed (without India) in November 2020 and includes an IP chapter with some TRIPS plus provisions relating to the enforcement of IP rights.[131]

8.4 | Cambodia

Table 3 below summaries the TRIPS flexibilities that Thailand, India and Cambodia have incorporated into law and which flexibilities are absent or not fully incorporated.

Cambodia is currently missing several key preventative, remedial and enforcement TRIPS flexibilities in its IP laws. Their absence could lead to low-quality patents being granted and fewer opportunities to challenge them. This can create barriers and delay the entry of more affordable generic medicines. It could also pose challenges for Cambodia's burgeoning domestic generic pharmaceutical industry. Although there are only a small number of generic pharmaceutical companies in Cambodia, there is growing awareness of the need to develop the industry to ensure the availability and sustainability of medical products such as vaccines, diagnostics and medicines. This has become particularly evident during the Covid-19 pandemic. Prime Minister Hun Sen recently granted permission to a local generic company to produce molnupiravir (Lagevrio), an antiviral medicine used in the treatment of COVID-19. This was in response to supply and distribution concerns.[132] 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.

8.4.1 | Preventative flexibilities

Under Article 5 of the Cambodian Law on the Patents, Utility Model Certificates and Industrial Designs, an invention is patentable if it '(i) new; (ii) involves an inventive step; and (iii) is industrially applicable'.[133]

TABLE 3 Summary of TRIPS flexibilities implemented into law in Thailand, India and Cambodia.

Measure	Thailand	India	Cambodia
Preventative flexibilities			
Exclusion from patentability: Exclude new use of known substances, methods and processes	P	F	P
Patentability criteria: Develop and apply strict patentability criteria for examination of pharmaceutical patents. Mitigate frivolous patents and "evergreening" opportunities	P	F	P
Patent opposition: Allow pre-grant and post-grant patent opposition in fast, accessible and cost-efficient manner.	P	F	P
Waiver for LDCs: LDCs should utilize the waiver to provide patent protection for pharmaceuticals until 2033	N/A	N/A	F
Remedial flexibilities			
Compulsory Licenses and Government Use Orders	P	F	F
Exceptions: Bolar (early working) exception, research and experimental use exception, individual use	F	F	P
Use of National Competition Laws to prevent IPR abuse and provide remedies	F	F	F
Parallel Importation	F	F	P
Enforcement			
No border measures for suspected patent infringement	F	F	F
No criminalization of patent infringement	N	F	N

Abbreviations: F, fully incorporated; N, not incorporated; N/A, not applicable; P, partially incorporated.

Article 7 further defines inventive as 'not have been obvious to a person having ordinary skill in the art'.[134] This is less specific and a lower threshold than India's Patent Act Section 2(1)(ja) which defines an inventive step as:

> a feature of an invention that involves technical advance as compared to the existing knowledge or having economic significance or both and that makes the invention not obvious to a person skilled in the art;[135]

Cambodia's lower threshold for inventiveness could result in more low-quality patents being granted.

Article 4 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 body; plants and animals other than micro-organisms, biological processes for the production of plants or animals and importantly, pharmaceutical patents.[136] 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, Cambodia has made full use of the LDC wavier to avoid granting patents for pharmaceutical products and patents, 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[137] and will undoubtedly lead to patents being granted (from the filing date) which 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, Utility Model Certificates and Industrial Designs has provision for postgrant invalidation but like Thailand, has no provision for an administrative postgrant opposition process. Any challenges to existing patents must be filed in court. This is a more onerous and lengthy process than filing a postgrant opposition procedure at the patent office and is out of step with patent acts in developed countries such as Japan and the United States. This limitation could deter interested parties from challenging low-quality patents and lengthen the time taken to revoke a patent granted in error.

8.4.2 | Remedial flexibilities

The adoption of the Law on Compulsory Licencing for Public Health[138] 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. UNAIDS and many civil society organisations including the Cambodian People living with HIV Network (CPN+), played an active role in advocating for this law.[139] The Law on Compulsory Licencing for Public Health, 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, Utility Model Certificates and Industrial Designs allows for exemptions for research purposes but has no provision for Bolar/early working exemption.[140] This exemption allows for the development, testing, and experimental work necessary to obtain regulatory approval 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 2 or more years and extend the effective monopoly period for originator medicines.[141]

Cambodia has some conflicting laws and policies in relation to parallel importation. The Law on Patents, Utility Model Certificates and Industrial Designs Article 44 includes the international exhaustion of patent rights which allows for the importation of a patented product sold in a foreign country.[142] Trademark law, however, adopts a national exhaustion doctrine that prohibits parallel imports of trade marked products.[143] This could potentially hinder Cambodia's ability to import cheaper patented products from foreign markets.[144] 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.

8.4.3 | Enforcement

Infringement of the Law on Patents, Utility Model Certificates and Industrial Designs attracts criminal penalties of up to 5 years imprisonment and can result in the seizure and destruction of the infringing goods.[145] The TRIPS Agreement limits criminalisation offenses to commercial level wilful trademark counterfeiting and copyright piracy.[146] 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.[147]

8.4.4 | Patent treaties

In addition to the above, Cambodia has signed on to a raft of Memorandums of Understanding (MoUs) and patent treaties designed to expedite and facilitate the granting of patents. These include the Joint Statement of Intent between the MIH and the Japan Patent Office (JPO),[148] the MOU with the Intellectual Property Office of Singapore (IPOS),[149] the Patent Cooperation Treaty (PCT),[150] the Patent Validation Agreement between Cambodia and the European Patent Organization (EPO),[151] the MoU with China,[152] the MoU with South Korea[153] and the Work sharing agreement with the United States Patent and Trademark Office (USPTO).[154] Given these agreements, three registration schemes have been established: recognition/Reregistration scheme (China and Singapore), acceleration scheme (Japan, Korea and the United States), and validation scheme (EU). These agreements have no impact while the TRIPS LDC waiver is in play, however, once Cambodia starts to provide patent protection for pharmaceuticals, they will invariably accelerate and increase the number of patents being granted.

8.4.5 | National Committee for Intellectual Property Rights (NCIPR)

Cambodia has created a 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, their patent office lacks the institutional, human, IT, and financial resources to fulfil their mandate.[155] 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.[156]

8.4.6 | Cambodia FTAs

Cambodia has so far only signed bilateral trade agreements with China[157] and South Korea[158] and seven agreements as part of ASEAN.[159] None of these contain TRIPS-plus measures. Cambodia has also signed onto RCEP which includes an IP chapter with TRIPS-plus provisions relating to the enforcement of IP rights.[160] Cambodia will need to be mindful of and resist signing onto future trade agreements or investment treaties that contain TRIPS-plus provisions.

9 | LIMITATIONS

Patents are not the only IP barrier to affordable vaccines, medicines and diagnostics. Other IP barriers such as trade secrets, copyright and trademarks can also be an impediment to affordable health products, however, they are beyond the scope of this paper but do warrant future exploration. It is possible that limitations in the methodological approach of the targeted search of the literature failed to capture literature that could further elucidate Thailand and India's use of TRIPS flexibilities.

10 | CONCLUSION AND RECOMMENDATIONS

Cambodia will soon graduate from LDC status and will need to grant patents for pharmaceutical products and processes. Accessing an affordable and sustainable supply of generic medications will require reform of its IP regulatory system including its Law on Patents, Utility Model Certificates and Industrial Designs 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 especially in relation to compulsory licencing. 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 preventative TRIPS flexibilities. These include removing the mailbox facility from the LDC TRIPS waiver transition period and adding a provision similar to Section 11A(7) of the IPA. This would allow Cambodia to continue to import (or manufacture) generic versions of medicines with a mailbox patent application provided they offer a reasonable royalty. Cambodia needs to include a provision for pre-grant opposition in its Law on Patents, Utility Model Certificates and Industrial Designs and not just the Prakas, as well as the provision for postgrant opposition in addition to the existing invalidation procedure. Additionally, Cambodia should develop and apply strict patentability criteria for the examination of pharmaceutical patents to mitigate against 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 should also incorporate or reflect these preventative TRIPS flexibilities into any future amendment or renewal of the MoUs which Cambodia currently has with other countries within the framework of recognition, acceleration or validation of foreign patents, in particular when it has obligation to grant patents for pharmaceutical products and processes.

Cambodia should 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. Although Cambodia has adopted the Law on Compulsory Licencing for Public Health, it is yet to draft and adopt the regulations for the law's implementation. These regulations should be accompanied by building the capacity of the Ministry of Health and the patent office in how to implement the law and to raise public awareness of the law's importance. 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 its IP offices, in particular the patent office, to adequately examine and assess patent applications to avoid over reliance on external patent offices, to facilitate the use of preventative TRIPS flexibilities and to reject low quality patent applications. Patent examiners could benefit

from training in public health and public interest perspectives of IP issues. Such training can be conducted by UN agencies, intergovernmental organisations such as the South Centre and civil society organisations. Additionally, it is critical that the patent office and the government consult health and patient groups and civil society organisations in adopting and implementing TRIPS flexibilities. This will help to better balance the interests of business and multinational corporations with the public interest and public health imperatives.

Another option for Cambodia, but one that is it is unlikely to consider, is to request a delay in graduation until at least 2033 to make full use of the LDC TRIPS transition period. It is important that Cambodia consider the timing of graduation in light of the enormous impact of patent protection, the ongoing COVID pandemic, the possible emergence of new pandemics and the accelerating climate crisis.

The Indian Patent Act provides an exemplary example 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 postgrant opposition, to facilitate greater access to affordable medicines for its citizens. 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.

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CONFLICT OF INTEREST STATEMENT

The authors declare no conflict of interest.

DATA AVAILABILITY STATEMENT

The data that support the findings of this study are available in WIPO Lex at https://www.wipo.int/wipolex/en/index.html. These data were derived from the following resources available in the public domain: Cambodia Patent Laws, https://wipolex.wipo.int/en/legislation/results?countryOrgs=KH&subjectMatter=1&subjectMatter=12&subjectMatter=8&typeOfText=207&typeOfText=205&typeOfText=210&last=true; India Patent Laws, https://wipolex.wipo.int/en/legislation/results?countryOrgs=IN&subjectMatter=1&subjectMatter=12&subjectMatter=8&typeOfText=207&typeOfText=205&typeOfText=210&last=true; Thailand Patent Laws, https://wipolex.wipo.int/en/legislation/results?countryOrgs=TH&subjectMatter=1&subjectMatter=12&subjectMatter=8&typeOfText=207&typeOfText=205&typeOfText=210&last=true.

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[50] 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.

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

[52] 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 2 years or to a fine not exceeding 400,000 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.

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[55] Article 44 (iii) The rights under the patent shall not extend (iii) to acts done only for experimental purposes relating to a patented invention.

[56] Article 1: This law has the objective to protect the marks and trade names duly registered in the register of marks in the Kingdom of Cambodia and prevent the acts of unfair competition on the creation, the utilization of marks and trade names. Article 22: Any act of competition contrary to honest practices in industrial, commercial, service matters shall be considered as act of unfair competition.

[57] Article 1: The objective of this law is to enhance access to Pharmaceutical Products for public health by granting compulsory licenses for production, exportation and importation of Pharmaceutical Products in cases of National Emergency or Extreme Urgency or Public Noncommercial Use or any other public health circumstances that defined by Ministry of Health.

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SUPPORTING INFORMATION

Additional supporting information can be found online in the Supporting Information section at the end of this article.

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