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An Examination of Selected Public Health Exceptions in Asian Patent Laws

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SOUTH CENTRE

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AN EXAMINATION OF SELECTED PUBLIC HEALTH EXCEPTIONS IN ASIAN PATENT LAWS[1]

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ABSTRACT

This study examines the variations within Asia of two exceptions to patent rights that are commonly justified under Article 30 of the World Trade Organization (WTO) Agreement on Trade-related Aspects of Intellectual Property Rights (the TRIPS Agreement), namely the research and experimentation exception and the regulatory review (or “Bolar”) exception. Both these exceptions are important in the context of the 2001 Doha Declaration on the TRIPS Agreement and Public Health insofar as they are designed to provide flexibility to protect public health and support countries’ overall scientific and technological aspirations. The study examines, from a comparative perspective, examples of these respective exceptions in patent legislation in South, Southeast and East Asia, and identifies peculiarities in the variations among countries in these sub-regions.

En este estudio se examinan las variaciones dentro de la región de Asia de dos excepciones a los derechos de patente que suelen justificarse en virtud del artículo 30 del Acuerdo de la OMC sobre los Aspectos de los Derechos de Propiedad Intelectual relacionados con el Comercio (el Acuerdo sobre los ADPIC), a saber, la excepción de investigación y experimentación y la excepción de examen reglamentario (o "Bolar"). Ambas excepciones son importantes en el contexto de la Declaración de Doha de 2001 sobre los ADPIC y la salud pública, en la medida en que están diseñadas para proporcionar flexibilidad para proteger la salud pública y apoyar las aspiraciones científicas y tecnológicas generales de los países. El estudio examina, desde una perspectiva comparativa, ejemplos de estas respectivas excepciones en la legislación sobre patentes en el sur, el sudeste y el este de Asia, e identifica las peculiaridades de las variaciones entre los países de estas subregiones.

Cette étude examine les variations au sein de l'Asie de deux exceptions aux droits de brevet qui sont couramment justifiées en vertu de l'article 30 de l'Accord de l'OMC sur les aspects des droits de propriété intellectuelle qui touchent au commerce (l'Accord sur les ADPIC), à savoir l'exception pour la recherche et l'expérimentation et l'exception pour l'examen réglementaire (ou l'exception "Bolar"). Ces deux exceptions sont importantes dans le contexte de la déclaration de Doha de 2001 sur les ADPIC et la santé publique, dans la mesure où elles sont conçues pour offrir une certaine flexibilité afin de protéger la santé publique et de soutenir les aspirations scientifiques et technologiques globales des pays. L'étude examine, dans une perspective comparative, des exemples de ces exceptions respectives dans la législation sur les brevets en Asie du Sud, du Sud-Est et de l'Est, et identifie les particularités des variations entre les pays de ces sous-régions.

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INTRODUCTION

At the global level, exceptions to patent rights are legitimized through clauses in the 1994 Agreement on Trade-related Aspects of Intellectual Property Rights (the TRIPS Agreement), to which all members of the World Trade Organization (WTO) must adhere. The TRIPS Agreement permits member countries to introduce in national legislation exceptions to rights conferred under Article 30, which states:

> Members may provide limited exceptions to the exclusive rights conferred by a patent, provided that such exceptions do not unreasonably conflict with a normal exploitation of the patent and do not unreasonably prejudice the legitimate interests of the patent owner, taking account of the legitimate interests of third parties.

Exceptions related to public health and access to medicines that are understood to fall under the ambit of TRIPS Article 30 include the **research and experimentation exception** and the **regulatory review ("Bolar") exception** to patent rights. Both these exceptions are designed to ensure that important research and related activities can take place on matters of importance to advancing public health without having to rely on the willingness of a patent owner to permit the activity prior to the expiration of the patent.

These exceptions are not defined further in the TRIPS Agreement, so national legislation shaping the contours of each will often differ in scope from one country to the next. The purpose of this paper will be to examine these public health exceptions as they are currently designed in national legislation of countries in South, Southeast and East Asia, using a comparative approach. An overarching question associated with this examination is whether the current formulation of these exceptions in these countries effectively balances public health interests and the incentive of granting exclusive rights to the patent owner to prevent third parties not having the owner's consent from making, using, offering for sale, selling or importing for these purposes the technology/invention in question (TRIPS, Article 28).

These exceptions will be discussed in turn, followed by a brief conclusion and suggestions for future research.

1. THE RESEARCH AND EXPERIMENTATION EXCEPTION

The research and experimentation exception to patent law permits unlicensed scientific research related to a patented invention within the scope defined by national law. National intellectual property legislation allowed such research even prior to the TRIPS Agreement, including in the United States (UNCTAD-ICTSD, (2005)). During the negotiation process, early drafts of the TRIPS Agreement considered enumerating various exceptions and included a research exception, though in the end, countries agreed not to enumerate specific acts that would be exempted, essentially borrowing text from the exceptions clause of the Berne Convention on copyrights (Ibid.).

The underlying rationale for the exception is well explained in a 2000 WTO Dispute Settlement decision, which states in its relevant part that "a key public policy purpose underlying patent laws is to facilitate the dissemination and advancement of technical knowledge and that allowing the patent owner to prevent experimental use during the term of the patent would frustrate part of the purpose of the requirement that the nature of the invention be disclosed to the public."[3] The policy question therefore becomes one of defining the research and experimental use that is permitted under the exception at the country level. For purposes of public health-related research including the development of medicines, a broad exception for research and experimental use would allow researchers greater access and use of patented inputs in their research without having to obtain a license, while a narrower exception would conversely require the payment of royalties in more instances.

The exact scope of research that falls under this exception varies from country to country mainly in two ways.[4] The first distinction that is found in national examples are countries that limit the exception to non-commercial research and experimentation, while at the other end, some countries opt to permit all scientific research and experimentation. Countries such as Kenya, Lebanon, and the United States,[5] for example, have stipulated, either through law or judicial precedents, that only non-commercial research would be exempt from having to obtain a license from the patent owner. Other countries, such as Germany[6] and the United Kingdom,[7] specifically permit experiments done for commercial purposes. The scope of the law still remains unclear with other countries such as Brazil, China, and India, where the patent legislation does not specifically indicate that commercial research requires the permission of a patent owner. While a plain reading of the text would seem to indicate that such a license is not required, challenges could be interpreted in the courts in the light of the qualifying condition of Article 30, which requires that the exception must "not unreasonably prejudice the legitimate interests of the patent owner". The practicality of making a commercial/non-commercial distinction has been questioned, however. Adachi and Misati (2010), for example, have pointed out that the line between commercial and non-commercial experimentation is increasingly difficult to distinguish.

The second way in which patent laws may differ is that some jurisdictions opt to permit research **on** the research tool without a license from the patent owner, but require a license

[3] Canada-Patent Protection of Pharmaceutical Products (hereafter European Commission (EC)-Canada), WT/DS114/R, 17 March 2000, para. 7.69.
[4] A third way in which the research and experimentation exception may vary from country to country is to distinguish between the purposes of the organization conducting the research. Most jurisdictions do not make this distinction in their laws, however. For purposes of this paper, the distinction will be treated more as a subset of the commercial/non-commercial distinction.
[5] The leading US case on this issue is *Madey v. Duke University*, 307 F.3d 1351, 1362 (Fed. Cir. 2002). The precise scope of the exception has fluctuated in the US, however (Holzapfel and Sarnoff).
[6] German Patent Act 1981, s. 11.2.
[7] UK 1977 Patents Act, s. 60 (5) b).

for research **with** the tool (emphases added). Germany and the United Kingdom, while permitting all research to be covered under the exceptions above, follow this approach. By contrast, Belgium law allows both.[8] The Swiss approach exempts research on a patented invention while research with a patented research tool is allowed, but gives rise to a right of the patent owner to claim a non-exclusive license to use the new invention (so they cannot prevent its use in research and experimentation, but may claim a reasonably royalty from the researcher).[9] A study by the World Intellectual Property Organization (Annex VI, 2011) points out that the distinction is important because "when it is possible to experiment with an invention without infringing a patent, researchers have greater access to research tools without a license, especially when it is difficult to invent around an invention". As with the commercial/non-commercial distinction, it is often difficult to determine when work is being done on a research tool as compared to with a research tool, a factor that led to Belgium's decision to amend their patent law in 2005 to permit both without a license.

The methodology followed in this section examines how the research and experimentation exception is handled across Asia, which is defined for purposes of this paper to include the countries of the Association of Southeast Asian Nations (ASEAN); the South Asia Association for Regional Cooperation (SAARC) countries; China and its Special Administrative Regions; Japan, the countries of the Korean peninsula, Mongolia and Taiwan (Province of China).[10] The results of the research are contained in Chart 1 below. The findings and observations from the research are summarized after the Chart.

Chart 1:
Research and Experimentation Exceptions in Asian Patent Laws

Country	Law	Provision	Text[11]
Bangladesh	Patents and Designs Act	No Research and Experimentation Exception[12]	
Bhutan	Industrial Property Act	Section 13(4)(a)	The rights under the patent shall not extend: (iii) to acts done only for experimental purposes relating to a patented invention.
Brunei Darussalam	Patents Order	Section 64(2)(b)	An act which, apart from this subsection, would constitute an infringement of a patent for an invention shall not be so if - b) it is done for experimental purposes

[8] Belgium Patent Act, Art. 28 s. 1(b).
[9] Swiss Patent Act, Art. 9 and Art. 40(b).
[10] Country nomenclature, for purposes of this paper, follows United Nations practice.
[11] Official translations of the laws are used where the original controlling language is not in the English language.
[12] A number of commentaries suggest that a research and experimentation exception could be read into Section 21 of the 1911 Patents and Design Act (as amended), although there is no explicit mention of research or experimentation in the text as such. See Monirul Azam, Chapter 4, *Intellectual Property and Public Health in the Developing World*. Cambridge, UK: Open Book Publishers, 2016, found at http://dx.doi.org/10.11647/OBP.0093; and Mohammed Towhidul Islam, p. 164, *TRIPS Agreement and the WTO: Implications and Challenges for Bangladesh*. Newcastle-upon-Tyne, UK: Cambridge Scholars Publishing, 2013. In any event, even if this were the case, the only entity entitled to take advantage of such as exception would be the government of Bangladesh. In its response to WIPO's questionnaire on exceptions to patent law, the government of Bangladesh indicated that the current law contains no text to support the existence of a research and experimentation exception (see footnote 23).

			relating to the subject-matter of the invention.
Cambodia	Law on Patents, Utility Model Certificates and Industrial Designs	Article 44(iv)	The rights under the patent shall not extend (iv) to acts done only for experimental purposes relating to the patented invention.
China	Patent Law	Article 69(4)	The following shall not be deemed to be infringing the patent right: (4) any person using the relevant patent exclusively for the purpose of scientific research and experimentation.
Hong Kong SAR	Patents Ordinance	Article 75(b)	The rights conferred by a patent shall not extend to – (b) acts done for experimental purposes relating to the subject-matter of the relevant patented invention.
India	Patents Act	Section 47(3)	Any machine or apparatus or other article in respect of which the patent is granted or any article made by the use of the process in respect of which the patent is granted, may be made or used, and any process in respect of which the patent is granted may be used, by any person, for the purpose merely of experiment or research including the imparting of instructions to pupils.
Indonesia	Patent Law	Article 16(3)	Exempted from the provisions as referred to in paragraph (1) and paragraph (2) if the use of said patent is for the sake of education, research, experiment, or analysis, as long as it does not harm the normal interest of the Patent holder.
Japan	Patent Act	Article 69(1)	A patent right shall not be effective against the working of the patented invention for experimental or research purposes.

Lao PDR	Law on Intellectual Property	No Research and Experimentation Exception	
Korea (Democratic People's Republic of)	Law on Inventions	Article 33(2)	A patented science and technology may be used without the consent of the patent owner if: (2) it is used for scientific research of experiment.
Korea (Republic of)	Patent Act	Article 96(1)(i)	The effect of a patent right does not extend to any of the following subparagraphs: (i) working a patented invention for research or experimental purposes (including approval and registration of drugs under the Pharmaceutical Affairs Act and research or experiments for registration of agrochemicals under the Agrochemicals Control Act).
Macau SAR	Industrial Property Code	Article 105	The rights conferred by the patent shall not include: (b) acts performed exclusively for test or experimental purposes, including experiments in preparation for the administrative processes necessary for the approval of products by the relevant official bodies, because the industrial or commercial exploitation of those products cannot begin before checking whether the patent protecting them has lapsed.
Malaysia	Patents Act	Section 37	The rights under the patent shall extend only to acts done for industrial or commercial purposes and in particular not to acts done only for scientific research.
Maldives	No Patent Law, No Research and Experimentation Exception		
Mongolia	Patent Law	Article 18(2)2	The performance of the following acts of using

			patented inventions or industrial designs shall not constitute an infringement of the exclusive rights of patent owners: 2) use for scientific research or experimental purposes in Mongolia.
Myanmar	Patent Law[13]	Section 54	Patent rights shall not apply to the following: (b) making an invention for the purpose of experiments or research.
Nepal	Patent, Design and Trademark Act	No Research and Experimentation Exception	
Pakistan	Patents Ordinance	Article 30(5)(c)	The rights under a patent shall not extend to – c) acts done only for experimental purposes relating to a patented invention.
Philippines	Republic Act 8293, as amended	Section 72.3	The owner of a patent has no right to prevent third parties from performing, without his authorization act/s such as making, using, selling, offering for sale, or importing the patented article where the act/s consists of making or using exclusively for experimental use of the invention for scientific purposes or educational purposes and such other activities directly related to such scientific or educational experimental use
Singapore	Patents Act	Article 66(2)(b)	An act which, apart from this subsection, would constitute an infringement of a patent for an invention shall not be so (b) if it is done for experimental purposes relating to the subject-matter of the invention.
Sri Lanka	Intellectual Property Act	Section 86(1)(i)	The protected rights extend only to acts done for industrial or

[13] A new Patent Law was enacted on 11 March 2019. Provisional translation of the Patent Law, made available from Japan International Cooperation Agency (JICA).

			commercial purposes and in particular do not extend to acts done only for the purpose of scientific research.
Taiwan (Province of China)	Patent Act	Article 59(2)	The effects of an invention patent right shall not extend to the following circumstances: (2) necessary acts to exploit the invention for research or experimental purpose(s).
Thailand	Patent Act	Section 36	The preceding paragraph shall not apply to: any act for the purpose of study, research, experimentation or analysis, provided that it does not unreasonably conflict with a normal exploitation of the patent and do not unreasonably prejudice the legitimate interests of the patent owner.
Viet Nam	Law on Intellectual Property, as amended	Article 125.2/a	Owners of industrial property objects shall not have the right to prevent others from performing the following acts: a) Using inventions for purpose of evaluation, analysis, research, teaching, testing, trial production.

Source: Compiled by the author, using WIPO data[14] and original research (2019).

Three general observations can be made from the above chart.

First, all Asian jurisdictions that have a research and experimentation exception have codified the exception in their respective patent laws. Such a finding may not be surprising as the majority of the above jurisdictions follows a largely civil law tradition. However, the finding holds true also for the former British colonies such as India, Hong Kong SAR, Malaysia, Pakistan, Singapore, and Sri Lanka, where common law traditions tend to be stronger. By contrast, the research and experimentation exception to patent law evolved more through judicial precedent in countries such as Canada and the United States.

Second, all the above Asian jurisdictions that have a research and experimentation exception have not made a distinction in their patent laws that explicitly clarifies whether the exception applies to commercial or non-commercial research, or whether it applies to research/experimentation on or with a research tool. Some countries specify that the exception applies only to “scientific research”, such as Malaysia and Sri Lanka, without stipulating in the law whether this is meant to exclude commercially related research. A number of jurisdictions

[14] See http://www.wipo.int/scp/en/exceptions.

specify that the exception applies only for "experimental purposes", such as Cambodia, again without stipulating the exact scope of what constitutes "experimental" research. Some jurisdictions have also cautiously tailored their research exception to emulate the language of TRIPS Article 30, stipulating that the exception is limited to the extent that it does not unreasonably conflict with a normal exploitation of the patent and do not unreasonably prejudice the legitimate interests of the patent owner (e.g., Thailand). Thus, the major distinction between Asian jurisdictions and many jurisdictions in other parts of the world such as Europe, the Americas, and Africa is that none of the above countries have expressly either included or excluded "**commercial research**" from the scope of patent rights, nor have any of the above jurisdictions specified that their research exception applies only to research *on* the patented invention, or includes experimentation *with* it.

Third, the jurisdictions above which do not have a codified research and experimentation exception are either least developed countries (LDCs) (Bangladesh, Lao PDR, and Nepal), or as in the case of the Maldives, have relatively recently "graduated" from LDC status.

A number of the national laws cited in the chart are obtained from a WIPO survey on exceptions to patent law (see footnote 14), which also indicated that many of these jurisdictions intended not to limit the exception to non-commercial research. While these sub-regions consist mainly of developing countries, technology leaders such as China, Japan and the Republic of Korea also have chosen to maintain a research and experimentation exception that makes no distinction between commercial and non-commercial research. It should also be noted that keeping their statutory language either vague or open may enable countries to experiment with alternate approaches. One of China's domestic courts, for instance, issued in 2013 Guidelines for Judgment of Patent Infringement that encourages resolving cases using a "research on the patent" and "research with the patent" distinction.[15] Notably, these Guidelines are not binding. The WIPO surveys also indicate that the intellectual property offices of Asian jurisdictions are generally satisfied with their research and experimentation exception, though it is not clear from the surveys exactly how the IP offices came to this conclusion (although one could guess that, most likely, this is because they are not aware of litigation on their patent law research and experimentation exception, nor have they received many complaints or inquiries).

The formulations of the research and experimentation exception by countries in Asia that have them have, to date, not been challenged at WTO Dispute Settlement. While the 2003 *EC-Canada* case explicitly mentions the research exception in its decision, it is arguably *dicta*, as the actual dispute concerned the legitimacy of Canadian generic manufacturers availing of the regulatory review exception and the stockpiling exception, respectively under the TRIPS Article 30 "three-step test" (discussed in the following section). Aside from the pervasiveness of broad-based research exceptions in the region, the 2001 Doha Declaration on the TRIPS Agreement and Public Health, which affirms the right of developing countries to avail of existing flexibilities in the TRIPS Agreement to the fullest for health purposes, has likely made it more difficult for countries to challenge the formulations adopted by Asian jurisdictions.

Far more problematic, however, is the situation of countries that do not have a research and experimentation exception. At first glance, the fact that all but one of these countries are LDCs means that they have little in the way of health-related registered patents, including on medicines and diagnostics. Bangladesh, however, has a robust pharmaceutical industry that is now capable of producing generic medicines at an advanced level, both for domestic needs and for export (UNCTAD, 2011a and 2013; World Bank). The country is also producing vaccines, and one of its firms has been designated as a global sub-licensed manufacturer for

[15] Beijing Higher People's Court, Art. 123, Guidelines for Judgment of Patent Infringement, found at http://www.chinacourt.org/article/detail/2014/01/id/1175142.shtml (in Chinese only).

the Medicines Patent Pool.[16] A major issue for this country is that, while it has stopped issuing patents for pharmaceuticals since 1 January 2008 availing of the WTO TRIPS waiver that allows all LDCs to exclude medicines from patentability as products until 2033,[17] Bangladesh had initiated a system under which patent applications can be filed and kept in a "mailbox" during the LDC waiver period as had been the case in India. Applications that had been submitted and placed in the "mailbox" include a number of prospective pharmaceutical patents (Azam, 2016). Additionally, Bangladesh is seeking to "graduate" from LDC status well ahead of the expiration of the current LDC waiver. Should its LDC status end, the country will need a robust research and experimentation exception incorporated into a new patent law. In its absence, its local pharmaceutical firms will, upon "graduation", be exposed to legal liability if they attempt to utilize patented health products or processes in R&D. The advanced level of their pharmaceutical industry means, moreover, that they will need to consider more than just introducing a Bolar exception, which is meant to deal with the early entry of generic competition after the expiration of the patent.

Of the three remaining countries without a research and experimentation exception (Lao PDR, the Maldives and Nepal), none of them have advanced domestic pharmaceutical production capabilities as such, although Nepal has a few local manufacturers that can produce relatively simple medicaments for the domestic market (UNCTAD, 2016). They are, however, countries that are rich in biodiversity and have a keen interest in protecting their genetic resources, and seeing those genetic resources utilized to develop not only medicines but also a range of health products/nutraceuticals and cosmetics, in line with international access and benefit-sharing rules. All three countries have ratified the Nagoya Protocol to the Convention on Biological Diversity, the most recent being the Maldives which became a party to the Protocol in September 2019. For these low-income countries, the absence of a research and experimentation exception is likely to act as a disincentive to conduct R&D on genetic resources found locally to the extent that domestic institutions would not be able to pay for licenses to conduct research on products based on genetic resources that are developed abroad. While local R&D is suggested as a "benefit" that can accrue from access to utilization of local genetic resources under the Annex to the Nagoya Protocol, it is included as a suggestion amidst a laundry list of possible benefits, and is not mandatory.

These countries have already started to update their intellectual property laws with a view to TRIPS compliance as WTO members and, as applicable, eventual "graduation". In this regard, the Maldives already "graduated" from LDC status in 2011 and is a WTO member, meaning that, notwithstanding the absence of a patent law, it needs to already have in place TRIPS-compliant IP legislation. While there is no requirement under the TRIPS Agreement to include a research and experimentation exception in their patent legislation, these countries may wish to take on board the approach used by other Asian countries when determining if and how they wish to include a research and experimentation exception to patent rights. In this regard, the situation in Lao PDR is especially puzzling, given that its Industrial Property Law expressly provides for a research and experimentation exception to breeders' rights in the case of plant variety protection (PVP), but has apparently elected not to include such an exception for patents.[18] The rationale as to why the country decided to incorporate only a research exception for PVPs is unclear.

[16] Beximco Pharmaceuticals Ltd. manufactures a drug under a sub-license from the Medicines Patent Pool to produce a drug for the treatment of hepatitis C developed by Bristol-Myers Squibb.
[17] WTO IP/C/73 of 15 November 2015.
[18] Lao PDR Law No. 38/NA of 15 November 2017, on Intellectual Property (2018). See article 86(2) for the research exception to plant variety protection breeders' rights.

2. THE REGULATORY REVIEW ("BOLAR") EXCEPTION

The regulatory review exception to patent rights is similarly an Article 30 exception under TRIPS. This exception allows generic manufacturers to conduct activities short of marketing approval by the national drug regulatory activity (DRA) in order that generic alternatives to medicines will be available immediately after the expiration of the patent on a pharmaceutical. Such activities may include experiments to reverse engineer the pharmaceutical in question and submitting proof of bio-equivalence of generic substitutes to the DRA, or undertaking their own clinical trials and submitting the relevant supporting data. The rationale for this exception is that since the drug approval process for generic equivalents takes time, patent owners should not be able to *de facto* extend their patents beyond the expiration date by withholding permission to conduct preparatory activities to would-be generic competitors during the patent term (UNCTAD, 2011b). It differs from the research and experimentation exception in that, depending upon how the text of the exception is worded, it can potentially cover more than just scientific research and experiments. At the same time, the scope is also narrower in that the permissible activity under the exception is limited to preparatory activities for the early entry of generics into the market after patent expiry.

The origins of the regulatory review exception lie largely in case law. The exception is also known as the "Bolar" exception taking its name from a US judicial precedent.[19] In this case, the Court of Appeals for the Federal Circuit ruled against the generic manufacturer Bolar Pharmaceutical, who was being sued by patent owner Roche. Bolar had conducted bioequivalence testing on a generic equivalent of Roche's drug flurazepam with a view to putting the generic equivalent on the market shortly after the patent's expiration. The court held that preparatory activities such as bioequivalence testing do not fall under the ambit of the research and experimentation exception since the purpose of the bioequivalence testing was clearly commercial. As mentioned above, US law on the research and experimentation exception developed largely through jurisprudence, rather than statutorily, and is limited to non-commercial research. Shortly after the decision, the US passed the Hatch-Waxman Act[20] codifying a "Bolar" exception into federal law, and effectively reversing the practice developed under the Bolar judgment.

At the international level, the regulatory review exception was upheld by a WTO Dispute Settlement panel as a valid Article 30 exception to TRIPS in the *EC-Canada* case in 2000.[21] As mentioned above, in this case, Canada's Bolar and stockpiling exceptions were challenged by the EC as overstepping the boundaries of Article 30. The Panel held that the regulatory review exception met the three-step test insofar as it was limited as it would not impact the majority of the patentee's rights of production, use and sale for commercial purposes; and that because no commercial use is made of the generic equivalent until after the expiration of the patent, the exception did not unreasonably conflict with a normal exploitation of the patent and did not unreasonably prejudice the legitimate interests of the patent owner. By contrast, the Panel held that Canada's stockpiling exception, which allowed unlimited production of patented medicines during the last six months of the patent term in order to ensure against stockouts of drugs, violated the patentee's exclusive right to make and to use the protected product during the patent term and could therefore not be considered a valid TRIPS, Article 30 exception.

As in the above section, the methodology followed for this section examines the state of the regulatory review exception to patent rights across Asian countries, using the same

[19] *Roche Products Inc. v. Bolar Pharmaceutical Co.*; 733 F.2d. 858, Fed. Cir., cert. denied 469 US 856, 1984.
[20] § 272-e-1, The Drug Price Competition and Patent Term Restoration Act [Public Law 98-417].
[21] See footnote 3.

geographical scope as in Section 1. The main difference is that Chart 2 below is limited to those countries in Asia where there are significant generic manufacturers that can take advantage of a regulatory review exception and conduct activities needed to establish bioequivalence and submit the relevant dossier to the national DRA.

Chart 2:
Regulatory Review Exceptions in Asian Patent Laws

Country	**Law**	**Provision**	**Text**[22]
Bangladesh	Patents and Designs Act	No Regulatory Review Exception	
China	Patent Law	Article 69(5)	The following shall not be deemed to be patent infringement: (5) any person who produces, uses, or imports patented drugs or patented medical apparatus and instruments, for the purpose of providing information required for administrative examination and approval, or any third party who imports patented drugs or patented medical apparatus and instruments especially for that person.
Hong Kong SAR	Patents Ordinance	No Regulatory Review Exception	
India	Patents Act	Section 107(a)	Certain acts not to be considered as infringement: For the purposes of this Act, (a) any act of making, constructing, using, selling or importing a patented invention solely for uses reasonably related to the development and submission of information required under any law for the time being in force, in India, or in a country other than India, that regulates the manufacture, construction, use, sale or import of any product.
Indonesia	Patent Law	Article 135(b)	The production of a pharmaceutical product protected by a patent in Indonesia in a period of five (5) years before the termination of the patent protection with the purpose to process the permit and to do marketing after the

[22] As with Chart 1, translations of the laws are used where the original controlling language is not in the English language.

			termination of the patent protection shall not be considered patent infringement.
Japan	Patent Act	Article 69(1)	A patent right shall not be effective against the working of the patented invention for experimental or research purposes.
Korea (Republic of)	Patent Act	Article 96(1)(i)	The effect of a patent right does not extend to any of the following subparagraphs: (i) working a patented invention for research or experimental purposes (including approval and registration of drugs under the Pharmaceutical Affairs Act and research or experiments for registration of agrochemicals under the Agrochemicals Control Act).
Malaysia	Patents Act	Section 37(1A)	The rights under the patent shall not extend to acts done to make, use, offer to sell or sell a patented invention solely for uses reasonably related to the development and submission of information to the relevant authority which regulates the manufacture, use or sale of drugs.
Pakistan	Patents Ordinance	Article 30(5)(e)	The rights under a patent shall not extend to – c) acts, including tests, necessary for the approval of a product for its commercialization after the expiration of the patent.
Philippines	Republic Act 8293, as amended	Section 72.4	The owner of a patent has no right to prevent third parties from performing, without his authorization, the acts referred to in Section 71 (making, using, offering for sale, selling or importing) of RA No 8293 in the case of drugs and medicines, where the act includes testing, using, making or selling the invention including any data related thereto, solely for purposes reasonably related to the development and

			submission of information and issuance of approvals by government regulatory agencies required under any law of the Philippines or of another country that regulates the manufacture, construction, use or sale of any product: Provided, that, in order to protect the data submitted by the original patent holder from unfair commercial use provided in Article 39.3 of the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS Agreement), the Intellectual Property Office, in consultation with the appropriate government agencies, shall issue the appropriate rules and regulations necessary therein not later than one hundred twenty (120) days after the enactment of this law.
Singapore	Patents Act	Article 66(2)(h)	An act which, apart from this subsection, would constitute an infringement of a patent for an invention shall not be so (h) if it consists of the doing of anything set out in subsection (1) in relation to the subject-matter of the patent to support any application for marketing approval for a pharmaceutical product, provided that anything produced to support the application is not — (i) made, used or sold in Singapore; or (ii) exported outside Singapore, other than for purposes related to meeting the requirements for marketing approval for that pharmaceutical product.
Sri Lanka	Intellectual Property Act	No Regulatory Review Exception	
Taiwan (Province of China)	Patent Act	Article 60	The effects of the patent right shall not extend to research and trials, including

			their practical requirements, necessary for obtaining registration and market approval of drugs under the Pharmaceutical Affairs Act or obtaining market approval of pharmaceuticals from a foreign country.
Thailand	Patent Act	Section 36(4)	The preceding paragraph shall not apply to: (4) any act concerning an application for drug registration, the applicant intending to produce, distribute or import the patented pharmaceutical product after the expiration of the patent term.
Viet Nam	Law on Intellectual Property, as amended	Article 125.2.a	Owners of industrial property objects shall not have the right to prevent others from performing the following acts: a. testing, trial production or information collection for carrying out procedures of application for licenses for production, importation, or circulation of products.

Source: Compiled by the author, using WIPO data[23] and original research (2019).

While there is a wider range of legal formulations than in the case of the research and experimentation exception in the examples above, most countries strive to include the possible activities that a potential generic manufacturer may wish to engage in short of marketing a competing product. This includes research and experimentation, trial production, information collection, bioequivalence testing and the like. Broad language is used to permit acts related to obtaining regulatory approval not only for pharmaceuticals, but also for "medical apparatus" in the case of China, which presumably includes diagnostics and devices, or any product that requires regulatory approval (Viet Nam).

There are only two countries and one region in the above dataset that do not have a regulatory review exception written into their patent legislation, namely, Bangladesh, Hong Kong SAR and Sri Lanka. As noted in the above section, Bangladesh is aware of the need to update their patent law in view of their goal of "graduating" from LDC status, when they will have to grant patents to pharmaceutical products that meet the requisite patentability criteria. Given that its pharmaceutical industry is as capable as that in many middle-income countries that produce pharmaceuticals, the need to include a regulatory review exception should be a priority for the country. Patent and pharmaceutical legislation in Hong Kong SAR remains separate from that of China, the latter of which has a regulatory review exception in their patent law. Given the advanced capabilities of some of the firms operating in the administrative region, the lack of a regulatory review exception in their patent legislation would appear to place their companies at a disadvantage with competitors in other Asian countries and regions. Sri Lanka also has an Intellectual Property Act (2003) that includes provisions for the grant of a patent, but does

[23] See http://www.wipo.int/scp/en/exceptions.

not include a regulatory review exception as a limitation to patent rights. This could be problematic as the country is attempting to improve its self-sufficiency in medicines.[24]

Other countries have a Bolar exception in their patent law, but have placed certain limitations on the exception. Indonesia, for example, limits the Bolar exception to the five years preceding the expiration of a patent, even though the Canadian Bolar exception that was upheld in the WTO decision affirming the compatibility of a regulatory review exception with TRIPS places no particular limits on when work on a competing generic could start before the expiration of a patent.[25] It is acknowledged that the Bolar exception in Indonesia's current Patent Law, however, had actually expanded the scope of the regulatory review exception, compared with before the revision was passed in 2016 by their legislature. Before then, the exception only permitted work on a competing generic product starting three years before patent expiration, and provided only a safe harbor against criminal liability. A study by UNCTAD (2011c) indicates that the minimal protections granted in the old law was a reason why Indonesian pharmaceutical manufacturers, which include some of the largest medicines firms in Asia, refrained from starting work to develop generic equivalents until only after expiration of the patent. The 2016 revisions to Indonesia's Patent Law extend the period to five years and make clear that the Bolar exception provides a shield to both civil and criminal liability.

Most countries above do not specify whether their Bolar exception applies when they are seeking marketing approval in a different country. The one that does in this dataset is India, which makes it clear that their generic firms can utilize the Bolar exception to conduct preparatory activities with a view to submitting dossiers for approval in other countries, a practice that has been upheld by India's courts.[26] By contrast, in Singapore, the exception is expressly limited to clinical testing for obtaining marketing approval domestically.

An anomaly is Japan, which subsumes its regulatory review exception within its research and experimentation exception. The scope of the Bolar exception is not entirely clear, however. While the Japanese Supreme Court has clarified that it includes at least clinical trials,[27] it is not clear whether the judgment is intended to be interpreted as encompassing all activities short of marketing. Subsuming the Bolar exception under the research and experimentation exception of Japan's patent legislation has also meant that there is apparently no limitation in subject matter, i.e., that experiments and clinical trials of medical devices and diagnostics could also conceivably be included within its scope (Johnson, 2003). Given the Government's push to increase the uptake and production of generic medicaments domestically in order to reduce healthcare costs,[28] it would be important to clarify the exact scope of permissible acts under Japanese law, as the development of this area of law has been left to be defined by court cases, as noted above.[29]

[24] See "Lanka Targets Self-Sufficiency in Pharmaceuticals", *Daily News*, 4 April 2018 (last accessed at http://www.dailynews.lk/2018/04/04/business/147480/lanka-targets-self-sufficiency-pharmaceuticals on 3 October 2019).
[25] §55.2, Patent Act of Canada.
[26] See *Bayer Corporation vs Union Of India* & Ors. (2019) and *Bayer Intellectual Property GMBH & Anr. v. Alembic Pharmaceuticals Ltd.* RFA(OS)(COMM) 6/2017, https://indiankanoon.org/doc/85364944/.
[27] *Ono Pharmaceuticals Co. Ltd. v. Kyoto Pharmaceutical Co. Ltd.*, 1998. Supreme Court Case No. Heisei 10, 153.
[28] See https://www.mhlw.go.jp/english/policy_report/2012/09/120921.html, Japan's Ministry of Health, Labor and Welfare website, last accessed on 3 October 2019.
[29] For examples of policy options for crafting a Bolar exceptions, see Correa, C. *The Bolar Exception: Legislative Models and Drafting Options*, Research Paper 66 (Geneva, South Centre, March 2016).

3. CONCLUSIONS AND RECOMMENDATIONS

Health is an important area where the public interest requires that extensive research and trials are conducted to ensure the safety and efficacy of medical technologies, including medicines and devices. Exclusive rights associated with patents no doubt help to ensure that the fruits of technology can be commercialized, but such rights are not absolute and are subject to certain exceptions. Both the research and experimentation exception and the regulatory review exception to patent rights are both important exceptions to patent rights that allow countries to preserve a balance between the exclusive rights of the owner of a technology and the wider public interest as envisaged under the Doha Declaration—in the case of the former so that a patent owner will not have the absolute discretion to impede technological progress, and in the case of the latter so that a patent owner's rights do not, *de facto*, extend beyond the 20 years during which exclusivity is granted in the case of pharmaceuticals. A key distinction between the two is that the former is intended to be broader in scope, while the latter is more typically limited to pharmaceuticals and in some cases, related health technologies such as devices and diagnostics. Both are governed, at the international level, by Article 30 of the TRIPS Agreement, and are mentioned as common exceptions to patent law in WTO dispute settlement.

To the extent that scientific progress is an area of concern to all countries, and not just those with a sizeable pharmaceutical industry, this study examined the research and experimentation exception for all countries within South, Southeast and East Asia. The comparison and contrasting of Bolar exceptions in this study was instead limited to those countries that the author considers as having a pharmaceutical industry capable of benefiting from such an exception. Both exceptions had a number of variations in text, as is permitted under TRIPS.

It is therefore worthwhile for policymakers to ask whether the scope of the exceptions in their national law is suited to its larger objectives in not only public health, but also in science, technology, and innovation, as well as in industrial development (especially in the case of pharmaceuticals). There is room to tailor and to experiment, as many jurisdictions have left their exceptions broadly defined. It is hoped that this study can give policymakers ideas on possible areas where they may wish to consider changes, such as possibly expanding the regulatory review exception beyond pharmaceuticals, or to remove distinctions between commercial and non-commercial research or between research with or on the invention in their research and experimentation exception if they should conclude that such distinctions are no longer tenable.

Noteworthy are the few jurisdictions in Asia that do not have research exceptions or Bolar exceptions in their patent law (though there is no obligation to include such exceptions in their patent legislation). While these are largely LDCs in the region that have mostly excluded pharmaceuticals from patentability as they are currently permitted to do, they will need to consider the scope of permissible exceptions to the extent that they are seeking to "graduate" from LDC status in the near term. There are other countries that may find that they are at a disadvantage when attempting to scale up their scientific and technological base. This is particularly true in the case of countries that have a significant pharmaceutical industry, or countries that hope to benefit from R&D related to their biodiversity/genetic resources. Such countries are identified in the body of the text.

Finally, it should be noted that the original text of this paper was prepared shortly before the COVID-19 pandemic.[30] If anything, the pandemic has only heightened the urgency for countries to find an appropriate scope for their research-related exceptions. Those jurisdictions seeking to manufacture their own vaccines, diagnostics, and medicines to treat COVID-19 may need to re-visit their existing policies on both the research and experimentation exception and the Bolar exception, and decide whether they need to be changed.

With respect to future research, the two exceptions examined in this study are post-grant exceptions. A more complex topic to examine across Asia is the patent exclusion of methods of medical treatment. This exclusion is specifically mentioned at the international level in TRIPS, Article 27.3(a), which states that "Members may also exclude from patentability: diagnostic, therapeutic and surgical methods for the treatment of humans or animals". The effects of this provision need to be closely examined in the light of new and emerging medical technologies that defy easy classification, and are intertwined with issues of access and the policy goal of enabling physicians to treat patients unfettered and helping them with the latest medical advances (WIPO Annex IV, 2011). Another related topic to this is how the second and later uses of a pharmaceutical compound are treated under patent law, as some jurisdictions allow the patentability of second uses through process patents, while other jurisdictions strictly prohibit the patentability of second uses. This issue is made more complex insofar as preferential trade and investment agreements sometimes include provisions requiring signatories to recognize the patentability of second and further uses. These topics are addressed by the author in subsequent papers.

Returning to the question of the research exception, the Organization for Economic Cooperation and Development (OECD) had suggested that future empirical research be done on whether the exception had an impact on investor behavior (OECD, 2006). Such a study would be difficult to design, insofar as investment decisions are generally made utilizing a combination of factors, and is unlikely to be due to a single factor such as intellectual property even in industries that are more IP-sensitive (such as pharmaceuticals and other health technologies). While it does not focus on the research and experimentation exception as such, earlier work by UNCTAD found that the evidence on the correlation between the scope of IP protection and decisions to locate an R&D investment in a developing country is mixed, at best (UNCTAD, 2005). For purposes of the Asia region, however, it may be possible to design a study to see if there may be a correlation between the scope of the research exception and decisions to locate research and development facilities in each country.

[30] An earlier version of this paper was presented at the 2nd Intellectual Property and Innovation Researchers of Asia Conference in Depok-Jakarta, Indonesia in February 2020.

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