

# Research Synthesis: Patentability Criteria

*v1.0 researched and written by Danielle Navarro, edited by Marcela Vieira and Suerie Moon, last updated January 2020*

## Introduction

The literature around patentability criteria is rich\*, with most of the discussion focusing on secondary patents related to drugs. The majority of the identified literature was produced from 2005 onwards.

## Search terms

Patentability Criteria; Patentability Standards; Incremental Innovation: Incremental Patentability; Secondary Patents; Evergreening.

Search was conducted using a combination of search mechanisms, mainly in English, with no specific time period of publication.

## Synthesis of the literature

### TRIPS Agreement

Article 27.1 of the Trade-Related Aspects of Intellectual Property Rights Agreement ('TRIPS Agreement') provides that inventions fulfilling the following criteria are patentable: "[t]hey are new, involve an inventive step and are capable of industrial application." These are the three patentability criteria otherwise referred to as "novelty," "inventive step," and "industrial applicability." The footnote of this Article allows WTO Members to consider as equivalent concepts: "inventive step" to "non-obvious" and "capable of industrial application" to "useful" (UNCTAD and ICTSD 2005).

Prior to the application of the above-mentioned patentability criteria, the subject matter of a patent application is first assessed on the basis of whether or not it would qualify as a product or process invention in any technological field and is not otherwise excluded as a patentable subject matter. The term "invention" is not defined under the TRIPS Agreement, which effectively permits WTO Members to define this concept nationally. This "invention" qualification implies a dichotomy between this concept and that of a "discovery", and raises a significant policy concern as to the extent of patentability of the latter, especially as many national patent laws exclude "discoveries" from patentability. WTO Members are also permitted under Articles 27.2 and 27.3 to exclude certain inventions from patentable subject

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[globalhealthresearch@graduateinstitute.ch](mailto:globalhealthresearch@graduateinstitute.ch)

matter including those “necessary to protect ordre public or morality, including to protect human, animal or plant life or health” and “diagnostic, therapeutic and surgical methods for the treatment of humans or animals” (Correa 2007a).

An invention is considered new if it is not yet publicly available before the priority date of the patent application. Availability in the public is understood as any prior disclosure of the subject invention made either nationally or in any part of the world (referred to as relative or absolute novelty, respectively). Inventive step requires that the invention is not part of the “state of the art” and is not obvious for a person skilled in the art. The third criterion of industrial applicability generally requires that the invention can be produced or used in any kind of industry, including agriculture. In the U.S., the standard of utility or usefulness of an invention is applied (UNCTAD and ICTSD 2005).

The TRIPS Agreement did not define each of these requirements and instead, gave the WTO Members discretion on how to implement them in their national legislation (UNCTAD and ICTSD 2005). It has been said that the discretion to define national patentability criteria is the most significant among the measures available under the TRIPS Agreement that can be used to preserve public health interests (known as “TRIPS flexibilities” or “TRIPS safeguards”) (Velasquez 2015). In order to protect national health interests, WTO Members have been encouraged to use this flexibility to address national public health concerns, particularly in dealing with secondary or “evergreening” of patents (United Nations Secretary General’s High-Level Panel on Access to Medicines 2016; Commission on Intellectual Property Rights, Innovation and Public Health 2006).

## Secondary Patents

### Description

Patents dealing with medicines and drugs have often been classified into two types: (i) those that protect the base chemical compound, and (ii) those that protect “[m]odified forms of th[e] base compound, medical uses of a known chemical compound, combinations of known chemical compounds, particular formulations (tablets, topical forms), dosage regimens, and processes, among others,” – what is otherwise referred to in the literature as “secondary patents” (Kapczynski, Park, and Sampat 2012) or “later-issued patents” (Amin and Kesselheim 2012), or “follow-on patents” (Gurgula 2019).

Secondary patents in relation to pharmaceutical products and processes have been viewed from two contrasting angles. On the one hand, the pharmaceutical industry deems secondary patents as an integral part of their product “life cycle management”. On the other hand, secondary patents are seen as part of commercial strategies employed by industry to prolong their products’ “monopoly protection,” which are collectively referred to as “evergreening” practices (Kapczynski, Park, and Sampat 2012). Other similar or related terms used are “patent

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layering” (Bergström 2015), “strategic patenting” (Gurgula 2019), “stockpiling”, “line extension” (Dwivedi, Hallihosur, and Rangan 2010) and “product hopping” (Carrier 2019). In relation to this, Correa highlights certain legal fictions employed in different patent laws, which have possible public health repercussions and can allow secondary patents: (i) the use of the “swiss claim” form permitting the patenting of a “second use of a known product” and (ii) a “selection patent” being considered new and thus patentable even if already disclosed in a “Markush claim” patent (Correa 2014b).

### Effect of secondary patents

Correa notes the observable increase in the number of pharmaceutical patents through the years and this occurrence can be explained by lenient patentability criteria being applied on patent applications. The existence of secondary patents owned by large pharmaceutical companies effectively limit competition from generic drug companies and this in turn, can keep medicine prices high (Correa 2014a). Dwivedi, Hallihosur and Rangan discuss cases of patent evergreening strategies – 30-month FDA patent litigation stay provision, line and franchise extensions – usually employed by the large pharmaceutical companies and how these practices impact the brand originators, the generic companies and the consuming public, with the latter being deemed the “biggest loser.” They opined that while patent evergreening practices are made within legal boundaries by exploiting ambiguities in regulatory provisions, they ultimately defeat the objective of patent laws of promoting innovation and development (Dwivedi, Hallihosur, and Rangan 2010). Abbas analyzed the legitimacy of secondary patents in light of the theories used to justify the patent system and concluded that “the practice of evergreening is not consistent with any of these theories and therefore lacks any plausible justification” (Abbas 2019).

Ducimetière investigated the issue of patentability of new uses of known products, a type of secondary patent that she points to as part of “strategic patent filing from pharmaceutical companies to extend the life of existing patents, justified mainly for financial reasons”. According to the author, despite increasing acceptance both in developing and developed countries, “second medical uses do not qualify per se for patent protection and have only been protected in several jurisdictions by means of a legal fiction”. The paper highlights that patents on new uses have a “detrimental impact on generic competition and, hence, on access to medicines and public health, in particular in developing countries”. And concludes that a patent policy aligned with public health objectives should not allow for the grant of second use patents (Ducimetière 2019).

The US National Academies of Science, Engineering, and Medicine, investigated causes of high prices of prescription drugs in the US and, among other findings, found that “extensions of product exclusivity based on minor modifications to existing patents—known as “evergreening”—adversely affect consumers” (Finding 2-6). The report recommended measures “to reduce “evergreening” of drug exclusivity via new patents or extensions on

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existing drugs” to make medicines more affordable and accessible to patients (National Academies of Science, Engineering, and Medicine 2018).

Empirical studies found that secondary patents can prolong market exclusivity of patented drugs and medicines. Kapczynski, Park and Sampat analyzed a total of 1304 patents connected to 528 U.S. Food and Drug Administration (“FDA”)-approved new molecular entities (NME) (from 1988 to 2005) by coding all the patent claims therein as either a chemical compound or any of the secondary claims. Among others, they found that: (i) these NMEs involve more patents with secondary claims than patents for the chemical compounds, (ii) many “independent secondary patents” (defined as patent applications that contain only secondary claims) are filed after obtaining FDA approval as compared to patents for the chemical compounds which are mainly filed before FDA approval, and (iii) on average, patent terms of drugs are extended substantially by these independent secondary patents. They notably observed that the “[f]irms propensity to obtain independent secondary patents after drug approval increases over the sales distribution, suggesting they reflect deliberate attempts by branded firms to lengthen their monopoly for more lucrative drugs” (Kapczynski, Park, and Sampat 2012).

Gaudry analyzed new drug applications (NDA) approved by the FDA from 2000 to 2010 and found that evergreening was a common practice by pharmaceutical companies to extend the patent exclusivity period over new drugs. The author suggested that this practice is part of the strategy to recoup R&D investments incurred by the companies (Gaudry 2011). In a comprehensive study of evergreening, Feldman and Wang investigated the patents listed in FDA’s Orange Book related to all drugs on the market in the US between 2005 and 2015 (3,372 drugs) and found that “78% of the drugs associated with new patents were not new drugs, but existing ones” and that out of 106 blockbuster drugs, 72% had their patent protection extended at least once. The authors conclude that evergreening is harming innovation, since it directs pharmaceutical companies to focus their R&D investments in extending patent protection of old products rather than in developing new medicines. They suggest the adoption of the “principle of one-and-done”, by which a drug would receive only one period of exclusivity and not more (Feldman and Wang, 2017).

In Brazil, a recent study analyzed the content of 564 pharmaceutical patent applications related to 65 medicines and classified them as primary or secondary patents. They found “a ratio of 2.25 secondary applications for every primary”. The study also classified the medicines as synthetic-chemical or biological and found that the secondary:primary “ratio is higher for chemical ones (2.76) than for biological ones (1.8)” (Chaves et al. 2019). Villardi investigated the patent status in Brazil of 24 medicines used in the treatment of HIV/AIDS, finding a total of 98 patent applications. Furthering the investigation on four selected medicines, he found that secondary patent applications, if all granted, could extend the patent monopoly of abacavir by 3 years, tipranavir by 6 years, darunavir by 8 years and lopinavir/ritonavir by 9 years (Villardi 2012).

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Through patent searches done until April 2011, Amin and Kesselheim identified and analyzed 108 patent applications and grants in relation to ritonavir and lopinavir/ritonavir, which are important antiretroviral drugs. They found that these patents can prolong the period of market exclusivity for these two drugs until 2028, specifically “[t]welve years after the expiration of the patents on their base compounds and thirty-nine years after the first patents on ritonavir were filed.” They also observed possible validity challenges to some of the patents that do not seem to fulfill the “inventiveness” criteria (Amin and Kesselheim 2012).

Abud, Halla and Helmers analyzed 504 pharmaceutical patents in Chile and observed a ratio of 1 primary patent to 4 secondary patents. They further noted that private companies owned a larger proportion of these secondary patents as compared to universities or non-profit research entities, the latter having a larger share of the primary patents. They concluded that secondary patents are primarily employed by private companies to prolong their products’ market exclusivity (Abud, Hall, and Helmers 2015).

Two conference papers examined pharmaceutical patent applications in Thailand using the national patent examination guidelines that were drafted based on the 2007 ICTSD, UNCTAD and WHO guidelines. They reported the following observations: (i) 1,960 out of 2,034 patent applications between 2000 to 2010 are “evergreening” patents, mainly involving “new use of a known substance” claim, among others (Kessomboon et al. 2012) and (iii) evergreening patent applications related to 59 drugs would effectively result in 32 years of market exclusivity from 1996 to 2028 and a “cumulative market value” of about US\$283 million. Thus, if the patent examination guidelines are implemented, this could result in US\$ 283 million in possible savings (Kessomboon et al. 2014).

Looking at medicine/device product combinations, Beall, Nickerson, Kaplan and Attaran investigated patent data for 49 products, finding a total of 235 patents/applications out of which 55% were related to the device (considered as a type of secondary patent). They found that “the median additional years of patent protection afforded by device patents was 4.7 years (range: 1.3-15.2 years) (Beall, Nickerson, Kaplan and Attaran 2016).

Chandrasekharan and colleagues investigated the role of patents in limiting the ability of new manufacturers to produce vaccines in developing countries, specifically Brazil, China and India. They found “intense patenting activity for the HPV and pneumococcal vaccines that could potentially delay the entry of new manufacturers” and concluded that “increased transparency around patenting of vaccine technologies, stricter patentability criteria suited for local development needs and strengthening of IPRs management capabilities where relevant, may help reduce impediments to market entry for new manufacturers and ensure a competitive supplier base for quality vaccines at sustainably low prices” (Chandrasekharan et al 2015).

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## Mechanisms to limit secondary patents

Patent applications or grants may be challenged by third parties for failure to meet the patentability criteria, among other grounds. These proceedings are referred to as “pre-grant” or “post-grant” oppositions,<sup>1</sup> respectively, and if provided in national intellectual property laws, can reduce the number, the scope and duration of granted patents (Correa 2014a). Hemphill and Sampat’s study found that patent challenges in relation to drugs tend to be directed against “lower quality and later expiring patents”, which indicates that these challenges keep the “historical baseline of effective market life” for drugs and in effect restrict the patent evergreening strategies of firms manufacturing branded drugs (Hemphill and Sampat 2012). However, in dealing with pharmaceutical patents especially in the developing countries, Drahos argues that, it is better to take a preventive approach – i.e. by restricting the grant of questionable patents than a curative approach – i.e. by resorting to expensive litigation to invalidate the same (Drahos 2008). Some developing countries, such as India, Brazil and Argentina, have imposed specific measures to address the issue of secondary patents (B. Sampat and Shadlen 2017).

### a. Stringent Patentability Criteria

Correa opines that the stringent implementation of patentability criteria through patent examinations is a crucial policy measure available to governments to effectively limit the increasing number of patent grants and ensure that only those that qualify as inventions are patented (Correa 2014a). The results of a study (Correa 2011a) on patents granted in Argentina, Brazil, Colombia, India and South Africa between 2000 to 2008 in varying year intervals, revealed among others: (i) there is increased patenting activity for “incremental” improvements, a significant number of which having doubtful compliance as to the inventive step requirement, (ii) the application of a lenient inventive step standard have been taken advantage of by foreign rather than local entities, and (iii) oftentimes, a stricter implementation of the patentability criteria during patent examinations could have prevented the need to issue compulsory licenses (Correa 2011b).

Also, by reviewing United States and United Kingdom case law, Gurgula suggests the use of the “obvious to try with a reasonable expectation of success” standard when applying the inventive step requirement in order to screen pharmaceutical patent applications involving “follow-on inventions.” The standard works as follows: “[t]he patent can be found obvious if it can be shown that it was ‘obvious to try’ a specific route and there was a reasonable expectation of success that this would lead to a positive result” (Gurgula 2019). Holman, Minssen and Solovy argue against the view that, as compared to other pharmaceuticals,

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<sup>1</sup> There is a separate research synthesis on patent oppositions (under development).

“follow-on pharmaceutical innovation” should be considered as secondary patents and thus, warrant a stricter application of the patentability criteria. Examining U.S. and European interpretations of patentable subject matter and patentability criteria, they instead offer what they deem as “appropriate” standards for the examination of these follow-on innovations (Holman, Minssen, and Solovy 2018).

Some countries have adopted measures in their national intellectual property laws with the aim of specifically addressing the issue of secondary patents. One example of this is Section 3(d), which was introduced as an amendment to the Indian Patents Act of 1970 in 2005. This provision has three parts: (1) “[t]he discovery of a new form of a known substance; (2) the discovery of a new property or new use of a known substance; [and] (3) the use of a known process” (Park 2010). The first and third parts involve “conditional exceptions” to patenting that can still be overcome by the showing of: (i) an enhancement of the efficacy of the substance, and (ii) that a new product is produced or involves “one new reactant” at the minimum, respectively. However, the second part is an outright prohibition on the patenting of a “mere discovery of any new property or new use for a known substance” without any exception (Ali et al. 2018).

Section 3(d) is said to be a “middle ground” provision, wherein new forms of known substances, with proven advancements may still be patentable, instead of simply prohibiting all types of secondary patents. In order to be granted Indian patents, pharmaceutical products and processes must comply with the patentability criteria including Section 3(d) (Sampat and Shadlen 2018). With respect to the “efficacy” condition, the Supreme Court ruling on the Novartis case, which involved a challenge of Section 3(d), agreed with the appealed decision ruling that “enhanced efficacy” should be understood as “therapeutic efficacy,” but the latter concept was not further defined. Discussing Section 3(d) from a natural science perspective, Bergström posited that “[t]he ‘enhanced therapeutic efficacy’ test, intended to curb ‘evergreening’ and promote genuine and valuable innovation, presently leaves a narrow and in some regards random window for patenting incremental innovation”, concluding that “therapeutic” and “efficacy” are not suitable as patentability criteria (Bergström 2015).

As identified by Correa, one of the possible challenges against Section 3(d) is that it imposed an extra requirement from those provided under Article 27.1 by the TRIPS Agreement. However, he highlighted that the TRIPS Agreement granted WTO Members the flexibility to define each of the three patentability criteria. Thus, Section 3(d), even if interpreted to define the requirements of “inventive step and/or utility,” would still be consistent with Article 27.1 considering the leeway given to Members in adopting stringent, or less stringent, definitions of the patentability criteria. He further argued that a “rigorous and scientific” adherence to the inventive step criteria will yield the same outcome as countries adopting a similar Section 3(d) provision (Correa 2013). No Member has yet filed a formal dispute at the WTO on whether Section 3(d) is compatible with TRIPS.

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[globalhealthresearch@graduateinstitute.ch](mailto:globalhealthresearch@graduateinstitute.ch)

The Philippines in 2008 amended its intellectual property law to include language similar to Section 3(d) (Correa 2014a) in its non-patentable subject matter and inventive step provisions.

#### b. Patent Examination Guidelines

Velásquez notes the important, yet understudied, role of national patent offices and their implementation of the patentability criteria in the issue of access to medicines (Velasquez 2015). While there are three types of patent search and examination frameworks that may be adopted by national patent offices - namely, “formality examination only,” “formality examination and prior art” and “formality examination, prior art search and substantive examination” – the assessment of the patentability criteria, as laid down in the national patent law, is usually made during the substantive examination. The *World Intellectual Property Organization – Alternatives in Patent Search and Examination* discusses the benefits and limitations of adopting each of these patent search and examination frameworks (World Intellectual Property Organization 2014).

Correa emphasized that, while the conduct of a substantive patent examination does not guarantee adherence to the patentability criteria of granted patents, requiring a substantive examination offers a better approach against patent proliferation as compared to having no examination at all, as in the case of South Africa’s patent registration system (Correa 2014b). With respect to actual patent examination practices, Drahos discussed the influential impact of technical assistance programs sponsored by the U.S., Japan and European Patent Offices, referred to as the “Trilaterals” to the patent offices of developing countries in building “technocratic trust” of the latter with the former. He argued that this trust can lead developing country patent offices to rely on the patent examination results made by the Trilaterals and adopt patent examination practices that “[m]aintain patent-regulated pharmaceutical markets that will increase the difficulties surrounding their citizens’ access to medicines” (Drahos 2008). As an example of this, there have been numerous agreements between national patent offices for sharing of examination results, such as the PPH – Patent Prosecution Highway (“PCT-Patent Prosecution Highway Pilot (PCT-PPH and Global PPH)” n.d.), or validation agreements by which one patent office simply revalidates the patents already granted by another, such as the agreement between Tunisia and the European Patent Office (EPO) (“Validation of European Patents in Tunisia (TN) with Effect from 1 December 2017 (Official Journal October 2017)” 2017).

It is observed that national patent examination guidelines can narrowly or broadly apply patentability criteria. The *United Nations Development Programme – Guidelines for the examination of patent applications relating to pharmaceuticals* (UNDP Guidelines) provide specific guidance and recommendations to help patent examiners assess patent applications, particularly in applying the patentability criteria and dealing with the following 12 pharmaceutical patent claims: Markush claims, Selection patents, Polymorphs, Enantiomers, Salts, Ethers and esters, Compositions, Doses, Combinations, Prodrugs, Metabolites and New

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Medical Use (Correa 2016b). The Guidelines supplements the 2007 *Guidelines for the Examination of Pharmaceutical Patents: Developing a Public Health Perspective* from the International Centre for Trade and Sustainable Development, the United Nations Conference on Trade and Development and the WHO (Correa 2007b). However, Holman argued that the UNDP Guidelines adopt an “oversimplified” understanding of the 12 claims and disagreed that many of these claims are non-patentable for failure to meet the inventive step or non-obviousness requirement (Holman 2017).

Governments have adopted different practices with respect to patentability criteria. In Argentina, the 2012 Joint Regulation from Argentina’s Patent Office and Ministries of Industry and Health (Joint Resolution M1118/2012, MS546/2012, INPI107/2012) laid down patent examination guidelines on the patentability for identified types of pharmaceutical patent applications, such as salts, esters and other derivatives of known substances. Failure to meet the novelty or inventive step requirements are among the reasons for non-patentability of these pharmaceutical claims (Bensadon and Poli 2012). The adoption of the Guidelines was prompted by the observation that there were many granted patents failing to meet the patentability criteria. After the adoption of the Guidelines, the Argentinian Patent Office rejected 95% of antiretroviral patent applications according to a study by FGEP – Fundación Grupo Efecto Positivo (Vieira and Di Giano 2019). On the other end of the spectrum, the Chinese Intellectual Property Office guidelines on patent examination, which determine the patentability criteria relevant to pharmaceutical patents, are observed to allow the patentability of a wide range of pharmaceutical products, i.e. salts, combinations and “new uses” of known substances. Wang, Hu and Jia opine that this practice may negatively impact access to medicines in China (Wang, Hu, and Jia 2009).

### c. Collaborative examination process

In Brazil, the National Sanitary Regulatory Agency (ANVISA) is required by the patent law to give its “prior consent” before the grant of any pharmaceutical patent by the national patent office (INPI) in order to safeguard public health needs and assure a stringent patentability examination. This dual agency policy has been described as a strategy that “links patentability criteria in the area of pharmaceuticals to the goal of welfare-enhancing innovation in the health sector” (Drahos 2008). The adoption of similar mechanisms has been recommended by WHO as a positive measure to enhance the examination of pharmaceutical patents from a public health perspective (CIPIH/WHO, 2006, p. 134). It should be noted that ANVISA’s prior consent mechanism is applicable to all patent applications in the pharmaceutical sector, and not specifically to secondary patents.

From 2001-2012, Anvisa rejected over 400 patent applications that would have been otherwise granted by INPI. In addition, 40 per cent of the patent applications which obtained prior consent had to comply with demands such as to improve clarity or to reduce scope before being granted, therefore increasing the quality of the patents that were granted (Vieira and Di

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Giano, 2019). Kunisawa highlights the contrasting opinions of INPI and ANVISA on the patentability of inventions dealing with “second medical uses,” with the former considering that the said inventions are patentable and the latter having the opposite opinion. Considering the impact on pharmaceutical patents, she argues for a re-examination of this current patent examination practice in Brazil (Kunisawa 2009).

This prior consent requirement, initially adopted in 2001, has been opposed by the pharmaceutical companies and the national patent office (INPI) and its validity challenged, leading to changes in the role of ANVISA. It is currently considered a “third-party opinion” in the analysis of patentability, as opposed to being considered a “binding decision” as was the case initially (Vieira and Di Giano 2019). Joint Ordinance No. 1 issued by the INPI and ANVISA in 2017 changed the role of the latter in the pharmaceutical patent examination process. Under this Ordinance, INPI first conducts a “formal examination” of the application. If the applicant seeks a substantive examination afterwards, the application will then be reviewed by ANVISA for public health concerns only. If the patent application is deemed to be of public health importance, ANVISA may issue a non-binding third-party opinion on whether or not the application complies with the patentability criteria. Ultimately, the final assessment with respect to compliance with the patentability criteria lies with the INPI. Moreover, Joint Ordinance No. 2 published later in 2017 created an Interinstitutional Articulation Group tasked with building consensus between the INPI and ANVISA on the patentability criteria for the examination of pharmaceutical patents that are deemed of public health importance (Blasi 2018).

### **Efficacy of mechanisms to limit secondary patents**

Assessments of these mechanisms limiting secondary patents, mainly focusing on Section 3(d), indicate that these measures are not fully producing their expected results.

#### a. Comparative study

Sampat and Shadlen studied the impact of different mechanisms against secondary patents adopted by developing countries – specifically, Section 3(d) in India, the INPI-ANVISA dual agency patent examination in Brazil and the 2002 patent examination guidelines prohibiting patents on “second medical uses” (most of the Argentinian patents analyzed in the study fall under this category) as well as the 2012 guidelines restricting majority of secondary patents on pharmaceuticals in Argentina. This study compared a large sample of 4,765 pharmaceutical patent applications with national filings in the U.S., Japan and Europe, which do not have any specific mechanism regarding secondary patents, and their corresponding applications in India, Brazil and Argentina. By comparing primary vs. secondary grant rates in the different countries, the authors conclude that the mechanisms to restrict secondary patents had limited impact. In India and Brazil, the policies had a marginal effect on reducing the rate of

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secondary patent grants as compared to primary patent grants. In contrast, the Argentinian mechanism seems to be more effective considering a lower rate of secondary patent grants (Sampat and Shadlen 2017).

#### b. India's Section 3(d)

Park conducted an initial assessment of the implementation of India's Sections 3(d) to 3(i) by examining patent grants issued by the Chennai, Mumbai, Kolkata and Delhi Patent Offices. The study revealed that: (i) "composition/formulation" type of secondary patents composed 67% out of the 84 examined patent grants and another 19% were for claims of "new use" or "method of treatment" but worded as composition claims, (ii) the requirements of Sections 3(d) to 3(i) do not seem to be consistently applied in all the patent applications, and (iii) some of the Indian patent grants that fall within the "exclusions" had counterpart patents that were refused in the U.S. or Europe for failing to comply with the requirements of "novelty or inventive step." He recommended, among others, for clarifications on the exclusions in these provisions, through changes in the patent examination guidelines or the law, in order to prevent possible abuses (Park 2010). Further, Sampat and Amin compared the grant rates of 2,803 "twin" patent applications filed in India and Europe. With respect to patent applications that would be covered under Section 3(d), they observed that India and Europe followed the same trend, such that these applications "have a lower grant rate and a higher rejection rate than other applications." This result is interesting considering that Europe has no similar Section 3(d) provision. In this regard, India's Section 3(d), as implemented, does not seem to have resulted in a considerable difference in the rates of patent grants or rejections in Europe (Sampat and Amin 2013).

More recently, Ali et al. analyzed 2293 pharmaceutical patents granted by the Indian Patent Office from 1995 to 2016 and classified these into two groups: primary and secondary patents. They found that: (i) 1645 (72%) of these patents are secondary patents and thus, should not have been granted under the "anti-evergreening provisions" in the Indian Patents Act – specifically, Sections 3(d) and (e), (ii) 91% of these secondary patents were either "formulations, composition and combinations," (iii) 85% of these patents were granted without undergoing "[d]etailed scrutiny by the Controller." The study also identified the various ways by which the applicants overcame the objections raised against those secondary patents that underwent detailed scrutiny, including by arguing that the patent application falls under Section 3(e), which refers to "combinations" obtained through "mere admixtures", not Section 3(d) or that the provision on patentability conditions apply instead of the provisions on exceptions to patentability. Ali et al. recommended that Sections 3(d) and 3(e) be amended to expressly prohibit the grant of secondary patents by deleting the exceptions provided in the provisions (Ali et al. 2018).

Finally, analyzing the first examination reports of the Indian Patent Office, Sampat and Shadlen observed that, among others, Section 3(d): (i) is commonly invoked as a ground for

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patent application refusal with failure to meet the requirements of novelty or inventive step as objections to patent grants by patent examiners and (ii) is also being used during the examination of primary patent applications, which indicates that the provision “may be used in a way that is different from what it was designed to accomplish” (Sampat and Shadlen 2018).

### Research gaps

- Further comparative studies on patentability criteria and practices applying them to health technologies across different countries, as existing research covers only a handful of countries
- Patentability criteria applied to other health products beyond drugs.
- Impact of secondary patenting on innovation

### Cited papers with abstracts

Abbas, Muhammad Z. 2019. “Evergreening of Pharmaceutical Patents: A Blithe Disregard for the Rationale of the Patent System.” *Journal of Generic Medicines: The Business Journal for the Generic Medicines Sector* 15 (2): 53–60. <https://doi.org/10.1177/1741134319848797>.

Abstract: Evergreening of pharmaceutical patents has emerged as a serious challenge for access to affordable drugs as it aims to delay the generic competition by extending the length of the exclusivity period beyond the legitimate patent term without any considerable improvement in therapeutic benefits of the already patented pharmaceutical drug. This paper endeavours to question the legitimacy of the evergreening of pharmaceutical patents. This study applies all the recognized theories in support of the patent system – namely the ‘natural law’ or ‘natural rights’ theory, the ‘reward by monopoly’ theory, the ‘monopoly-profit incentive’ theory, the ‘exchange for secrets’ theory or the ‘contract’ theory, and the ‘prospect’ theory – to the practice of evergreening of drug patents in order to check whether or not any of these theories can be used to justify the practice. The study concludes that the practice of evergreening is not consistent with any of these theories and therefore lacks any plausible justification.

Abud, María José, Bronwyn Hall, and Christian Helmers. 2015. “An Empirical Analysis of Primary and Secondary Pharmaceutical Patents in Chile.” Edited by L. Michel Espinoza-Fonseca. *PLOS ONE* 10 (4): e0124257. <https://doi.org/10.1371/journal.pone.0124257>.

Abstract: We analyze the patent filing strategies of foreign pharmaceutical companies in Chile distinguishing between “primary” (active ingredient) and “secondary” patents (patents on modified compounds, formulations, dosages, particular medical uses, etc.). There is prior evidence that secondary patents are used by pharmaceutical originator companies in the U. S. and Europe to extend patent protection on drugs in length and breadth. Using a novel dataset that comprises all drugs registered in Chile between 1991 and 2010 as well as the corresponding patents and trademarks, we find evidence that foreign originator companies pursue similar strategies in Chile. We find a primary to secondary patents ratio of 1:4 at the

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#### CONTACT

[globalhealthresearch@graduateinstitute.ch](mailto:globalhealthresearch@graduateinstitute.ch)

drug-level, which is comparable to the available evidence for Europe; most secondary patents are filed over several years following the original primary patent and after the protected active ingredient has obtained market approval in Chile. This points toward effective patent term extensions through secondary patents. Secondary patents dominate “older” therapeutic classes like anti-ulcer and anti-depressants. In contrast, newer areas like anti-virals and anti-neoplastics (anti-cancer) have a much larger share of primary patents.

Ali, Feroz, Sudarsan Rajagopal, Venkata S. Raman, and Roshan John. 2018. “Pharmaceutical Patent Grants in India: How Our Safeguards against Evergreening Have Failed, and Why the System Must Be Reformed.” *accessibsa*. <https://www.accessibsa.org/media/2018/04/Pharmaceutical-Patent-Grants-in-India.pdf>.

Abstract: Not available

Amin, Tahir, and Aaron S. Kesselheim. 2012. “Secondary Patenting Of Branded Pharmaceuticals: A Case Study Of How Patents On Two HIV Drugs Could Be Extended For Decades.” *Health Affairs* 31 (10): 2286–94. <https://doi.org/10.1377/hlthaff.2012.0107>.

Abstract: Pharmaceutical manufacturers rely on patents to protect their intellectual property and often seek to extend market exclusivity for their products to maximize their return on investment. One method is by obtaining patents on features other than the original active drug ingredient, including secondary patents on alternate formulations of the drug or on methods of administration. This article examines how secondary patents can extend market exclusivity and thus delay generic competition, using as an example two key antiretroviral drugs for the management of HIV: ritonavir (Norvir) and lopinavir/ritonavir (Kaletra). We identified 108 patents, which together could delay generic competition until at least 2028—twelve years after the expiration of the patents on the drugs’ base compounds and thirty-nine years after the first patents on ritonavir were filed. Some of the secondary patents that were reviewed were found to be of questionable inventiveness. We argue that increased transparency for existing patents, stricter patentability standards, and increased opportunities to challenge patent applications and patents could reduce inappropriate market exclusivity extensions on brand-name drugs and open the door to lower-cost generics.

Beall, Reed F., Jason W. Nickerson, Warren A. Kaplan, and Amir Attaran. 2016. “Is Patent ‘Evergreening’ Restricting Access to Medicine/Device Combination Products?” Edited by Heinz Fehrenbach. *PLOS ONE* 11 (2): e0148939. <https://doi.org/10.1371/journal.pone.0148939>.

Abstract: Background: Not all new drug products are truly new. Some are the result of marginal innovation and incremental patenting of existing products, but in such a way that confers no major therapeutic improvement. This phenomenon, pejoratively known as “evergreening”, can allow manufacturers to preserve market exclusivity, but without significantly bettering the standard of care. Other studies speculate that evergreening is especially problematic for medicine/device combination products, because patents on the device component may outlast expired patents on the medicine component, and thereby keep competing, possibly less-expensive generic products off the market. Materials and

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Methods: We focused on four common conditions that are often treated by medicine/device product combinations: asthma and chronic obstructive pulmonary disease (COPD), diabetes, and severe allergic reactions. The patent data for a sample of such products (n = 49) for treating these conditions was extracted from the United States Food and Drug Administration's Orange Book. Additional patent-related data (abstracts, claims, etc.) were retrieved using LexisNexis TotalPatent. Comparisons were then made between each product's device patents and medicine patents. Results: Unexpired device patents exist for 90 percent of the 49 medicine/device product combinations studied, and were the only sort of unexpired patent for 14 products. Overall, 55 percent of the 235 patents found by our study were device patents. Comparing the last-to-expire device patent to that of the last-to-expire active ingredient patent, the median additional years of patent protection afforded by device patents was 4.7 years (range: 1.3–15.2 years). Conclusion: Incremental, patentable innovation in devices to extend the overall patent protection of medicine/device product combinations is very common. Whether this constitutes “evergreening” depends on whether these incremental innovations and the years of extra patent protection they confer are proportionately matched by therapeutic improvements in the standard of care, which is highly debatable.

Bensadon, Martin, and Ivan Alfredo Poli. 2012. “Prepare for Strict Rules against Pharmaceutical Patents.” *Managing Intellectual Property*, 2012. <https://heinonline.org/HOL/Page?handle=hein.journals/manintpr221&id=38&collection=journal&index=>.

Abstract: Not available

Bergström, Jenny. 2015. “The Efficiency of India’s Patent Layering Regime – Section 3(d) from Scientific Terminology to Patenting Implications.” *IIC - International Review of Intellectual Property and Competition Law* 46 (6): 665–81. <https://doi.org/10.1007/s40319-015-0375-3>.

Abstract: Amidst the controversy about promoting innovation through patents while maintaining access to medicines, India's 2005 Patents (Amendment) Act on patent layering offers a novel attempt at entering a middle path. Genuine advance is to be filtered from “evergreening” by requiring new forms of known substances to display enhanced therapeutic efficacy in order to be patentable. For this purpose, substance derivatives are presumed to be the same as the original known substance. While this heightened patentability standard for incremental innovation has been widely discussed from economic, political and legal standpoints, it has not yet been fully considered on natural scientific grounds. In this article, the Sec. 3(d) criteria “enhanced therapeutic efficacy” and the negative presumption on substance derivatives will be explored on the scientific basis of drug development in order to assess the regime's efficiency. This analysis reveals that “therapeutic” and “efficacy” are not entirely suitable as patentability criteria, while the presumption may entail undesired effects. Section 3(d) as it stands offers a novel approach to limiting evergreening and endorsing some incremental innovation, but much can be gained from a closer congruence between natural and legal scientific terminology in the pharmaceutical patenting context. A few interpretive adaptations are proposed to further fine-tune it to this end.

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Blasi, Gabriel Di. 2018. "Reaching a Milestone in Pharmaceutical Patenting in Brazil." *Pharmaceutical Patent Analyst* 7 (6): 229–33. <https://doi.org/10.4155/ppa-2018-0025>.

Abstract: Not available

Carrier, Michael A. 2019. "PRODUCT HOPPING: THE US APPROACH." In *EU Law of Competition and Trade in the Pharmaceutical Sector*, by Pablo Figueroa and Alejandro Guerrero, 716–32. Edward Elgar Publishing. <https://doi.org/10.4337/9781785362613.00028>.

Abstract: Not available

Chaves, Gabriela Costa, Marcela Cristina Fogaca Vieira, Roberta Dorneles F. da Costa, and Mariani Nunes Sadock Vianna. 2019. *Medicines under Exclusivity Situation Funded by the Ministry of Health: Analysis of the Patent Situation and Public Procurement*. 1st ed. Rio de Janeiro, RJ, Brasil: Fundacao Oswaldo Cruz and Escola Nacional de Saude Publica Sergio Arouca. <https://accessibsa.org/media/2019/08/Medicines-under-Exclusivity-Situation-funded-by-the-Ministry-of-Health.pdf>.

Abstract: Not available

Chandrasekharan, Subhashini, Tahir Amin, Joyce Kim, Eliane Furrer, Anna-Carin Matterson, Nina Schwalbe, and Aurélia Nguyen. 2015. "Intellectual Property Rights and Challenges for Development of Affordable Human Papillomavirus, Rotavirus and Pneumococcal Vaccines: Patent Landscaping and Perspectives of Developing Country Vaccine Manufacturers." *Vaccine* 33 (46): 6366–70. <https://doi.org/10.1016/j.vaccine.2015.08.063>.

Abstract: The success of Gavi, the Vaccine Alliance depends on the vaccine markets providing appropriate, affordable vaccines at sufficient and reliable quantities. Gavi's current supplier base for new and underutilized vaccines, such as the human papillomavirus (HPV), rotavirus, and the pneumococcal conjugate vaccine is very small. There is growing concern that following globalization of laws on intellectual property rights (IPRs) through trade agreements, IPRs are impeding new manufacturers from entering the market with competing vaccines. This article examines the extent to which IPRs, specifically patents, can create such obstacles, in particular for developing country vaccine manufacturers (DCVMs). Through building patent landscapes in Brazil, China, and India and interviews with manufacturers and experts in the field, we found intense patenting activity for the HPV and pneumococcal vaccines that could potentially delay the entry of new manufacturers. Increased transparency around patenting of vaccine technologies, stricter patentability criteria suited for local development needs and strengthening of IPRs management capabilities where relevant, may help reduce impediments to market entry for new manufacturers and ensure a competitive supplier base for quality vaccines at sustainably low prices.

Commission on Intellectual Property Rights, Innovation and Public Health (CIPRH). 2006. "Public Health, Innovation and Intellectual Property Rights: Report of the Commission on Intellectual Property Rights, Innovation and Public Health." World Health Organization (WHO). <https://www.who.int/intellectualproperty/report/en/>.

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[globalhealthresearch@graduateinstitute.ch](mailto:globalhealthresearch@graduateinstitute.ch)

Abstract: Not available

Correa, Carlos. 2007a. *Trade Related Aspects of Intellectual Property Rights: A Commentary on the TRIPS Agreement*. Oxford Commentaries on International Law. Oxford; New York: Oxford University Press.

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———. 2007b. “Guidelines for the Examination of Pharmaceutical Patents: Developing a Public Health Perspective. A Working Paper.” International Centre for Trade and Sustainable Development, World Health Organization, United Nations Conference on Trade and Development. <http://apps.who.int/medicinedocs/documents/s21419en/s21419en.pdf>.

Abstract: Not available

———. 2011a. “Pharmaceutical Innovation, Incremental Patenting and Compulsory Licensing.” Colombia: Fundacion Instituto para la Investigacion del Medicamento en los Sistemas de Salud. <https://idl-bnc-idrc.dspacedirect.org/bitstream/handle/10625/47912/IDL-47912.pdf>.

Abstract: Despite in decline in the discovery of new chemical entities, there is a significant proliferation of patents on pharmaceutical products that cover minor, incremental innovations. The application of low standards of patentability does not promote innovation in pharmaceuticals in the studied countries (Argentina, Brazil, Colombia, India and South Africa) but rather the use of the patent system to delay or block generic competition. The study of patents granted in the five countries shows the acceptance of overly broad claims, an overwhelming dominance of foreign patenting and a little research and development activities regarding diseases that predominate in developing countries. Insufficient information made available on the covered products makes it difficult to monitor the process of grant and to determine the patent status of particular medicines.

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Abstract: Not available

———. 2013. “Is Section 3(d) Consistent with TRIPS?” *Economic and Political Weekly* 48 (32): 49–52.

Abstract: Not available

———. 2014a. “Tackling the Proliferation of Patents: How to Avoid Undue Limitations to Competition and the Public Domain.” Research Paper no. 52. South Centre. [https://www.southcentre.int/wp-content/uploads/2014/09/RP52\\_Tackling-the-Proliferation-of-Patents-rev\\_EN.pdf](https://www.southcentre.int/wp-content/uploads/2014/09/RP52_Tackling-the-Proliferation-of-Patents-rev_EN.pdf).

Abstract: Not available

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———. 2014b. “Patent Examination and Legal Fictions: How Rights Are Created on Feet of Clay.” Research Paper no. 58. South Centre. [https://www.southcentre.int/wp-content/uploads/2014/12/RP58\\_Patent-Examination-Legal-Fictions\\_EN.pdf](https://www.southcentre.int/wp-content/uploads/2014/12/RP58_Patent-Examination-Legal-Fictions_EN.pdf).

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Abstract: Not available

Drahos, Peter. 2008. “‘Trust Me’: Patent Offices in Developing Countries.” *American Journal of Law & Medicine* 34: 151–74. <http://go.galegroup.com/ps/i.do?p=EAJM&u=hei&id=GALE%7CA181990664&v=2.1&it=r>

Abstract: Not available

Ducimetière, Clara. 2019. “Second Medical Use Patents - Legal Treatment and Public Health Issues.” South Centre. Research Papers 101. [https://www.southcentre.int/wp-content/uploads/2019/12/RP101\\_Second-Medical-Use-Patents-Legal-Treatment-and-Public-Health-Issues\\_EN.pdf](https://www.southcentre.int/wp-content/uploads/2019/12/RP101_Second-Medical-Use-Patents-Legal-Treatment-and-Public-Health-Issues_EN.pdf).

Abstract: This paper attempts to give an overview of the debate surrounding the patentability of new therapeutic uses for known active ingredients, both in developed and developing countries. After close scrutiny of international patentability standards, this paper concludes that second medical uses do not qualify per se for patent protection and have only been protected in several jurisdictions by means of a legal fiction. The increasing acceptance of second medical use patents seems to result from strategic patent filing from pharmaceutical companies to extend the life of existing patents, justified mainly for financial reasons. However, these practices have a detrimental impact on generic competition and, hence, on the access to medicines and the public health, in particular in developing countries. Therefore, this paper argues that a sound patent policy in line with public health objectives, in particular, an enhanced access to medicines, should not allow for the grant of second medical use patents.

Dwivedi, Gaurav, Sharanabasava Hallihosur, and Latha Rangan. 2010. “Evergreening: A Deceptive Device in Patent Rights.” *Technology in Society* 32 (4): 324–30. <https://doi.org/10.1016/j.techsoc.2010.10.009>.

Abstract: Patents are the most important way by which inventors can protect their invention and the income that might derive from innovations developed in return for the full disclosure that enters into public domain after expiration of the patent term. In certain domains,

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monopolies over patent rights are being extended beyond the patent period, particularly in high-revenue-earning pharmaceutical sectors. This article presents evergreening strategies that are regularly employed by the giant branded pharmaceutical firms as a tactic to bypass existing patent laws and limit generic competition in the marketplace. The article examines the implications of evergreening for different stakeholders, including branded and generic drug companies and consumers. Problems that arise due to evergreening are also discussed. The frequency of such strategies necessitates strong patent interpretations that are protective of the spirit of patent laws.

Feldman, Robin, and Connie Wang. 2017. "May Your Drug Price Be Ever Green." SSRN Electronic Journal. <https://doi.org/10.2139/ssrn.3061567>.

Abstract: Presenting the first comprehensive study of evergreening, this article examines the extent to which evergreening behavior—which can be defined as artificially extending the protection cliff—may contribute to the problem. The author analyses all drugs on the market between 2005 and 2015, combing through 60,000 data points to examine every instance in which a company added a new patent or exclusivity. The results show a startling departure from the classic conceptualization of intellectual property protection for pharmaceuticals. Rather than creating new medicines, pharmaceutical companies are largely recycling and repurposing old ones. Specifically, 78% of the drugs associated with new patents were not new drugs, but existing ones, and extending protection is particularly pronounced among blockbuster drugs. Once companies start down the road of extending protection, they show a tendency to return to the well, with the majority adding more than one extension and 50% becoming serial offenders. The problem is growing across time.

Gaudry, Kate S. 2011. "Evergreening: A Common Practice to Protect New Drugs: The Common Strategy of Evergreening Using Patents and Other Exclusivity Periods Likely Contributes to the Total Incentives That Justify a Pharmaceutical Company's Investment in a New Drug." *Nature Biotechnology* 29 (10): 876+.

<https://link.gale.com/apps/doc/A270813255/EAIM?u=hei&sid=EAIM&xid=925ad314>

Abstract: Pharmaceutical companies using an evergreening strategy -- extend both total patent monopolies and total exclusivities granted by US Food and Drug Administration (FDA) -- complex time-evolving and scope-varying approach taken by pharmaceutical companies when pursuing exclusivity periods -- patent-associated exclusivity -- FDA-approval exclusivity - - studies show pharmaceutical companies will expand their R and D programs when they have more opportunities to make profits -- current R and D efforts partly supported by additional exclusivities offered by evergreening strategies.

Gurgula, Olga. 2019. "The 'obvious to Try' Method of Addressing Strategic Patenting: How Developing Countries Can Utilise Patent Law to Facilitate Access to Medicines." Policy brief no. 59. South Centre. [https://www.southcentre.int/wp-content/uploads/2019/04/PB59\\_The-obvious-to-try-method-of-addressing-strategic-patenting\\_EN.pdf](https://www.southcentre.int/wp-content/uploads/2019/04/PB59_The-obvious-to-try-method-of-addressing-strategic-patenting_EN.pdf).

Abstract: The current patentability standards for pharmaceutical inventions, as well as

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strategic patenting used by pharmaceutical companies, have substantially impacted access to affordable medicines. This has been especially detrimental for developing countries, which are under significant pressure to remain compliant with their international and bilateral obligations, while also providing their people with essential drugs. In order to improve access to medicines, developing countries may choose from a range of various mechanisms that may help to facilitate such access, while also allowing them to remain compliant with their international and bilateral obligations. This policy brief suggests that one of such mechanisms is to strengthen the obviousness requirement by applying the ‘obvious to try with a reasonable expectation of success’ test to pharmaceutical follow-on inventions. It is argued that the application of this test may be an effective tool in addressing the negative effect of strategic patenting. It may help to prevent the extension of patent protection and market exclusivity of existing drugs by pharmaceutical companies and, as a result, may open such medicines to generic competition.

Hemphill, C. Scott, and Bhaven N. Sampat. 2012. “Evergreening, Patent Challenges, and Effective Market Life in Pharmaceuticals.” *Journal of Health Economics* 31 (2): 327–39. <https://doi.org/10.1016/j.jhealeco.2012.01.004>.

Abstract: Observers worry that generic patent challenges are on the rise and reduce the effective market life of drugs. A related concern is that challenges disproportionately target high-sales drugs, reducing market life for these “blockbusters.” To study these questions, we examine new data on generic entry over the past decade. We show that challenges are more common for higher sales drugs. We also demonstrate a slight increase in challenges over this period, and a sharper increase for early challenges. Despite this, effective market life is stable across drug sales categories, and has hardly changed over the decade. To better understand these results, we examine which patents are challenged on each drug, and show that lower quality and later expiring patents disproportionately draw challenges. Overall, this evidence suggests that challenges serve to maintain, not reduce, the historical baseline of effective market life, thereby limiting the effectiveness of “evergreening” by branded firms.

Holman, Christopher M. 2017. “In Defense of Secondary Pharmaceutical Patents: A Response to the UN’s Guidelines for Pharmaceutical Patent Examination.” *Indiana Law Review* 50: 759. [https://papers.ssrn.com/sol3/papers.cfm?abstract\\_id=2833983](https://papers.ssrn.com/sol3/papers.cfm?abstract_id=2833983)

Abstract: In 2015 the United Nations Development Programme issued a document entitled Guidelines for Pharmaceutical Patent Examination: Examining Pharmaceutical Patents from a Public Health Perspective (the “Guidelines”). The heart of the Guidelines is a category-by-category examination of eight types of “secondary” pharmaceutical patent claims: Markush claims; selection patents; polymorphs; enantiomers; salts; ethers and esters; compositions; doses; combinations; prodrugs; metabolites; and new medical uses. The Guidelines advise patent offices to apply heightened patentability requirements to these claims in a manner that would effectively deny patent protection to important pharmaceutical innovations currently afforded patent protection. In particular, the Guidelines postulate that many forms of pharmaceutical innovation are inherently routine, and absent some sort of exceptional

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[globalhealthresearch@graduateinstitute.ch](mailto:globalhealthresearch@graduateinstitute.ch)

circumstance should be treated as obvious/non-inventive, and hence unpatentable. In my experience, however, the Guidelines' assumption that many types of pharmaceutical inventions are inherently obvious and undeserving of patent protection is incorrect, and based on an oversimplified view of how these inventions come about. This article provides an evidence-based response to the Guidelines that refutes, or at least qualifies, some of the significant conclusions and recommendations set forth by its author.

Holman, Christopher M., Timo Minssen, and Eric M. Solovy. 2018. "Patentability Standards for Follow-On Pharmaceutical Innovation." *Biotechnology Law Report* 37 (3): 131–61. <https://doi.org/10.1089/blr.2018.29073.cmh>.

Abstract: Follow-on pharmaceutical innovation occurring after the initial discovery of a drug active ingredient plays an important, but at times underappreciated, role in providing innovative solutions to compelling medical needs. Examples of follow-on innovation include new forms of a drug with improved safety-efficacy profiles, new formulations and dosages providing improved patient outcomes, and new methods of using an established drug more safely or to treat new indications. Patents play a critical role in incentivizing the research, development, testing, and ultimately commercialization of follow-on pharmaceutical innovation, and in doing so provide substantial benefits for public health and patients' quality of life. There is, however, a body of literature characterizing patents directed towards follow-on innovations as "secondary pharmaceutical patents." Some have even gone so far as to propose that the criteria for patentability should be enforced more stringently with respect to follow-on pharmaceutical inventions as compared to other inventions. The underlying assumption of such proposals is that follow-on pharmaceutical innovations are somehow secondary to other pharmaceutical innovation, and thus less deserving of patent protection. In this article, we refute the notion that follow-on pharmaceutical innovation should be categorically singled out for unfavorable treatment under the patent laws, and provide numerous examples of the value that follow-on innovation brings to medicine, and ultimately to patients. We also propose, in view of the international treaty obligations set out in, inter alia, the World Trade Organization (WTO) Agreement on Trade-Related Aspects of Intellectual Property Rights ("TRIPS Agreement"), standards and best practices for assessing the patentability of inventions arising out of follow-on pharmaceutical innovation. These are essentially the same stringent standards applicable to "primary" pharmaceutical innovation, and inventions in general. This article provides numerous examples from jurisdictions around the world in which patent offices and courts have applied the well-recognized requirements of patentability, including patent eligibility, novelty, inventive step and industrial application, to follow-on pharmaceutical inventions, and in so doing have advanced innovation in public health and ultimately the lives of patients.

Kapczynski, Amy, Chan Park, and Bhaven Sampat. 2012. "Polymorphs and Prodrugs and Salts (Oh My!): An Empirical Analysis of 'Secondary' Pharmaceutical Patents." Edited by Barbara Mintzes. *PLoS ONE* 7 (12): e49470. <https://doi.org/10.1371/journal.pone.0049470>.

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[globalhealthresearch@graduateinstitute.ch](mailto:globalhealthresearch@graduateinstitute.ch)

**Abstract:** Background: While there has been much discussion by policymakers and stakeholders about the effects of “secondary patents” on the pharmaceutical industry, there is no empirical evidence on their prevalence or determinants. Characterizing the landscape of secondary patents is important in light of recent court decisions in the U.S. that may make them more difficult to obtain, and for developing countries considering restrictions on secondary patents. Methodology/Principal Findings: We read the claims of the 1304 Orange Book listed patents on all new molecular entities approved in the U.S. between 1988 and 2005, and coded the patents as including chemical compound claims (claims covering the active molecule itself) and/or one of several types of secondary claims. We distinguish between patents with any secondary claims, and those with only secondary claims and no chemical compound claims (“independent” secondary patents). We find that secondary claims are common in the pharmaceutical industry. We also show that independent secondary patents tend to be filed and issued later than chemical compound patents, and are also more likely to be filed after the drug is approved. When present, independent formulation patents add an average of 6.5 years of patent life (95% C.I.: 5.9 to 7.3 years), independent method of use patents add 7.4 years (95% C.I.: 6.4 to 8.4 years), and independent patents on polymorphs, isomers, prodrug, ester, and/or salt claims add 6.3 years (95% C.I.: 5.3 to 7.3 years). We also provide evidence that late-filed independent secondary patents are more common for higher sales drugs. Conclusions/Significance: Policies and court decisions affecting secondary patenting are likely to have a significant impact on the pharmaceutical industry. Secondary patents provide substantial additional patent life in the pharmaceutical industry, at least nominally. Evidence that they are also more common for best-selling drugs is consistent with accounts of active “life cycle management” or “evergreening” of patent portfolios in the industry.

Kessomboon, N., U. Maleewong, K. Kijtiwatchakul, A. Eksaengsri, S. Atsawintarakun, and J. Limpananont. 2012. “Evergreening™ Patent: Playing Monopoly with Minor Incremental Development of Pharmaceuticals in Thailand.” *Research in Social and Administrative Pharmacy* 8 (6): e23–24. <https://doi.org/10.1016/j.sapharm.2012.08.055>.

**Abstract** [*only the conference abstract is publicly available*]: Objectives: To explore the situation of ‘evergreening’ of pharmaceutical patents in Thailand during 2000-2010. Methods: The pharmaceutical patent applications during 2000-2010 were re-examined by using the guideline for the examination of pharmaceutical patents in Thailand. The guideline was developed from the guideline elaborated by the International Center for Trade and Sustainable Development, the United Nations Conference on Trade and Development, and the World Health Organization (2007) and adopted from the focus group discussions among key informants including academics; the Department of Intellectual Property, Ministry of Commerce; Pharmaceutical Research and Manufacturers Association; and Thai Pharmaceutical Manufacturers Association. The patent application examiners were also standardized until reaching the almost perfect agreement among the examiners (kappa coefficient  $\frac{1}{4}$ 0.89). Results: Patents over minor incremental developments (often termed as ‘evergreening’ patents) may be used to exclude generic competition and thereby block access to affordable drugs. Of the 2,034 patent applications during 2000-2010, 1,960 were categorized

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[globalhealthresearch@graduateinstitute.ch](mailto:globalhealthresearch@graduateinstitute.ch)

as 'evergreening'. The 'evergreening' ranged from new use of a known sub-stance (73.7%), formulations (36.4%), markush claims (34.7%), and combinations (15.2%). Top three of the patent application holders, (58.2%) in Thailand were US, German, and Swiss. Only 0.5% of patent applications were from Thai companies. Conclusions: This study was presented the problems associated to the pharmaceutical patenting of minor incremental developments. The large number of patents applied for was not a reliable indicator of innovation. It means that patent strategies on pharmaceutical products in Thailand may have a direct negative impact on access to medicines by blocking generic competition. Therefore, rigorous criteria to assess the inventive step of patent applications relating to pharmaceuticals should be applied so as to ensure the patents are only granted where genuine contributions to the state of the art are made.

Kessomboon, N., U. Sutapak, K. Kijtiwatchakul, A. Eksaengsri, and S. Atsawintarangkun. 2014. "Impact of 'Evergreening' Patent Applications of Pharmaceuticals on Pharmaceutical Expenditure." *Research in Social and Administrative Pharmacy* 10 (5): e26–27. <https://doi.org/10.1016/j.sapharm.2014.07.072>.

Abstract [*only the conference abstract is publicly available*]: To estimate the impact of 'evergreening' of pharmaceutical patent applications on pharmaceutical expenditure Methods: The new guidelines for the examination of pharmaceutical patents in Thailand which was developed from the guidelines elaborated by ICTSD, UN-CTAD, and WHO 2007 and adopted following focus group discussion among academics and stakeholders. The 59-selected items of pharmaceuticals, which were examined as the pharmaceutical patenting of minor incremental developments or evergreening, were then calculated the impact on pharmaceutical expenditures. The impact was estimated based upon the difference between the discounted cumulative expenditure of the relevant market over time horizon under innovative drug scenario and generic scenario. Thereafter, we simulated the 18-year potential additional expense on the 2010 unit price of the patented and monopolized non-patented medicines. Results: The patent applications of selected 59 drugs were examined and were found to be evergreening, It would result in the monopoly market for 32 years during the year 1996-2028. The cumulative market value of the evergreen was approximately 8,477.7 million baht (US\$283 million). If we consider only the impact for 14 years monopoly during 1996-2010, the estimated lost from evergreening was 1,177.6 million baht (US\$ 39 million). Therefore, if the Department of Intellectual Property consider to use the new guidelines to examine the patent applications, potential savings will be in the total amount of 8,477.7 million baht (US\$ 283 million). Conclusions: This study has presented that patent strategies on pharmaceutical products in Thailand may have a direct negative impact on access to medicines by blocking generic competition. Therefore, rigorous criteria to assess the inventive step of patent applications relating to pharmaceuticals should be applied so as to ensure the patents are only granted where genuine contributions to the state of the art are made. Keywords: patent applications, evergreening, pharmaceutical expenditure

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#### CONTACT

[globalhealthresearch@graduateinstitute.ch](mailto:globalhealthresearch@graduateinstitute.ch)

Kunisawa, Mitsuuchi and Viviane Yumy. 2009. "Patenting Pharmaceutical Inventions on Second Medical Uses in Brazil." *The Journal of World Intellectual Property* 12 (4): 297–316. <https://doi.org/10.1111/j.1747-1796.2009.00362.x>.

Abstract: The current Brazilian industrial property law (Law 9279 of 14 May 1996) allows patents for pharmaceuticals, along with the Agreement on Trade Related Aspects of Intellectual Property Rights provisions. Since 1999, after an amendment in the legislation, two governmental authorities—the Instituto Nacional da Propriedade Industrial (INPI) and the Agência Nacional de Vigilância Sanitária (ANVISA)—have been concomitantly acting in the patent-granting procedures for pharmaceuticals. The INPI is the office usually responsible for the examination and granting of patents, and the ANVISA is the agency primarily responsible for the granting of marketing approval of drugs. In a peculiar situation, the two institutions have been responsible for the granting or denial of applications and have very often been divergent in their positions. The patentability of pharmaceutical inventions claiming second medical use is an example. The purpose of this work is to analyze the current situation of the Brazilian patent-granting system in the pharmaceutical field, with a special focus on the patentability of inventions claiming second medical use. It debates the two governmental positions and questions whether the existing conflicts are harmful to the system.

National Academies of Sciences, Engineering, and Medicine 2018. *Making Medicines Affordable: A National Imperative*. Washington, DC: The National Academies Press. <https://doi.org/10.17226/24946>.

Abstract: Over the past several decades, the biopharmaceutical sector in the United States has been successful in developing and delivering effective drugs for improving health and fighting disease, and many medical conditions that were long deemed untreatable can now be cured or managed effectively. At the same time, spending on prescription drugs has been rising dramatically, to the point that many individuals have difficulty paying for the drugs that they or their family members need. Drug costs are now a significant part of the nation's total spending on health care. A new report, *Making Medicines Affordable: A National Imperative*, from the National Academies of Sciences, Engineering, and Medicine recommends a number of actions aimed at improving the affordability of prescription drugs without discouraging continued innovation in drug development. The report looks at a number of related areas including the role of generics and biosimilars, intellectual property, financial transparency, drug advertising, as well as insurance benefit designs.

Park, Chan. 2010. "Chapter 2A: Implementation of India's Patent Law: A Review of Patents Granted by the Indian Patent Office." In *Five Years into the Product Patent Regime: India's Response*, by Sudip Chaudhuri, Chan Park, and K M Gopakumar. United Nations Development Programme. <https://doi.org/10.13140/RG.2.1.4584.0088>.

Abstract: Not available

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[globalhealthresearch@graduateinstitute.ch](mailto:globalhealthresearch@graduateinstitute.ch)

“PCT-Patent Prosecution Highway Pilot (PCT-PPH and Global PPH).” n.d. World Intellectual Property Organization. Accessed September 28, 2019. [https://www.wipo.int/pct/en/filing/pct\\_pph.html](https://www.wipo.int/pct/en/filing/pct_pph.html).

Abstract: Not available

Reis, Renata, Marcela Fogaça Vieira, and Gabriela Costa Chaves. 2009. “Access to Medicines and Intellectual Property in Brazil: A Civil Society Experience.” In *Intellectual Property Rights and Access to ARV Medicines: Civil Society Resistance in the Global South*, edited by Renata Reis, Veriano Terto Júnior, Maria Cristina Pimenta, and Associação Brasileira Interdisciplinar de AIDS. Rio de Janeiro, RJ, Brasil: ABIA.

[http://www.abiaids.org.br/\\_img/media/Intellectual\\_Property\\_internet.pdf](http://www.abiaids.org.br/_img/media/Intellectual_Property_internet.pdf)

Abstract: During the last decade the Brazilian civil society organizations have played a crucial role in the implementation and sustainability of universal access to AIDS drugs in the country. The following text intends to shed light on that experience, notably on the current effort of a group of nongovernmental organizations (NGOs) that work together in the fields of public health, HIV/AIDS, and intellectual property. This article addresses the Brazilian system of intellectual property law in respect to the country’s policy of universal access to AIDS medicines. It also presents the key working strategies of a Brazilian civil society group – GTPI/REBRIP – in tackling the main identified problems and challenges that it has identified in that regard in the field.

Sampat, B. N., and T. Amin. 2013. “How Do Public Health Safeguards in Indian Patent Law Affect Pharmaceutical Patenting in Practice?” *Journal of Health Politics, Policy and Law* 38 (4): 735–55. <https://doi.org/10.1215/03616878-2208594>.

Abstract: The 1995 Trade Related Intellectual Property Rights (TRIPS) agreement required developing countries to grant product patents in pharmaceuticals. Developing countries have since explored various measures to ameliorate potential negative effects of the new laws on public health. A prominent example is India, whose post-TRIPS patent laws include a provision, section 3(d), that restricts patents on incremental pharmaceutical innovations. Its critics and supporters alike suggest that this provision makes Indian patent law very different from that in other jurisdictions. Yet there are concerns that given resource constraints facing the Indian patent office, this novel feature of Indian patent laws on the books may not have an effect on Indian patent prosecution in practice. We test this by examining the prosecution outcomes of 2,803 applications filed in both India and Europe, coded by whether they include claims that trigger 3(d) considerations. We find that having the 3(d) provision on the books does not translate into very different patent outcomes in practice in India, relative to Europe, a jurisdiction without this provision.

Sampat, Bhaven N., and Kenneth C. Shadlen. 2018. “Indian Pharmaceutical Patent Prosecution: The Changing Role of Section 3(d).” Edited by Joshua L. Rosenbloom. *PLOS ONE* 13 (4): e0194714. <https://doi.org/10.1371/journal.pone.0194714>.

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Abstract: India, like many developing countries, only recently began to grant pharmaceutical product patents. Indian patent law includes a provision, Section 3(d), which tries to limit grant of "secondary" pharmaceutical patents, i.e. patents on new forms of existing molecules and drugs. Previous research suggests the provision was rarely used against secondary applications in the years immediately following its enactment, and where it was, was redundant to other aspects of the patent law, raising concerns that 3(d) was being under-utilized by the Indian Patent Office. This paper uses a novel data source, the patent office's first examination reports, to examine changes in the use of the provision. We find a sharp increase over time in the use of Section 3(d), including on the main claims of patent applications, though it continues to be used in conjunction with other types of objections to patentability. More surprisingly, see a sharp increase in the use of the provision against primary patent applications, contrary to its intent, raising concerns about potential over-utilization.

Sampat, Bhaven N., and Kenneth C. Shadlen. 2017. "Secondary Pharmaceutical Patenting: A Global Perspective." *Research Policy* 46 (3): 693–707. <https://doi.org/10.1016/j.respol.2017.01.005>.

Abstract: Pharmaceutical firms' use of secondary patents to extend periods of exclusivity generates concerns among policymakers worldwide. In response, some developing countries have introduced measures to curb the grant of these patents. While these measures have received considerable attention, there is limited evidence on their effectiveness. We follow a large sample of international patent applications in the US, Japan, the European Patent Office, and the corresponding filings in three developing countries with restrictions on secondary patents, India, Brazil, and Argentina. We compare primary vs. secondary grant rates across countries, consider the differential fates of "twin" applications filed in multiple countries, and across countries, and undertake detailed analyses of patent prosecution in the three developing countries. Our analyses indicate that measures to restrict secondary patents in developing countries are having limited impact. In none of these three countries are specific policies toward secondary patents the principal determinant of grant rates. Our analyses also suggest the importance of other procedural aspects of patent systems, beyond the formal policies targeting secondary applications that affect outcomes for these applications in developing countries.

UNCTAD, and ICTSD. 2005. *Resource Book on TRIPS and Development*. United States of America: Cambridge University Press. [https://unctad.org/en/PublicationsLibrary/ictsd2005d1\\_en.pdf](https://unctad.org/en/PublicationsLibrary/ictsd2005d1_en.pdf)

Abstract: Not available

United Nations Secretary General's High-Level Panel on Access to Medicines. 2016. "Report of the United Nations Secretary-General's High-Level Panel on Access to Medicines: Promoting Innovation and Access to Health Technologies." United Nations Development Programme. <http://www.unsgaccessmeds.org/final-report>.

Abstract: Not available

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“Validation of European Patents in Tunisia (TN) with Effect from 1 December 2017 (Official Journal October 2017).” 2017. European Patent Office. October 31, 2017. <https://www.epo.org/law-practice/legal-texts/official-journal/2017/10/a85.html>.

Abstract: Not available

Velasquez, German. 2015. “Guidelines on Patentability and Access to Medicines.” Research Report no. 61. South Centre. <https://www.southcentre.int/research-paper-61-march-2015/>.

Abstract: Not available

Vieira, Marcela Fogaça, and Lorena Di Giano. 2018. “Taking on the Challenge of Implementing Public Health Safeguards on the ground.” In *Routledge Handbook on the Politics of Global Health*, edited by Richard Parker and Jonathan Garcia, 1st Edition. London: Routledge. <https://www.taylorfrancis.com/books/e/9781315297255>.

Abstract: The World Health Organization estimates that the deaths of 18 million people, one-third of all deaths, are caused by treatable medical conditions. In developing countries it has been a central point of concern and action for governments and health activists. In Brazil, the response to the Human Immuno-Deficiency Virus epidemic in the 1990s was based on a public policy of providing free antiretroviral treatment for all in need, which was possible especially through the local production of affordable generic drugs by national public laboratories. Since 2001, Brazil has adopted a double-step mechanism of examination of patent applications in the pharmaceutical sector. Argentina and Brazil have adopted public health safeguards in their national laws to reduce the negative impacts of intellectual property rules on access to medicines. Civil society organisations and patients' groups have been engaged in litigation to use public health safeguards and also oppose attempts to introduce Trade Related Aspects of Intellectual Property Rights-plus provisions in the Indian law.

Villardi, Pedro. 2012. “Panorama Do Status Patentario e Registro Sanitario Dos Medicamentos Antiretrovirais No Brasil: Implicações Para o Acesso e Para a Política Industrial de Saude.” ABIA - Associação Brasileira Interdisciplinar de AIDS. [http://deolhonaspateentes.org/wp-content/uploads/2015/11/Publica%C3%A7%C3%A3o-Pedro\\_Final\\_23OUT.pdf](http://deolhonaspateentes.org/wp-content/uploads/2015/11/Publica%C3%A7%C3%A3o-Pedro_Final_23OUT.pdf).

Abstract: Not available

Wang, Xiangyu, Yuanqiong Hu, and Ping Jia. 2009. “Multi-Sector Approaches on Improving Access to ARVs in China.” In *Intellectual Property Rights and Access to ARV Medicines: Civil Society Resistance in the Global South*, edited by Renata Reis, Veriano Terto Júnior, Maria Cristina Pimenta, and Associação Brasileira Interdisciplinar de AIDS. Rio de Janeiro, RJ, Brasil: ABIA. [http://www.abiaids.org.br/\\_img/media/Intellectual\\_Property\\_internet.pdf](http://www.abiaids.org.br/_img/media/Intellectual_Property_internet.pdf)

Abstract: Since China launched its national HIV/AIDS treatment program in 2003, the issue of ARV access has become a major obstacle to expanding treatment and prolonging patients' lives. Examining the efforts and limitations of multiple stakeholders in the process of attaining full access to ARVs in China, this paper presents and analyzes the problems surrounding ARV access in China from different standpoints, focusing on the epidemic situation, capacities and

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constraints on domestic production, legal and policy barriers hampering access to ARVs, and noteworthy civil society responses and advocacy for ARV access. This paper not only describes how national stakeholders play their respective roles in the process of reaching national objectives in terms of access to ARVs, but also offers a comparative view of international stakeholders and practices respectively. This comparison in turn assists us in exploring and testing out ways for China to overcome the obstacles blocking access to ARVs.

World Intellectual Property Organization. 2014. "Alternatives in Patent Search and Examination (Policy Guide)." [https://www.wipo.int/edocs/pubdocs/en/wipo\\_pub\\_guide\\_patentsearch.pdf](https://www.wipo.int/edocs/pubdocs/en/wipo_pub_guide_patentsearch.pdf).

Abstract: Not available

World Health Organization, Regional Office for South-East Asia. 2017. "Country Experiences in Using TRIPS Safeguards: Part I." <https://apps.who.int/iris/bitstream/handle/10665/272977/Country-experiences-TRIPS-Part1.pdf?sequence=1&isAllowed=y>.

Abstract: Not available

*\* For the purposes of this review, we have established three categories to describe the state of the literature: thin, considerable, and rich.*

- *Thin: There are relatively few papers and/or there are not many recent papers and/or there are clear gaps*
- *Considerable: There are several papers and/or there are a handful of recent papers and/or there are some clear gaps*
- *Rich: There is a wealth of papers on the topic and/or papers continue to be published that address this issue area and/or there are less obvious gaps*

*Scope: While many of these issues can touch a variety of sectors, this review focuses on medicines. The term medicines is used to cover the category of health technologies, including drugs, biologics (including vaccines), and diagnostic devices.*

*Disclaimer: The research syntheses aim to provide a concise, comprehensive overview of the current state of research on a specific topic. They seek to cover the main studies in the academic and grey literature, but are not systematic reviews capturing all published studies on a topic. As with any research synthesis, they also reflect the judgments of the researchers. The length and detail vary by topic. Each synthesis will undergo open peer review, and be updated periodically based on feedback received on important missing studies and/or new research. Selected topics focus on national and international-level policies, while recognizing that other determinants of access operate at sub-national level. Work is ongoing on additional topics. We welcome suggestions on the current syntheses and/or on new topics to cover.*

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