Research Article

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The Patentability of Second and Subsequent Medical Uses in Asia’s Patent Legislation

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Abstract: This study examines, from a comparative law perspective, how jurisdictions across East, Southeast and South Asia deal with the issue of the patentability of second/subsequent medical uses. The Covid-19 pandemic highlighted the importance of subsequent medical uses of known medical compositions, as a number of medicines that are being used to treat Covid-19 were originally developed for other illnesses. The decision whether second/subsequent medical uses of pharmaceuticals are patentable in any given jurisdiction is, however, a policy decision to the extent that it is one of the main exclusions available to countries as a ‘flexibility’ under the World Trade Organization’s Agreement on Trade-related Aspects of Intellectual Property Rights (the TRIPS Agreement). The results of this study show that there is a wide variation in Asia regarding the patentability of second/subsequent uses, and examines the possible reasons for this variation. The paper concludes with recommendations for countries in the region.

Keywords: patents, pharmaceuticals, TRIPS agreement, new use of known medical substances, novelty, inventive step, Asian patent law

The findings contained in this study were first presented by the author at the 4th Intellectual Property and Innovation Researchers of Asia conference (held online, February 2022).

This paper was prepared in the author’s capacity as a Visiting Scholar at the National Graduate Institute for Policy Studies (GRIPS) in Tokyo, Japan. He is also a Legal Officer of the Division on Investment and Enterprise, United Nations Conference on Trade and Development (UNCTAD) and an Adjunct Lecturer in International Law at Hosei and Meiji Gakuin Universities. The views expressed in this paper are those of the author, and do not necessarily represent the views of any of the abovementioned institutions.

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1 The Second and Subsequent Uses of Medical Compounds

Under Article 27.1 of the TRIPS Agreement, patents are granted to applicants whose inventions are judged by patent examiners to be novel, involve an inventive step and are industrially applicable. Two distinguishing features of the TRIPS Agreement are that first, it is one of the basic treaties of the World Trade Organization (WTO), and as a result, any country that wishes to be part of the WTO must tailor their domestic intellectual property laws to meet TRIPS Agreement minimum standards unless specifically exempt, and second, that by making patents available for all inventions, whether a product or process, the TRIPS Agreement effectively overrides the ability of a country wishing to join the WTO from the leeway to exclude certain ‘inventions’ (such as pharmaceuticals and vaccines) from the scope of patentability on public health grounds. The tradeoff for the possibility to obtain a uniform 20 years of patent exclusivity from the date of application is that the technology in question must be fully disclosed, in the interests of promoting innovation by allowing others to refer to and/or build on that technology.

A straightforward reading of TRIPS, Article 27.1 in the context of medicines is that once a new pharmaceutical compound has been disclosed, then it has lost its novelty, with the result that any subsequent use of the same compound to treat a condition that is different from the one for which it had originally been developed normally would no longer be patentable. Thus, after the expiration of the patent term, generic manufacturers would theoretically be free to produce, generally at a lower cost, the same medicament without a license from the patent holder.

In the field of pharmaceutical R&D, however, existing medicines are sometimes found to treat conditions that were not originally anticipated. Some well-known examples include minoxidil, which was first developed as an anti-hypertension drug and later found to treat hair loss; pregabalin, which was developed to treat epilepsy and later approved to treat pain and anxiety; and sildenafil, more commonly known as Viagra®, which was developed to treat cardiovascular disease and later approved to treat erectile dysfunction. One study argues that fierce competition from generics and drying product development pipelines has led to increasing emphasis on ‘re-tooling’ or ‘tweaking’ existing medications by large R&D-based pharmaceutical firms as a business model (Baghwat et al. 2016). Even if one were to discount this argument, to be approved for marketing by drug regulatory authorities, those wishing to market an existing compound for a new use would need to show data that establishes both the safety and efficacy for that new use, which means that potentially costly clinical trials will need to be conducted.
While novel vaccines and therapeutics continue to be developed as of the date of this manuscript, the current Covid-19 pandemic has heightened awareness of some of the challenges of developing new vaccines,¹ and a realization that drugs can sometimes be ‘re-tooled’ for different purposes. The drug remdesivir was originally developed as an anti-viral to be used in the treatment of Ebola, but has since been approved in a number of countries to treat symptoms of Covid-19. The US Food and Drug Administration (FDA) has also approved for emergency use the rheumatoid arthritis drug baricitinib for the treatment of Covid-19. Since the timeline to develop new medicines can often be 10 years or more (Rick 2014), it would make sense that pharmaceutical companies would look to test existing medications as immediately deployable arsenal when faced with an emergency pandemic situation such as with Covid-19, and it should come as no surprise, then, that owners of pharmaceutical patents will often try to seek fresh patents for new uses of existing compounds if a jurisdiction offers a way for those owners to obtain exclusive rights over second and subsequent uses (Helm 2009).

Western European countries and the US have generally been at the forefront of permitting the patentability of second/subsequent uses of existing pharmaceutical products. In order to get around the novelty bar, jurisdictions that permit such patenting have done so either by allowing applications for second and subsequent uses as a method of treatment where such methods are not excluded from patentability, or by allowing applications that claim the new use as some form of a process patent. Baghwat et al., has identified four different variations through which applicants can attempt to obtain patents on second/subsequent uses, three of which have their origins in Europe and one in the US. The former includes ‘Swiss-type’ claims (use of substance X in the manufacture/preparation of a medicament for the treatment of condition Y), ‘German-type’ or ‘bare use’ claims (use of substance X for the treatment of condition Y), and ‘purpose-limited’ claims based on the EPC 2000 format (substance X for the treatment of condition Y). The Swiss-type claim includes the term ‘manufacture’ in an attempt to distinguish the new use claim from a method of medical treatment, which is generally excluded from patentability in Europe (England). The US, unlike most of the countries in this data set, has chosen not to exclude methods of medical treatment from patentability as such, thereby allowing the submission of patent claims as a new therapeutic use. TRIPS, Article 27.3(a) explicitly permits countries to do so, and allows the straightforward filing of patent applications for second/subsequent use of an

existing medicines as a method of treatment, without including any ‘magic wording’ in the way that the claim is formulated.2

2 Methodology and Prior Research on Patentability of Second Uses

This study takes a comparative approach to the examination of how the patentability of second and subsequent medical uses is treated under domestic laws. Similar to my earlier studies on the medical treatment exclusion as well as the research/experimentation and regulatory review exceptions to patent law in Asia,3 it will address how laws, regulations, and administrative guidance across over 20 jurisdictions in East, Southeast and South Asia deal with the possibility of patenting a second/subsequent use of a medical compound (Chart 1). An attempt will be made to deduce trends if they exist, and to identify how policies in a given jurisdiction are designed to adapt to their particular situation.

Existing studies on the patentability of second/subsequent uses of medical compounds from a comparative law perspective have often been from the point of view of legal practitioners and selective in the countries covered. Notable works include Helm’s 2009 study on the enforcement of pharmaceutical patents in the US, Europe and Japan and Patent Protection for Second Medical Uses edited by J. Büling (Wolters Kluwer 2nd ed., 2016), the latter of which is designed as a guide to lawyers who deal with patent applications and litigation in the major jurisdictions where patent applications over second medical uses is likely to be submitted or contested. While comprehensive in its treatment of all possible aspects of the patentability of second medical uses, only a handful of jurisdictions from Asia (namely China, India, Japan, and Korea) are included in this book, and have been used as reference material for this paper where appropriate. While generally less comprehensive in its treatment of the topic, publicly available materials prepared by staff attorneys and uploaded onto international law firm websites generally take a similar approach.4

2 US law allows the patenting of medical procedures, with the only limitation being 35 USC §287(c), which establishes certain limits on a patent owner from enforcing his or her patent against a medical practitioner.
3 Presented at the Intellectual Property and Innovation Researchers of Asia Conference in 2021 (online) and 2020 (Depok, Jakarta, Indonesia), respectively. The latter has been published by the South Centre as a research paper in 2022.
<table>
<thead>
<tr>
<th>Country</th>
<th>Patentability</th>
<th>Statutory Provision</th>
<th>Scope</th>
</tr>
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<tbody>
<tr>
<td>Bangladesh</td>
<td>No</td>
<td>Notification of the Department of Patents, Designs and Trademarks (2008)</td>
<td>Inventions relating to pharmaceutical products are generally excluded from patentability in Bangladesh</td>
</tr>
<tr>
<td>Bhutan</td>
<td>Unclear</td>
<td>Industrial Property Act (2001)</td>
<td>Pharmaceutical products and processes are not excluded from patentability; the Industrial Property Act is silent as to whether second uses are potentially patentable</td>
</tr>
<tr>
<td>Brunei Darussalam</td>
<td>Yes</td>
<td>Patents Order (2011), Section 14(7)</td>
<td>The fact that the substance or composition forms part of the state of the art shall not prevent the invention from being taken to be new if the use of the substance or composition in any such method does not form part of the state of the art</td>
</tr>
<tr>
<td>Cambodia</td>
<td>No</td>
<td>Law on Patents, Utility Model Certificates, and Industrial Designs (2006), Article 136</td>
<td>Inventions relating to pharmaceutical products are excluded from patentability in Cambodia</td>
</tr>
<tr>
<td>China</td>
<td>Yes</td>
<td>Patent Law, Article 22.2 and Guidelines for Patent Examination, Chapter 10, Part II, Section 6.2</td>
<td>A use invention of a known product is regarded as involving an inventive step if the new use cannot be derived or expected from the structure, composition, molecular weight, known physical and chemical properties and existent use of the product, but utilizes a newly discovered property of the product and produces an unexpected technical effect^9^</td>
</tr>
<tr>
<td>Hong Kong SAR^b</td>
<td>Yes</td>
<td>Patents Ordinance (2016), Section 9(B)(5)</td>
<td>Second and subsequent uses of existing pharmaceutical products are recognized through jurisprudence (‘Swiss-type’ claims)^5^ and under a 2016 revision to the Patents Ordinance</td>
</tr>
<tr>
<td>India</td>
<td>Generally not</td>
<td>Patent Act (1970), Section 3(d)</td>
<td>The discovery of a new form of a known substance which does not result in enhancement of any efficacy, any new property or new use for a known substance or mere new use of a known process, machine or apparatus is excluded</td>
</tr>
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^1^ Medical Uses in Asia’s Patent Legislation
<table>
<thead>
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</tr>
</thead>
<tbody>
<tr>
<td>Indonesia</td>
<td>No and yes</td>
<td>Law of the Republic of Indonesia, No. 13, Article 4(f) (2016)</td>
<td>2016 revision of the Patent Law eliminates patentability of second medical uses; Patent Examination Guidelines issued by DGIPR in 2021 allow purpose-limited claims under the EPC 2000 format</td>
</tr>
<tr>
<td>Japan</td>
<td>Yes</td>
<td>Japan Patent Office, Examination Guidelines for Patent and Utility Model (2015),</td>
<td>Even if the compounds etc. of the claimed medicinal invention do not differ from the compounds etc. of the cited invention, the novelty of the claimed medicinal invention is not denied when the claimed medicinal invention and the cited invention differ in medicinal use of applying to a specific disease based on the attribute of such compounds etc.</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Part VII, Chapter 3 “Medicinal Inventions,” at. 2.2.2. (3-2-1)</td>
<td></td>
</tr>
<tr>
<td>Lao PDR</td>
<td>Unclear</td>
<td>Law on Intellectual Property (2017)</td>
<td>IP law is silent as to whether a second/subsequent use of a known substance is patentable</td>
</tr>
<tr>
<td>Korea (Democratic</td>
<td>Unclear</td>
<td>Law on Inventions (1999), Article 33(3)</td>
<td>Law on Inventions is silent as to whether a new use of a known substance is patentable, but notably, DPRK law does not exclude medical treatments as such from patentability; the exclusion does not apply to prescribed medicines, however</td>
</tr>
<tr>
<td>People’s Republic of)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Korea (Republic of)</td>
<td>Yes</td>
<td>Korea Intellectual Property Office Patent Examination Guidelines (2017)</td>
<td>Must describe the second use that is patentable independently from the use already known in the prior art (“composition/substance X for use in the treatment of disease Z” or “composition X for use as an anti-cancer treatment”)</td>
</tr>
<tr>
<td>Macau SARf</td>
<td>Unclear</td>
<td>Industrial Property Code Decree-Law No 97/99/M (1999)</td>
<td>Status unclear but IP office generally follows either Portuguese/EU or mainland China practices</td>
</tr>
<tr>
<td>Malaysia</td>
<td>Yes</td>
<td>Patents Act (1983), Section 14(4)</td>
<td>Protection of a new use for a known substance or composition is explicitly provided for if the substance or composition was not previously disclosed for use in surgery, therapy, or diagnosis (first medical use).</td>
</tr>
<tr>
<td>Maldives</td>
<td>No</td>
<td>No patent law</td>
<td>No patent law</td>
</tr>
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</table>

*Note: EPC 2000 format refers to the European Patent Convention 2000.*
<table>
<thead>
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</tr>
</thead>
<tbody>
<tr>
<td>Mongolia</td>
<td>Unclear</td>
<td>Law on Patents (1993)</td>
<td>No specific provision or guidelines for the patenting of new uses of known pharmaceutical products</td>
</tr>
<tr>
<td>Myanmar</td>
<td>No</td>
<td>Patent Law (2019)</td>
<td>Pharmaceutical products and processes are excluded from patent protection under the TRIPS waiver for LDCs</td>
</tr>
<tr>
<td>Nepal</td>
<td>Unclear</td>
<td>Industrial Property Act (1965)</td>
<td>No specific provision or guidelines for the patenting of new uses of known pharmaceutical products</td>
</tr>
<tr>
<td>Pakistan</td>
<td>No</td>
<td>Patents Ordinance (2000)</td>
<td>New or subsequent use of a known product or process is excluded subject matter</td>
</tr>
<tr>
<td>Philippines</td>
<td>Yes</td>
<td>Revised Guidelines on the Examination of Pharmaceutical Applications Involving Known Substances (2018)</td>
<td>Patent legislation generally follows the same approach as India, but the 2018 guidelines state that method of treatment claims may be amended to first medical use claim if a substance is known, but its pharmacological properties are not disclosed in the art; method of treatment claims can also be amended into a second medical use claim (i.e., a swiss-style claim) if the substance has a new therapeutic application that treats a different pathology</td>
</tr>
<tr>
<td>Singapore</td>
<td>Yes</td>
<td>Patents Act, Article 14(7)</td>
<td>In the case of an invention consisting of a substance or composition for use in a method of treatment of the human or animal body by surgery or therapy or of diagnosis practiced on the human or animal body, the fact that the substance or composition forms part of the state of the art shall not prevent the invention from being taken to be new if the use of the substance or composition in any such method does not form part of the state of the art</td>
</tr>
<tr>
<td>Sri Lanka</td>
<td>Unclear</td>
<td>Intellectual Property Act (2003)</td>
<td>No specific provision or guidelines for the patenting of new uses of known pharmaceutical products</td>
</tr>
<tr>
<td>Taiwan (Province of China)</td>
<td>Generally not</td>
<td>Taiwan Patent Examination Guidelines (2020)</td>
<td>IP office will assess whether the new use brings substantial or unexpected differences in its end use or applicable field</td>
</tr>
</tbody>
</table>
### Chart 1: (continued)

<table>
<thead>
<tr>
<th>Country</th>
<th>Patentability</th>
<th>Statutory Provision</th>
<th>Scope</th>
</tr>
</thead>
<tbody>
<tr>
<td>Thailand</td>
<td>Yes</td>
<td>Department of Intellectual Property Patent Examination Guidelines (2020)</td>
<td>a claim indicating a process or method which results in an actual/concrete outcome is considered a patentable process under the Patent Act 1999, so long as use is not directed to a method of treatment of human or animal disease under Section 9(4), which is not patentable; ‘Swiss-type’ claims will be scrutinized for sufficient disclosure.</td>
</tr>
<tr>
<td>Viet Nam</td>
<td>Generally not</td>
<td>Law on Intellectual Property (2005) and paragraphs 23.6.d and 25.5.d. (i) of Circular 01/2007/TT-BKHCN</td>
<td>Law on Intellectual Property makes no distinction between function and structure, but the IP office may be open to considering very limited instances where applications are based on novel functions, although the National Office of Intellectual Property has not specified the conditions under which a second/subsequent use of a known medicine could be patented.</td>
</tr>
</tbody>
</table>

A handful of studies also discuss the issue of the patentability of second medical uses from a policy perspective. Recent relevant research includes, for example, a 2016 study by Baghwat et al in the *Journal of Intellectual Property Rights* that reviews the practices of second medical use patenting across a number of jurisdictions globally, as well as a 2019 South Centre paper by C. Ducimitière. The South Centre publication is representative of literature that examines the policy options to limit the patenting of second and subsequent uses of known medical substances in the light of TRIPS Agreement ‘flexibilities’ available to countries that support the earlier introduction of generic medicines into the local market with a view to reducing the cost of health care, especially in developing countries. These studies also tend to be selective in the countries covered.

In this regard, the patentability of second uses is frequently discussed in the broader literature concerning the 2001 Doha Declaration on TRIPS and Public Health by international organizations, think tanks and non-governmental organizations (NGOs), including, for example, the 2005 *Resource Book on TRIPS and Development* by UNCTAD and the International Centre for Trade and Sustainable Development (ICTSD), UNCTAD’s 2011 publication *Using Intellectual Property Rights to Stimulate Local Pharmaceutical Production in Developing Countries: A Reference Guide*, and the United Nations Development Programme (UNDP) 2016 publication *Guidelines for the Examination of Patent Applications relating to Pharmaceuticals*, which updates an earlier publication of the same name originally issued by UNCTAD, ICTSD and the World Health Organization (WHO) in 2006.

The added value of this study is that this is likely the first examination of how countries and territories approach the patentability of second and subsequent medical uses in close to all the jurisdictions within a given region, allowing for a closer examination of how different governments in East, Southeast and South Asia have chosen to adapt their laws, regulations, and policies in the light of their particular circumstances. Underlying this approach is the assumption that these jurisdictions have (for the most part) made conscious decisions about how to approach this controversial issue. The study also serves as an important update to earlier studies, since legislation and regulations tend to change over time.

### 3 Findings

The present study found a variety of approaches to the patentability of second and subsequent medical uses across Asia. At one end of the spectrum, some countries adopted a blanket rule prohibiting the patentability of already known
compositions. Other countries make clear that subsequent medical uses are patentable, in many instances as process patents using some variation of a ‘Swiss-type’ or other European-type claim, subject to certain restrictions and limitations that are often found in regulations or detailed administrative guidance. A small handful of jurisdictions strictly curtail the possibility to patent but opts to deal with the issue flexibly through guidelines and administrative circulars. Lastly, other jurisdictions take an ambivalent approach which does not make clear in their legislation whether second/subsequent uses of known medicaments are patentable.

The patenting of new uses of known pharmaceutical products is not possible as a matter of law in 6 of the jurisdictions examined. Half of these countries are those that have taken advantage of the TRIPS waiver for Least Developed Countries (LDCs) that permits them to exclude all pharmaceuticals from patentability until 2033, notably Bangladesh, Cambodia, and Myanmar. In the case of the Maldives, there is no patent legislation despite being a member of the WTO. Pakistan does not allow the patenting of second/subsequent uses under its Patent Ordinance, and Indonesia, a major producer of generic medicines in Southeast Asia, barred the patenting of new uses of known pharmaceuticals in the revision to their Patent Law in 2016. Despite the revision, new guidelines issued by the country’s Directorate General for Intellectual Property (DGIP) in 2021 state, however, that purpose-limited new use applications under the EPC 2000 format would be allowed. As of the date of this manuscript, there does not appear to have been any legal challenges to the consistency of the recent guidelines with the Patent Law.

Patenting of second/subsequent uses remains very limited in the legislation of India, the Philippines, Taiwan (Province of China) and Viet Nam. The first three take an approach reflected in India’s Patent Act, Section 3(d), which excludes patents over the discovery of a new form of a known substance which does not result in enhancement of efficacy, any new property or new use for a known substance or mere new use of a known process, machine, or apparatus. Like Indonesia, however, administrative guidelines from the Intellectual Property Office of the Philippines (IPOPHL) permit the patenting of second and subsequent uses in a number of instances and, as in the case of Indonesia, there does not appear to have been any litigation challenging the inconsistency of the guidelines with existing legislation. Viet Nam has taken the position that new uses are generally not patentable, but the National Office of Intellectual Property (NOIP) may be open to considering extremely limited instances where new applications of

a known technology are based on novel functions. All these countries have strong local pharmaceutical industries that have focused largely on the manufacture of generic medicines.

The status of the patenting of second/subsequent uses of known pharmaceuticals is unclear in 7 jurisdictions examined in this study, namely, Bhutan, the Democratic People’s Republic of Korea (DPRK), Lao PDR, Macau SAR, Mongolia, Nepal, and Sri Lanka. In these cases, no sources could confirm whether or not new uses would be patentable. While they are LDCs, Bhutan, Lao PDR and Nepal do not exclude pharmaceuticals from patenting even though they are permitted to do so, but their respective laws give no guidance on the patenting of new uses of known substances as such. In the case of DPRK, it is notable that there is no exclusion for medical treatment in their patent legislation, so it is theoretically possible that the country could allow second/subsequent uses to be patented through this modality as is done in the United States. The actual practice in the country is, however, unclear. In the case of Macau SAR, while the law is not clear as to whether new uses could be patented, the authorities tend to follow the lead of either Portugal/EU or China, both of which allow the patenting of new uses.

Within the data set, the remaining 8 countries allow the patenting of second/subsequent uses of known pharmaceutical products. Of these, Brunei Darussalam, China, Hong Kong SAR, Malaysia, and Singapore have text in their respective laws that explicitly permit the patenting of new uses.

The remaining countries, i.e., China, Japan, Korea, and Thailand, have chosen to issue administrative guidelines that permit the patenting of new uses of known pharmaceutical substances without a clear statement in their patent legislation that clarifies the status of the patenting of second/subsequent uses. The guidelines specify the criteria that must be met in such patent applications. Jurisdictions that have guidelines concerning such new uses in the Asia region generally required adherence to either ‘Swiss-type’ language or the EPC 2000 ‘purpose-limited’ language in the patent application.

Some countries in the region have become a party to preferential trade and investment agreements that may limit the ability of a country to exclude the patenting of second and subsequent uses of existing pharmaceutical compounds. The most notable of these treaties is the Comprehensive and Progressive Agreement on a Trans-Pacific Partnership (CPTPP), which stipulates in Article 18.37.2 that:

> each Party confirms that patents are available for inventions claimed as at least one of the following: new uses of a known product, new methods of using a known product, or new processes of using a known product. A Party may limit those new processes to those that do not claim the use of the product as such.
While some of the signatories of the CPTPP are included in the data set for this manuscript, the above clause was later suspended from the treaty text, and the future of this and other suspended clauses of the CPTPP remains unclear at the present time. Elsewhere, in Article 18.8(1) of the 2007 US-Korea Free Trade Agreement (KORUS), the parties confirm “that patents shall be available for any new uses or methods of using a known product.” In either case, though, the text of the treaties leaves some leeway at the national level to determine how such applications would need to be formulated.

4 Policy Considerations

It is worth pausing at this juncture to reflect on why there may be such a variety of approaches to the patentability of new uses of known pharmaceutical substances across the Asia region, notwithstanding the legal ‘flexibility’ granted by the TRIPS Agreement on this issue.

Some of the reasons have already been alluded to in this paper. First, the region is home to a wide range of economies, ranging from technologically advanced and rich countries to LDCs, and all shades in between. A policy proposition that delays the entry of generic alternatives from entering the local market will no doubt be unwelcome in countries which are less able to absorb the increased cost of extending the patent monopoly on a pharmaceutical product, and especially so where both private and universal health care coverage that can cover the out-of-pocket cost of medicine is weak or insufficient. There are also significant differences in the sophistication of laws and regulations depending upon a jurisdiction’s level of development. Second, patent protection of new uses of known pharmaceutical substances is a legal concept that was born in the West (principally the US and Western Europe) and exported to Asia, sometimes through preferential trade and investment agreements such as the TPP and other bilateral agreements such as KORUS. There may be discomfort by some jurisdictions regarding what amounts to adopting a foreign legal fiction to bypass an otherwise lack of novelty, i.e., that patents on second and subsequent uses of medicines can be granted if it is considered either a method of treatment or a process patent. Third, the relative strength of the local generic manufacturing industry where one

7 Brunei Darussalam, Japan, Malaysia, Singapore, and Viet Nam. China, Korea and Taiwan (Province of China) have expressed interest in joining the CPTPP as of the date of this manuscript.
8 See Annex 2, CPTPP. The Annex 2 suspensions of various provisions related to intellectual property and investment took place as a result of the US withdrawal from the Trans-Pacific Partnership (TPP) negotiations in January 2017, and the subsequent deal with the negotiating developing countries to join and conclude the CPTPP in its place.
exists, both economically and politically, may have an impact in some jurisdictions such as India and Viet Nam, which appear to be taking a restrictive approach to the patentability of new uses. Fourth, prior research has noted some the difficulties of providing guidance on a satisfactory way of wording a patent application for new uses of existing substances where methods of medical treatment are excluded from patentability (England 2016; Helm 2009), which is the case for almost all of the countries examine in this study.

It could also be the case that the economic argument in favor of permitting the patentability of new uses of known pharmaceutical substances is not as strong as the argument for the original product patent. One researcher has suggested, for example, that there exists no good economic argument to support patents on new uses of known medicaments, and that European jurisdictions allowed the patenting of second uses largely as a concession to the R&D-based biopharmaceutical industry (Ducimitère).

The logic behind such a view tends to be as follows. The rationale for the granting of patents for inventions that meet the three respective conditions for patentability is that an exclusive monopoly of limited duration is granted to an inventor as an incentive to innovate, and in exchange, the inventor must disclose the underlying technology to allow others to build on it.9 Such incentives are thought to be necessary to the extent that in the absence of patents, technological ideas could be freely copied and lead to a less than optimal level of innovation. That the R&D-based pharmaceutical industry has relied on the exclusivity of patents as its business model to recoup costs to develop new medicines and extract profits from successful candidates is well known.10

In the case of second and subsequent uses of the same medicament, however, it could be argued that the cost of (and the incentive to invest in) most of the R&D has already been taken into consideration by the grant of the initial patent. This is not to say that there is no innovation involved in bringing a new use of an existing pharmaceutical compound to market. But with second and subsequent uses of an already known pharmaceutical, there is clearly less innovation to be incentivized as the medicament in question is not new as such, with the greatest proportion of the costs to be recouped relating to clinical trials to ascertain efficacy and safety vis-à-vis the different condition being treated, and the related costs of regulatory approvals. On the other hand, the social cost of granting patents on new uses

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9 See the World Intellectual Property Organization website (frequently asked questions on patents) at https://www.wipo.int/patents/en/faq_patents.html (last accessed on 9 October 2022).
10 See the International Federation of Pharmaceutical Manufacturers Association website at https://www.ifpma.org/subtopics/ip-2/?parentid=258 (last accessed on 9 October 2022).
would be the cost of the delay in entry of generic competition, which will generally be at a lower price to the buyer than the product under exclusivity.

From a policy making perspective, allowing the patenting of second and subsequent uses therefore needs to be seen along a continuum of various options to encourage testing the efficacy of existing pharmaceuticals in treating different conditions for which they were originally developed. While the Covid-19 pandemic has shown the importance of looking to the existing stock of medicines for possible treatments in emergency situations, there are a range of policy options to encourage pharmaceutical firms to ascertain the safety and efficacy of known substances to treat a new medical condition, of which allowing patenting of new uses is just one option. Alternatives range, for example, from government grants as in ‘Operation Warp-Speed,’ or allowing utility models or an alternate form of intellectual property such as trial data exclusivity for a duration shorter than 20 years, or not allowing any additional incentive for new uses at all, which could conversely serve as an incentive for generic manufacturers to test existing medicines for potential new uses. As patenting of new uses is not required under the TRIPS Agreement, each jurisdiction will need to weigh the relative costs and benefits of these respective options given their domestic circumstances and choose the course of action best suited to their needs. In line with the methodological orientation for comparative law studies suggested by Legrand (2021), this study shows that, given the diversity of Asia, there is unlikely to be any ‘one-size-fits-all’ policy model that can be applied throughout the region.

In this regard, it is not clear that the discovery of a new use of a known substance warrants an extra 20 years of patent protection. Allowing the patentability of new uses could effectively be interpreted to mean that the original 20 years of exclusivity granted to an applicant had been insufficient as an incentive to innovate and reward for the original product, and that an extra 20 years of exclusivity would need to be granted for that same product given its new use. While a full debate on the relative merits and disadvantages of a uniform 20 years of patent monopoly granted to applicants for all products and processes under the TRIPS Agreement is beyond the scope of this paper, it suffices to say that it should be irrelevant whether any given medicament may not have been approved for marketing by the drug regulatory authorities or successful in clinical trials, as this is generally considered a business risk that products successfully approved and marketed generally compensate for.

5 Conclusions and Recommendations

Compared with my earlier research on the research and experimentation and Bolar exceptions (Adachi 2022), and on the medical treatment exclusion in patent
legislation, respectively, there was a greater variety of approaches to the patentability of new uses of existing pharmaceutical products in Asia.

While globally there is generally agreement that such new uses could not be claimed as a product patent because the compound is already known, the TRIPS Agreement does not explicitly address the question of whether second and subsequent uses of medicines are patentable as processes (or methods of medical treatment). Nonetheless, many technologically advanced countries where pharmaceutical patents are filed have proceeded to allow such applications to proceed, including those in the Asia region. As suggested in the previous section, each jurisdiction will, however, need to decide for itself whether it makes sense to allow the patenting of second and subsequent uses of known pharmaceutical substances. The factors that will need to be taken on board are enumerated below.

1. At the heart of this debate is the central question of where a jurisdiction wishes to draw the line between what is patentable and what is not. The Covid-19 pandemic highlighted the importance of looking to the stock of known medicines for possible treatments in emergency situations, and an argument can be made that allowing such patentability is one means of incentivizing R&D and recouping costs, including fresh clinical trials that will need to be conducted to assess efficacy and safety. The question of incentivizing R&D on possible new applications of existing medicines will need to consider the option of patents alongside other incentives to bring useful medicines to the market, such as the United States’ ‘Operation Warp Speed’ in the case of Covid-19 vaccines and therapeutics.

2. On the other hand, not allowing patents over second and subsequent uses of pharmaceuticals could be seen as one way of encouraging the early generic production of medicines and thereby creating an incentive to keep prices competitive and improving access. As the Asia region is one that includes a wide range of socio-economic levels, from technologically advanced economies with efficient health care systems such as Japan and Singapore, to LDCs with only nascent health delivery systems in place, no uniform rule will neatly address the needs of every jurisdiction.

3. Although somewhat obvious, it should be kept in mind that allowing new uses to be patentable is different from letting all new uses qualify for a patent. Before adopting a rule that permits the patenting of second and subsequent uses of known pharmaceutical products, developing countries, in particular, need to carefully consider whether their patent examiners can competently assess the patentability of claimed new uses. Some new uses may fail, for instance, due to the lack of inventive step to the extent that the new use was obvious to someone who is trained in ‘the art’. Absent the technical ability of examiners to
consistently make the judgment as to when a new use merits 20 years of market exclusivity, the patent system could potentially be abused.

4. LDCs in the region that are seeking to ‘graduate’ from this status will need to consider the question of whether they intend to allow the patentability of second and subsequent uses insofar as they will be required to offer patents on pharmaceuticals under the TRIPS Agreement when they are no longer an LDC. This is especially the case where the LDC has a viable pharmaceutical industry, as is the case with Bangladesh.11

5. Several jurisdictions in the region have opted to keep the answer to the question of patentability of new uses of known pharmaceutical products vague, perhaps to leave room to experiment using circulars and other administrative guidance. This is also a viable approach, provided that overall national law complies with a country’s treaty commitments such as the TRIPS Agreement. Countries that severely restrict the patentability of new use of known substances in their patent law will need to bear in mind the possibility that such guidelines may be challenged on the grounds that it contravenes existing law, however.

6. When considering the question of the patentability of new uses of existing compounds for medical purposes, policy makers will need to take on board the effect of any preferential trade and investment agreements that may limit their policy space. Those countries currently involved in the negotiation of such agreements that contain provisions on such new use patents will need to ensure coordination of efforts between their patent offices, health officials, trade negotiators and other stakeholders.

7. For jurisdictions that are considering allowing the patenting of second and subsequent uses of known pharmaceutical productions, policy makers may wish to assess whether there is a need to address the question of the country’s policies regarding the exclusion of medical treatments from patentability. Countries and territories should be aware that policy changes to the medical treatment exclusion may, however, also impact access to health services more broadly.

References


