

# Research Synthesis: Compulsory Licensing

*v1.0 researched and written by Danielle Navarro and Marcela Vieira, reviewed by Suerie Moon and Adrián Alonzo Ruiz. Copy-edited by Anna Bezruki. Last updated February 2021.*

## Introduction

The literature on compulsory licensing in the pharmaceutical sector is rich.\* Although most of the literature provides information on legal provisions and discusses compulsory licensing from a theoretical perspective, this research synthesis focuses on empirical studies of implementation of such licenses and their economic and political impacts, as well as on the possibilities associated with issuing compulsory licenses beyond the legal provisions contained in patent laws.

## Search terms

Compulsory license, government use, march-in rights and patents, pharmaceutical, Article 31*bis*, foreign direct investment, economic or political impact, Special 301 report

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

## Synthesis of the literature

Compulsory licensing is a provision that allows patents to be licensed without the authorization of the patent holder. In the context of medical products, it is considered by some to be a tool that can help address access to medicine issues, such as high prices and shortages, because it temporarily removes the exclusivity rights granted by a patent and can allow for production and/or importation from a broader range of producers. It has been, and remains, a contentious topic, as can be gleaned from the research literature.

This research synthesis broadly examines compulsory licensing in the context of pharmaceutical patents and the global intellectual property framework under the World Trade Organization's (WTO) 1994 Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS Agreement). However, the emphasis is on the literature that examines the actual implementation, uses, and effects of compulsory licenses, since these aspects of compulsory licensing seem to be less known to, and understood by, the public.

There is considerable data on the use of compulsory licenses by different countries and their effects specifically on the prices of the subject medicines. There is also information in the literature about the broader economic impacts of compulsory licenses, including on the resulting medicine prices, and especially with respect to public procurement and national expenditures. The literature identifies several continuing challenges with respect to the use and implementation of compulsory licenses, including the political pressures exerted on countries that have used, or

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

are contemplating the use of, compulsory licenses. Comparisons on the compulsory licensing policies and use in certain countries are also available. The literature also examines the use of compulsory licenses as an anti-competitive remedy. Economic analysis and modelling are also used to understand and explain compulsory licensing and its potential effects.

## Summary of the contents

This research synthesis is organized into the following topics:

1. Definitions
2. Compulsory licensing provisions
3. Guides on compulsory licensing implementation
4. Instances of compulsory license use
5. Effects on medicine prices of compulsory license use and threats
6. Economic impacts of compulsory license use
7. Challenges to compulsory licensing use
8. Country comparisons of compulsory licensing policies and use
9. Compulsory licensing as an anti-competitive remedy
10. Economic analysis and modelling of compulsory licenses
11. Useful Resources

### 1. Definitions

Compulsory licensing is the authorized use of patent rights without the patent holder's consent. It exists both at the international level, under the TRIPS Agreement, and at the national level, as included in the patent laws of most countries. Other bodies of law might also contain provisions regarding compulsory licensing, such as competition law. Some laws have compulsory license-like provisions for government use and/or "march-in rights" for government-funded inventions.

Article 31 of the TRIPS Agreement provides for other "non-voluntary" uses of the patented subject matter not falling under the exceptions to patent rights provided in Article 30 – or compulsory licensing, as they are broadly described. As provided by the TRIPS Agreement, the instances when compulsory licensing for patents may be availed of include, but are not limited to, the following: (i) "[e]mergency and extreme urgency," (ii) "[a]nti-competitive practices," (iii) "[p]ublic non-commercial use" and (iv) "[d]ependent patents." Article 31 provides for specific requirements concerning the grant of compulsory licenses. However, the determination of the grounds upon which these may be issued is left to the discretion of the member states (C. M. Correa 1999). The 2001 Ministerial Conference of the WTO adopted the *Declaration on the TRIPS Agreement and Public Health*, also known as the Doha Declaration, which further clarified that "each Member has the right to grant compulsory licences and the freedom to determine the grounds upon which such licences are granted" (paragraph 5(b)).

Article 31*bis* of the TRIPS Agreement, which entered into force on 23 January 2017, waives the "predominantly for the supply of the domestic market" requirement under Article 31(f) in cases where compulsory licenses are issued in order to manufacture and export pharmaceuticals to a least-developed member country or any other member country who has expressed its intention to be an importer under this provision. 1(b) of the Annex to the TRIPS Agreement notes that several WTO member states have indicated that they either will not use this mechanism as

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importers or will only do so for “[s]ituations of national emergency or other circumstances of extreme urgency.”

The WTO’s Glossary defines the terms as follows:

1. Compulsory Licensing – “[f]or patents, when the authorities license companies or individuals other than the patent owner to use the rights of the patent – to make, use, sell or import a product under patent (i.e., a patented product or a product made by a patented process) – without the permission of the patent owner. Allowed under the WTO’s TRIPS (intellectual property) Agreement provided certain procedures and conditions are fulfilled” (“Compulsory Licensing,” n.d.)
2. Government Use – “[f]or patents, when the government itself uses or authorizes other persons to use the rights over a patented product or process, for government purposes, without the permission of the patent owner” (“Government Use,” n.d.)

“March-in rights,” which exist in the U.S., are a kind of compulsory license. Under the Bayh-Dole Act (35 U.S. Code § 203), a U.S. Federal agency may exercise “march-in rights” over patented inventions created with federal funding assistance. Should this request for a license be denied, the Federal agency may issue a compulsory license. This measure can be used to correct patent right abuses (Bayh-Dole Act 1980) (J. Love 2014b). The said Act (35 U.S. Code § 202) further provides “royalty free rights” in favor of the U.S. Government over federally-funded patented inventions, particularly “[a] nonexclusive, nontransferrable, irrevocable, paid-up license” allowing the use of the patented matter by the Government itself, or in its place, anywhere in the world (J. Love 2017) (J. Love 2014b).

## 2. Compulsory licensing provisions

According to the 2019 World Intellectual Property Organization’s (WIPO) *Draft Reference Document on the Exception Regarding Compulsory Licensing* (Draft Reference Document), 156 countries and territories have either domestic laws or are part of a regional agreement containing provisions on compulsory licensing. The Appendix of the Draft Reference Document provided a compilation of these legal provisions (World Intellectual Property Organization, Secretariat 2019). Further, Annex II of the 2010 WIPO *Patent Related Flexibilities in the Multilateral Legal Framework and their Legislative Implementation at the National and Regional Levels* included a comparative table of national legal provisions in relation to grounds for which compulsory licenses may be issued (World Intellectual Property Organization, Secretariat 2010). Some countries have amended their laws in response to the COVID-19 pandemic, such as France, Germany and Canada, concerning the issuance of compulsory licensing (“Data Sources: COVID-19” 2020).

## 3. Guides on compulsory licensing implementation

There are a few guides available to assist with the implementation of compulsory licensing provisions. Some guides specifically address the following issues: (i) the application and issuance of compulsory licenses, (ii) the grant of government-use licenses, (iii) the legal provisions on and the implementation of compulsory licensing grounds as well as Article 31*bis*, and (iv) the determination of royalties.

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The *Guide for the Granting of Compulsory Licenses and Government Use of Pharmaceutical Patents* (Guide) offers guidelines to governments and other interested institutions on matters pertaining to (i) the application for and issuance of a compulsory license, and (ii) the grant of authorization for government use of pharmaceutical patents for the purpose of procuring medicines, whether manufactured within the issuing country or imported from others (C. M. Correa 2020a). This Guide is an updated version of the World Health Organization's (WHO) *Guide for the Application and Granting of Compulsory Licences and Authorization of Government Use of Pharmaceutical Patents* (C. Correa and World Health Organization 2009). The South Centre's *Intellectual Property Rights and the Use of Compulsory Licenses: Options for Developing Countries* examines and identifies examples of domestic law provisions in developed and developing countries as well as actual cases pertaining to the implementation and use of the following grounds for compulsory licensing (primarily dealing with patents) – refusal to deal, non-working and inadequate supply, public interest, anti-competitive practices, governmental use, facilitating the use of dependent patents, compulsory licenses for medicines, and licenses of right (C. M. Correa 1999).

The Medicines Law & Policy website provides a “model” document for an authorization of government use of a pharmaceutical patent (“Model Government Use Licences, or ‘Public Non-Commercial Use’” n.d.). The World Bank's *Compulsory Licensing for Public Health* further provides “model” documents, i.e. templates for the required notifications and suggested provisions for needed legislative amendments, for adaptation and use by countries who wish to implement the WTO General Council's 30 August 2003 Decision on Paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health (Paragraph 6 – 2003 WTO Decision) (F. M. Abbott and Van Puymbroeck 2005), which is essentially Article 31*bis* of the TRIPS Agreement.

The TRIPS Agreement allows countries to determine for themselves how to implement the Article 31 condition of providing “‘reasonable’ royalties, or ‘adequate’ remuneration.” The United Nations Development Programme (UNDP) and WHO's *Remuneration Guidelines for Non-Voluntary Use of a Patent on Medical Technologies* (Guidelines) examines, among others, the different approaches adopted by countries with respect to setting royalty payments for compulsory licensing. The Guidelines recommend the use by countries of any of the following methods for determining royalty rates: (i) “2001/UNDP guidelines” – 4% royalty rate based on generic product price ( $\pm$  2% considering other relevant factors), (ii) “1998/Japanese Patent Office guidelines” – 2 to 4% royalty rates based on generic product price ( $\pm$  2%), (iii) “2005/Canadian export guidelines” – 0.02 to 4% royalty rates based on generic product price and dependent on the UNDP Human Development Index rank of the concerned country, and (iv) “Tiered Royalty Method” – 4% royalty rate based on U.S. or European country product prices with adjustments made depending on the concerned country's “relative capacity to pay.” It also recommends the establishment of a “Medical Innovation Prize Fund” that would allocate a part of the country's budget to compensate medical products that actually address public health needs. Examples of various compulsory licensing instances not limited to pharmaceutical patents, including related cases, discussed in the Guidelines indicate that the range of royalty rates or remunerations imposed in different countries and time periods is between 0.02% to 45%, with a few royalties specified in pre-determined amounts (J. Love 2005). The TRIPS Flexibilities Database indicates the rate of royalties for Article 31 measures issued by high-income, developing and least developed countries between 2002 to 2018 to range from 0-7%. There are six identified instances of Article 31 use by Ecuador between 2013 to 2014 wherein the royalty rates were determined according to the above-mentioned Guidelines (“The TRIPS Flexibilities Database”

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

n.d.). Further, the rate of royalties imposed for compulsory licenses issued by or for developing countries between 2003 to 2014 ranged from 0.5-7% (World Health Organization Regional Office for South-East Asia 2017).

#### 4. Instances of compulsory licensing use

Several studies and documents have mapped the use of compulsory licenses for pharmaceuticals by different countries. Hein and Moon (2016) discussed the first compulsory licenses issued by developing countries and how these measures shaped the access to medicines norm. They highlighted the 2006-2008 compulsory licensing measures adopted by Thailand, which included compulsory licenses for non-AIDS drugs - particularly treatments for cancer and heart disease, and opined that such measures “[e]xpanded policy space to use TRIPS flexibilities for medicines other than antiretrovirals (ARVs), increased the political acceptability of compulsory licensing, and strengthened global norms that prioritized public health over stringent IP protection” (Hein and Moon 2016).

Son and Lee (2018) mapped 108 attempts to issue compulsory licenses for 40 pharmaceuticals in 27 countries since 1995, mostly in Asian, Latin American, and African countries and mainly for HIV/AIDS medicines (Son and Lee 2018). 't Hoen et al. (2018) gathered information on, and created a database of, potential uses of TRIPS flexibilities between 2001 and 2016 involving 89 countries. From a total of 176 occasions involving potential use of TRIPS flexibilities, they identified 100 instances involving compulsory licenses (n = 48) and government-use licenses (n = 52). 81 of these were noted to have been successfully implemented ('t Hoen et al. 2018). The Trilateral Study of the WHO, WIPO and WTO (2020) provided a table summary of 34 requests for, and issuances of, compulsory licenses and government-use licenses in 13 countries between 1995 and 2019, involving medicines for various diseases (World Health Organization, World Intellectual Property Organization, and World Trade Organization 2020).

Cherian (2016) wrote a master's thesis about the use of compulsory licenses and developed a database compiling threatened and issued cases after 1994 in varying countries, including Low, Middle and High-Income countries (Cherian 2016). Khor (2014) described the use of compulsory licenses related to medicines in Brazil, Ecuador, Ghana, India, Indonesia, Malaysia, Thailand, Zimbabwe, United States and Italy, and provided copies of the actual compulsory licenses for reference (Khor 2014). Beall and Kuhn (2012) assembled a database of 24 compulsory licensing episodes in 17 countries since 1995, most of which occurred between 2003 and 2005, involving drugs for HIV/AIDS, and in upper-middle-income countries (R. Beall and Kuhn 2012). 't Hoen (2009), as part of her book, did a study that compiled 65 letters issued by countries to drug suppliers from 2004 to 2008 to procure and import generic medicines, mainly for AIDS treatment. In analysing these letters, she identified the issuance of compulsory or government-use licenses by 16 developing country - WTO members, 2 least-developed country - WTO members and 7 countries which are not WTO members (E. F. M. 't Hoen 2009).

Love (2007) compiled compulsory licensing and government-use instances – actual issuances, threats to use, applications for issuance – citing various grounds and involving different patented technologies such as those concerning pharmaceuticals, electronics and automobiles, in North America, Europe, Asia, Latin America, Africa and Middle East (J. P. Love 2007). The U.S. was noted to have widely used compulsory licensing for various public interest needs beginning in 2004 and Europe was observed to be following a similar approach to compulsory licensing, as can be gleaned from the Knowledge Ecology International's surveys of cases in the

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

said jurisdictions (J. Love 2014c) (J. Love 2014b) (J. Love 2014a).

Rahman (2017) discussed the government-use license in Malaysia for the medicine sofosbuvir (direct-acting antiviral) and how it led, afterwards, to the inclusion of the country as part of Gilead's (the patent-holder) voluntary license agreement for the purchase of generic versions of the drug, in which Malaysia was initially excluded (Rahman 2017). The inclusion in the voluntary license agreement included not only sofosbuvir, but also other medicines for the treatment of hepatitis C produced by the same company: sofosbuvir, ledipasvir and velpatasvir (World Health Organization 2018).

In the context of the COVID-19 pandemic, in March 2020, Israel's Minister of Health granted a compulsory license for the importation of generic versions of the lopinavir/ritonavir drug exclusively for COVID-19 treatment (Balasubramaniam 2020). Soon after Israel's compulsory license issuance, AbbVie declared that: (i) it would not enforce its patent exclusivity rights worldwide for the said drug (adult and pediatric), and (ii) with respect to the Medicines Patent Pool licenses, it waived the limitations imposed on generic manufacturers with respect to providing supplies of the same drug "[a]nywhere in the world for any purpose, effective immediately [...]" AbbVie's declaration had been noted to be an unusual industry response to the grant of a compulsory license (E. 't Hoen 2020). The South Centre compiled several instances of compulsory license and government use of patented medicines in the context of the COVID-19 pandemic (South Centre 2021).

Some of the studies included in their results instances when compulsory licensing or government-use authorizations were not implemented or issued for reasons such as the patent holder having offered lower prices, having made product donations or having entered into voluntary licensing agreements ('t Hoen et al. 2018) (R. Beall and Kuhn 2012) (World Health Organization, World Intellectual Property Organization, and World Trade Organization 2020). Requests have been made for the use of march-in and royalty free rights ("Several March-In and Royalty Free Rights Cases, under the Bayh-Dole Act," n.d.), but such rights have not yet been exercised by the U.S. Government (Hemel and Ouellette 2017) (Engelberg and Kesselheim 2016) (Haile 2020).

## **5. Effects on medicine prices of compulsory license use and threats**

Several papers analysed the effects of compulsory licenses - those that have been actually issued and threatened to be issued - on medicine prices and health expenditures.

From 15 peer-reviewed papers that included price information, Urias and Ramani (2020) identified 24 actual compulsory license issuances, mostly for AIDS treatment, by eight countries (Brazil, Ecuador, India, Indonesia, Malaysia, Rwanda, Zimbabwe and Thailand) between 2003-2012 and analysed the impact of these compulsory license issuances on medicine prices. The study observed that (i) the issuance of a compulsory license "is likely" to result in price reductions for the subject patented medicines (mean range of price reductions: 66.2 to 73.9%), and (ii) the resulting price reductions were higher for medicines under compulsory licenses that pursued product procurement through importation (mean range of price reductions: 67.1 to 79.4%) as opposed to local manufacturing (mean range of price reductions: 65 to 66.8%). They concluded, with reservations, that the study results indicate that compulsory licensing does result in lower medicine prices (Urias and Ramani 2020).

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The above-mentioned book by Khor (2014) provided calculations of price reductions after the issuance of compulsory licenses. In Malaysia, the government use for ARV medicines in 2003 led to significant price reductions by the patent holders and the introduction of generics, resulting in cost savings for the Ministry of Health of 68% and 83% for selected combination of drugs, and an increased number of people under treatment, from 1,500 to 4,000. In 2004, Indonesia issued compulsory licenses for two ARVs resulting in price reductions of about 90% for lamivudine and 70% for nevirapine with the purchase of generics. In 2006-2007, Thailand issued compulsory licenses for five medicines (two for HIV, one for heart disease and two anti-cancer drugs) leading to significant reductions between the prices of the patented medicines and those of the generic versions, which were as follows: 87% for efavirenz, 67% for lopinavir/ritonavir, 98% for clopidogrel, 96% for docetaxel and 98% for letrozole. In Ghana, there was a 50% price drop with the importation of generic ARVs after the government-use license was issued in 2005 (Khor 2014). In the Annex of the United Nations Development Programme's *Using Competition Law to Promote Access to Health Technologies* (UNDP's *Using Competition Law*), Abbott et al. (2014) listed seven examples of compulsory licenses and government-use licenses for AIDS and cancer treatments issued by India, Ecuador, Thailand, Brazil, Indonesia, Malaysia between 2003 to 2012 with resulting actual and anticipated price reductions ranging from 53% to 97% (F. Abbott et al. 2014).

Another study by Mohara et al. (2012) assessed the budget impact of government-use licenses on seven patented drugs in Thailand: efavirenz, lopinavir/ritonavir combination, clopidogrel, letrozole, docetaxel, erlotinib, and imatinib. The study indicated that the use of generic drugs could save the government approximately USD 370 million over five years (Mohara et al. 2012). Tantivess, Kessomboon and Laongbua (2008) analysed the actors and factors that played a role in Thailand's issuance and implementation of the government-use licenses for efavirenz, lopinavir/ritonavir (both AIDS treatment) and clopidogrel (for heart disease) in 2006-2007. The study included an initial assessment of the impact of the government-use licenses, with results showing medicine price reductions as follows: (i) in March 2008, a bottle of generic efavirenz purchased pursuant to the government-use license was about 40% of the branded version's cost in November 2006, and (ii) in January 2008, a bottle of generic lopinavir/ritonavir purchased pursuant to the government-use license was about 50% of the branded version's cost in March 2007 (Tantivess, Kessomboon, and Laongbua 2008). After the issuance of the government-use license for sofosbuvir, the generic version of the drug was purchased by Malaysia at the price range of USD 33-35 for a 28-day treatment regimen, which is less than 1% of the 2017 originator price of USD 11,200 (World Health Organization 2018).

In Brazil, da Silva, Hallal, and Guimarães (2012) conducted a study of the economic savings and impact on the number of patients under treatment four years after the issuance of the compulsory license for the HIV-medicine efavirenz in Brazil. They observed: (i) an increase of about 55% in the number of people using the medicine, (ii) savings of public resources amounting to USD 103.5 million for the period of 2007 to 2011 with the purchase of the generic version, and (iii) a reduction in price of 69.4%, if compared to the price of the branded version of efavirenz 600mg sold by Merck before the compulsory license (da Silva, Hallal, and Guimarães 2012). Vieira et al. (2017) compared, on the one hand, the savings and timeframe for the local production of a generic version of efavirenz after the issuance of the compulsory license and, on the other hand, the potential savings and timeframe for the local production of atazanavir under a voluntary license agreement signed between the Brazilian government and Bristol-Myers Squibb, the patent holder. The findings showed that under the compulsory license, the national generic version of efavirenz was available in 21 months and resulted in savings of USD 104 million in

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five years. In contrast, the estimated savings for the purchase of atazanavir under the voluntary license would be USD 17 million in five years and it took 26 months for a national producer to obtain regulatory approval in the country (Vieira et al. 2017).

Andia (2015) analysed the effect of the global campaign for the issuance of compulsory licenses for the HIV-medicine lopinavir/ritonavir in Colombia and Ecuador and showed a price reduction by the originator company Abbott of 80% and 27%, respectively, in 2013 compared to the amounts paid by the government before the launch of the campaign. It should be noted that the price in 2013 was the same in both countries, but the previous price was higher in Colombia. The author argued that even though a compulsory license was never issued in Colombia, the campaign contributed to the adoption of a price regulation policy that led to the reduction (Andia 2015).

Beall, Kuhn and Attaran (2015) compared the prices of antiretroviral drugs that were purchased by 8 countries under compulsory licenses between 2003 and 2012, by importation and local production, to those acquired from international procurement markets by “peer countries.” Their study revealed, among other findings, that: (i) in 19 out of the 30 compulsory licensing incidents, international market prices were lower than their compulsory license counterparts and (ii) in 9 out of the 11 compulsory licenses for domestic manufacture, international market prices were lower by more than 25% than those obtained through the compulsory licenses. They explained that the “[s]tudy should not be interpreted as ideologically opposing compulsory licensing [...]” but only shows that procurement from international markets has provided cheaper price values for antiretrovirals than compulsory licensing (R. F. Beall, Kuhn, and Attaran 2015). The appropriateness of this comparison of medicine prices purchased, on the one hand, from compulsory licensing and, on the other hand, from international markets, has been questioned. Critics of this approach have argued that “international procurement” only results in low medicine prices when there are no “patent barriers” involved, which is the opposite of the situation being addressed when compulsory licenses are issued (E. 't Hoen and Bermudez 2015) (Velásquez and Schoen-Angerer 2015).

Ooms and Hanefeld (2019) noted that a threat to issue a compulsory license may facilitate access to medicines as effectively as actually issuing a compulsory license. They noted that, in 2001, patent-holder Bayer agreed to lower the price of ciprofloxacin after the U.S. and Canadian governments threatened to issue compulsory licenses in order to accumulate sufficient supplies of the drug against possible anthrax terrorist attacks (Ooms and Hanefeld 2019). In the U.S., Bayer reduced the price of ciprofloxacin by 46% (J. Love 2005). Threats to exercise march-in rights have also been used as negotiating tool by U.S. federal agencies against patent holders. As a “concession” to prevent the issuance of a compulsory license, Abbott Laboratories reduced the price of ritonavir drug by about 80% for federally-funded HIV treatments in 2004 (J. Love 2014b).

Flanagan and Whiteman (2007) studied the strategies used by Brazil to obtain price reductions for HIV treatments in spite of the opposition of the patent-holding multinational pharmaceutical companies, and to demand adherence by said companies to their identified corporate social responsibility commitments. They noted that Brazil's threat to issue a compulsory license in 2003 played a significant role in helping the country negotiate lower medicine prices, i.e. 72 to 77% price reductions (Flanagan and Whiteman 2007). Scopel and Chaves (2016) studied the impact of Brazil's efforts to overcome patent barriers from 2001 to 2012 on the price of lopinavir/ritonavir (LPV/r) drug. Threats to issue compulsory licenses were used as a negotiating strategy by the Brazilian government. These threats were observed to have: (i) lowered the drug price by 46% in 2001 and (ii) lowered the national

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antiretroviral expenditure 37% in 2003. In 2005, shortly after the approval by the Brazilian National Health Council of a resolution supporting compulsory licensing for LPV/r and other medicines, Abbott agreed to reduce the LPV/r price by 46%. The LPV/r price further lowered by greater than 51% during the period of 2005 to 2006 (Scopel and Chaves 2016).

## 6. Economic impacts of compulsory license use

Beyond the effect on medicine prices and health expenditures, a few papers have shown the broader economic impacts of compulsory licenses.

Yamabhai et al. investigated the health and economic impacts of government-use licenses issued by Thailand's Ministry of Public Health for seven medicines within the period of 2006 to 2008. These impacts were calculated within a period of five years from the issuance of said licenses. The results showed that, within the five-year period, (i) an estimate of 84,158 more patients benefited from the involved drugs and (ii) the licenses resulted in about USD 132.4 million in "health-related economic benefits." The study also observed that the government-use licenses had no impact on the values of the country's aggregate exports or foreign direct investments. However, the study noted a decrease in export values of plastic, jewelry, and color TV products to the U.S. a year after their status as being included in the U.S. Generalized System of Preferences was withdrawn. In this regard, the results "[i]ndicated substantial improvement in access to drugs, resulting in public health benefits for the nation, while there is no evidence of negative impact on Thai's exports and from the trade retaliation [...]" (Yamabhai et al. 2011).

Rahman and Ling (2017) examined 3 "myths" concerning compulsory licensing, including the supposed negative effect of compulsory licenses on a country's foreign direct investment (FDI). In this respect, they did not observe a decrease in FDI inflows to Malaysia after its 2004 grant of compulsory license for HIV drugs. Rather, they noted that the country's FDI steadily increased from 2005 to 2008 (Rahman and Ling 2017). Goyal (2015) examined 14 instances of compulsory or government-use licenses, mostly for AIDS treatment, between the years 2002 to 2012 in relation to their (i) effect on foreign direct investment (FDI) flows in the concerned countries and (ii), regarding compulsory licenses on AIDS treatments, their effect on domestic prevalence of the HIV-related illness and deaths. The study made numerous observations, including that: (i) in general, the evidence does not indicate that use of compulsory licenses results in a decrease in FDI inflows to the issuing country, and (ii) a decrease in the number of deaths caused by HIV disease could be reasonably correlated to the issuance of compulsory licenses. He concluded that "[w]hether these firms [multinational pharmaceutical companies] actually end up withdrawing their investments is dependent more on the economic forces than their attitude of 'teaching governments a lesson' [...]" and suggested the relative importance of government "predictability" in using compulsory licensing measures to retain foreign investments (Goyal 2015).

Chien (2003) examined the effect of six compulsory licenses of pharmaceutical patents issued by the U.S. Federal Trade Commission in relation to antitrust consent decrees between 1980 to 1997 and their effect on innovation, particularly on the patenting activities of the affected entities. The study indicated that, in five out of the six investigated cases, there was no resulting decrease in the amount of patent applications made by the affected companies after the issuance of the compulsory licenses. She noted that, "[t]he results of this study are contrary to the prevalent assumption that compulsory licensing categorically harms innovation" (Chien 2003).

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

## 7. Challenges to compulsory licensing use

The literature identified several challenges to the use of compulsory licenses with respect to: (i) national compulsory licensing framework and implementation, (ii) the implementation of Article 31*bis*, (iii) political pressure exerted on countries who used or attempted to use compulsory licenses, (iv) limitations imposed by data exclusivity and trade secret protection, and (v) Free-Trade Agreement (FTA) provisions.

### *7.i National compulsory licensing framework and implementation*

Some studies analysed national/regional legal provisions and how they facilitated or complicated the use of compulsory license provisions. Vawda and Shozi (2020) examined the implementation of the TRIPS flexibilities by African countries 18 years after the adoption of the Doha Declaration. With respect to compulsory licensing laws and policies, they identified 20 countries that already permit the use of compulsory licenses and government-use licenses specifically to address public health needs or emergencies, which is in contrast to the grounds for compulsory licensing provided in African laws of colonial origin such as “[i]nsufficiency of exploitation of the invention, inability to meet demand, refusal to grant a licence on reasonable terms or in order to remedy anti-competitive practices and dependent patents.” Further, Malawi, Zimbabwe, and Tanzania adopted comparable legal presumptions favouring compulsory licensing with respect to certain applications, such as those concerning access to medicines. Among others, they recommended that countries adopt similar “public health oriented grounds” with respect to compulsory licenses and government-use licenses (Vawda and Shozi 2020).

Vawda (2018) examined the judicial interpretations of compulsory licensing provisions contained in South Africa’s Patent Act 57 of 1978. He argued that the country’s legal framework is restrictive with respect to the grant of compulsory licenses, considering that (i) the grounds for application are limited to concerns related to “dependent patents” and “abuse of patent rights,” and (ii) the courts’ “[o]verly formal approach to judicial interpretation and adjudication, including an apparent deference to patent holders over the broader public [...]” (Vawda 2018). Accoto (2011) examined compulsory licensing of pharmaceuticals in emerging economies and analysed differences between Brazil and Argentina in what refers to the implementation of TRIPS provisions and potential effects for the use of compulsory licenses (Accoto 2011).

### *7.ii The implementation of Article 31bis*

Correa (2019) examined the procedural requirements provided by Paragraph 6 – 2003 WTO Decision, now Article 31*bis* of the TRIPS Agreement, which waives the export limitation in Article 31(f) on pharmaceutical products produced pursuant to a compulsory license. He noted that the mechanism has been criticized by different actors, including by possible generic manufacturer suppliers, for imposing burdensome procedures. He argued that, “[b]y subjecting the use of the system to a large number of stringent conditions, it seems to be designed to protect the patent owner rather than facilitating access to pharmaceutical products where needed [...]” He highlighted the single occasion this mechanism was ever used, i.e. the export of HIV treatment by Canada-based firm Apotex to Rwanda, which took about four years to complete. Referring to the 2016 Report of the UN High-Level Panel’s recommendation to revise Paragraph 6 – 2003 WTO Decision, he proposed possible amendments “[t]o streamline the procedures” contained therein, but also acknowledged the difficulties associated with amending Article 31*bis* (C. M. Correa 2019).

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

An April 2020 Open Letter, written by health, law, and trade organizations and experts, requested 37 WTO member states (J. Love 2020), who previously declared that they would not avail themselves of the Article 31*bis* system as importers, to reconsider their position and to inform the WTO of their full or limited use of this mechanism. The letter expressed that such an “opt out” position is detrimental to their own domestic interests and those of other countries in meeting the global pharmaceutical needs of the COVID-19 pandemic by restricting their own access to patented pharmaceutical products available outside their territories and limiting the expected market size for manufacturers producing medicines under compulsory licenses issued by other countries, which may prevent them from achieving economies of scale (Access to Medicines Ireland et al. 2020). Garrison (2020) explained the problem of the 37 WTO high income countries’ (HICs) opt out decision with respect to the global manufacturing situation of active pharmaceutical ingredients (APIs) that heavily rely on firms based in India and China. Absent a voluntary license, a compulsory license for foreign-produced patented APIs and/or medicines that may be issued by any of the said HICs outside the Article 31*bis* system may be rendered futile since the available exportable supply for APIs/medicines produced under compulsory licenses by other countries will be limited by the Article 31(f) condition of the TRIPS Agreement (Garrison 2020).

### *7.iii Political pressure exerted on countries who used or attempted to use compulsory licenses*

Countries have faced lobbying and political pressure from the originator companies and their home governments over compulsory licensing measures. The 2016 *Report of the United Nations Secretary-General’s High-Level Panel on Access to Medicines* (2016 Report of the UN High-Level Panel) identified the exercise of “[u]ndue political and economic pressures” on governments to discourage or punish their use of TRIPS flexibilities for public health needs as among the reasons why these flexibilities remain unused by numerous governments. The Report declared that such behaviour, exerted by one government over another, “[v]iolates the integrity and legitimacy of the system of legal rights and duties created by TRIPS, as confirmed by the Doha Declaration [...]” (High-Level Panel on Access to Health Technologies 2016).

Balasubramaniam and Goldman (2017) reported instances of political pressure experienced by countries that have used or were looking to use the TRIPS flexibilities, such as compulsory licensing. The following are examples of the pressures exerted on developing and least-developed countries specific to compulsory licensing policies: (i) the U.S. threatened to stop funding the peace negotiations with FARC should Colombia issue a compulsory license for the imatinib drug, (ii) Swiss health and economic officials pressured Colombian health officials to refrain from issuing a compulsory license for the imatinib drug, and (iii) India was included in the 2013, 2014 and 2015 USTR’s Special 301 reports as a consequence of its issuance of a compulsory license for the sorafenib drug (Balasubramaniam and Goldman 2017).

Correa (2020) analysed the USTR assertions in the 2020 Special 301 report with respect to the patent policies of developing countries included in the Priority Watch List, such as those concerning the compulsory licensing regulations of Indonesia, India, and Chile. He noted that “[t]he patent-related claims made by the USTR in relation to the developing countries on the Priority Watch List primarily aim to address the demands by pharmaceutical (and biotech) US companies for increased levels of protection beyond the agreed-upon standards under the TRIPS Agreement [...]” (C. M. Correa 2020b). Baker (2018) noted that the issuance of

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

compulsory licenses and government-use authorizations on patents by countries are in compliance with the TRIPS Agreement provisions, despite the long-standing threats made by the U.S., on behalf of its pharmaceutical industry, against their use. He compiled country-specific complaints concerning compulsory licensing policies as included in the Special 301 reports since 1998 to 2017 (Baker 2018).

In their above-mentioned study, Tantivess, Kessomboon and Laongbua (2008) also discussed the reactions of multinational pharmaceutical companies and their governments to the government-use licenses. The following are examples of the industry's reactions to the said licenses: (i) Abbott Laboratories, as the patent holder of the Kaletra® lopinavir/ritonavir drug, responded by withdrawing its domestic marketing applications for seven new drugs, and threatening to cease seeking local registration approvals for any new medicine, and (ii) Sanofi-Aventis, as the patent holder of the Plavix® clopidogrel drug, threatened an Indian generic manufacturer with patent infringement lawsuits should it provide Thailand with generic versions of the drug. In addition, Thailand was included as a Priority Watch List (PWL) country in the U.S. Trade Representative's (USTR) 2007 Special 301 report, although the causal relationship between the government-use authorizations and the country's inclusion in the PWL was "officially denied" (Tantivess, Kessomboon, and Laongbua 2008).

Correa (2011) studied the increase in pharmaceutical patenting activities of "minor, incremental innovations" in five countries - Argentina, Brazil, Colombia, India and South Africa. As part of his analysis, he highlighted the "strong" oppositions made by the originator pharmaceutical companies and their home governments, i.e., in the U.S. and Europe, against potential compulsory licensing measures. He identified that, for the following patented treatments – lopinavir/ritonavir in Colombia, lamivudine/zidovudine in Malaysia, clopidogrel in Thailand – they would not have been granted patent protection if stringent patentability criteria had been applied during their patent examinations and thus, compulsory licensing measures, which require "political capital," would not have been needed (C. M. Correa 2011).

#### *7.iv Limitations imposed by data exclusivity and trade secret protection*

't Hoen, Boulet and Baker (2017) highlighted that the European Union's Regulation No. 726/2004, which provides for the grant of data and market protection exclusivity in favour of originator medicines, includes no exception that would allow the registration of generic versions of the medicines during the exclusivity periods. In effect, a marketing authorization application for a generic medicine cannot be "[b]ased solely on bioequivalence data" while the data exclusivity period is in effect. They noted that this lack of exception in the EU law hinders the ability of EU member states to "effective[ly] use" the compulsory licensing provisions provided in their national laws. Unless data and market exclusivity exceptions or waivers are introduced in the EU regulation, they argued that "[a]n entity authorized to make use of the patent to supply a generic medicine under a compulsory licence still might not be able to do so because it cannot obtain a marketing authorisation from the relevant medicine regulatory authority [...]" Thus, they recommended the adoption of data and market exclusivity waivers or exceptions into EU regulation to address this issue (E. F. M. 't Hoen, Boulet, and Baker 2017). Correa (2020) suggested that for countries providing for test data exclusivity, like the EU member states, U.S. and Japan, a request for a waiver of limitations arising from such exclusivity be made in the compulsory licensing applications (C. M. Correa 2020a).

Levine (2020) noted that there is a wide range of information relevant for access to medicine that includes "[p]otential trade secrets includ[ing] manufacturing

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

processes, test data, medical formulas, and cell lines and other biological resources.” Given this, he argued that access to some trade secrets may be needed for pharmaceutical products to be quickly developed and globally accessible. He highlighted, among other things, that Article 39 of the TRIPS Agreement does not provide for an “involuntary use exception” for trade secrets similar to patents and that compulsory licensing of trade secrets is uncommon. He suggested a re-examination of the existing legal framework to allow a “[p]ublic health exception for pharmaceutical, diagnostic, and medical device trade secrets” (Levine 2020).

### *7.v Free-Trade Agreement (FTA) provisions*

Provisions included in free-trade agreements have also been appointed as potential challenges for the implementation of compulsory licenses. The above-cited WTO-WHO-WIPO Trilateral study identified some free-trade agreements that have narrowed the compulsory licensing grounds to only “remedies under competition law, situations of extreme urgency and public non-commercial use.” (World Health Organization, World Intellectual Property Organization, and World Trade Organization 2020).

Correa (2004) analysed whether the issuance of a compulsory license could amount to an expropriation of the patent holder’s intellectual property right “investment” under bilateral investment treaties, free trade agreements, and regional trade agreements such that suits can be filed against the host States pursuant to the agreements’ rules on expropriation and compensation. He argued that it would be a challenge to assert that a TRIPS compliant-compulsory license is an illegal expropriation. Yet, he does not discount the possibility that “[c]ases may arise in which claims of this type could be made (for instance, when a patent owner were dissatisfied with the determination of the level or mode of compensation) [...].” Considering that this issue touches on a “[g]ray area that overlapping protections create [...],” he recommended that investment agreements incorporate provisions that expressly place compulsory licenses outside the ambit of the rules on expropriation and compensation. He noted that the Chile – U.S. FTA and U.S. Model BIT contain such exception (C. M. Correa 2004).

## **8. Country comparisons of compulsory licensing policies and use**

Correa and Velásquez’s (2019) paper included a study of the Latin American pharmaceutical compulsory licensing and government-use experiences with a focus on Ecuador, Peru, and Colombia. One difference they noted between Ecuador, on the one hand, and Peru and Colombia (including Guatemala) on the other hand, involved the type of applicants who filed the requests for compulsory licenses: the applications involved “[e]ntities with the capacity to produce or distribute medicines” for the former country and civil society organizations (CSOs) for the latter group of countries. They also noted the uncertainty as to whether the Ministry of Health or CSOs in Ecuador could be considered legitimate applicants for the issuance of “public interest” compulsory licenses (C. M. Correa and Velásquez 2019).

Lybecker and Fowler (2009) evaluated and compared the compulsory license issued by Canada to Apotex under the Access to Medicines Act for the exportation of AIDS treatment to Rwanda vis-à-vis Thailand’s government-use licenses issued to the Government Pharmaceutical Organization for AIDS, heart disease, and cancer treatments in 2006-2008 using their adopted criteria for “[d]istinguish[ing] legitimate from disingenuous regimes”: objective, implementation, pricing, quality, demand and evaluation. On the one hand, they assessed Canada’s compulsory

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license issuance as legitimate although faced with implementation challenges. On the other hand, they deemed Thailand's compulsory licenses to be disingenuous for the following reasons: pursuing a commercial rather than public health purpose, producing low quality drugs, and the determination that the local need for heart disease treatment does not amount to a "national emergency" (Lybecker and Fowler 2009). As part of his Comment, Reichman (2009) questioned the wisdom behind Lybecker and Fowler's comparison between Canada's compulsory license and Thailand's government-use licenses considering that the former was issued to export needed HIV treatments to Rwanda and the latter was issued to obtain price reductions for locally used medicines. He argued that the authors' opinions on the Thai compulsory licensing measure were influenced by the views of "industry propagandists." Contradicting their conclusion, he asserted that Thailand's government-use licenses were valid, but he also cautioned against the "low" royalty rates set by the Thai government (Reichman 2009).

As part of their paper, Reichman with Hasenzahl (2003) summarized and juxtaposed the practices of Canada and the U.S. in using "non-voluntary licensing" of patents. Before considering itself a developed country, Canada widely pursued compulsory licensing of pharmaceutical and food patents, which resulted in the creation of the Canadian generics industry. They pointed out that 613 licenses were issued for the importation or production of medicines during the period of 1969 to 1992. Compared to Canada, the non-voluntary licensing practice in the U.S. is noted to have been used to a lesser degree for "public interest" concerns. Before 1988, non-voluntary licensing was commonly used by U.S. federal courts in two areas: "[t]o regulate misuses of patent rights and antitrust violations [...]." Government-use licenses mainly involved national defence matters although they have also been employed to lower medicine prices, among others. They concluded that non-voluntary licensing is only one of many measures to encourage innovation. They further recommended that developing countries focus on achieving "[o]verall coherence and effectiveness" in their domestic policies and not unduly depend on non-voluntary licensing as a stand-alone measure (Reichman and Hasenzahl 2003).

## 9. Compulsory licensing as an anti-competitive remedy

A handful of papers discussed compulsory licensing specifically used as an anti-competitive remedy either under intellectual property or competition law frameworks.

A 2011 survey by the WIPO Secretariat with 34 country respondents revealed the following: (i) 15 countries have competition laws that provide for the issuance of compulsory licenses and (ii) 12 countries include "anti-competitive uses (practices) of IP rights" as a ground for issuance of compulsory licenses under their domestic Intellectual Property laws (World Intellectual Property Organization, Secretariat 2011).

Abbott et al. (2014) noted that compulsory licensing may be used as a remedy against anti-competitive practices following a judicial or administrative finding that such practices exist, as provided in Article 31(k) of the TRIPS Agreement. In this situation, the following conditions imposed by the TRIPS Agreement with respect to compulsory licensing are waived: (i) the requirement to negotiate with the patent holder before pursuing compulsory licensing, (ii) the need to adequately compensate the patent holder for use of the patented technology, and (iii) the limitation that products produced under a compulsory license are mainly for local use. They argued that the grant of compulsory licenses in order to correct anti-competitive behaviours is an established practice in the countries where most

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patent holding pharmaceutical companies are based. As such, pursuing compulsory licensing in this context may be a “less politically charged” matter as compared to granting compulsory licenses for health technologies by themselves, which are prone to receiving strong political responses from said countries (F. Abbott et al. 2014).

Quoting and citing Scherer and Watal’s 2002 paper, Correa (2007) noted that the U.S. has extensively used compulsory licensing in order to correct anti-competitive behaviour in relation to various patented technologies, including pharmaceuticals. The U.S. competition law allows the issuance of compulsory licenses for grounds such as “[t]he use of patents as a basis for price-fixing or entry-restricting cartels, the consummation of market-concentrating mergers in which patents played an important role and practices that extended the scope of patent restrictions beyond the bounds of the patented subject matter [...]” He also identified two examples wherein “merger reviews” involved the issuance of compulsory licenses by the U.S. FTC: 2002 compulsory cross-license concerning patent on Immunex tumour necrosis factor and 2005 compulsory license concerning patent on Drug-Eluting Stents’ RX delivery system (C. M. Correa 2007).

Senra de Morais (2017) provided an overview on the use of compulsory licensing as a competition instrument, with a focus on the pharmaceutical sector in the BRICS (Brazil, Russia, India, China and South Africa) countries. Among these countries, it was only in South Africa where a case was brought before the national competition authority concerning anticompetitive practices adopted by pharmaceutical companies in relation to patents. This case was noted to have resulted in a historical decision in 2003 that led to a settlement, which included the issuance of broad voluntary licenses. While the domestic legal frameworks of the other BRICS countries allow the issuance of compulsory licenses in the context of antitrust violations, the study did not find any relevant case law in those jurisdictions. Brazil and India have issued compulsory licenses for medicines based on health considerations, but none pursuant to competition law grounds (Senra de Morais 2017).

## 10. Economic analysis and modelling of compulsory licenses

Bond and Saggi (2014) developed an economic model to study the effects of price control measures and compulsory license threats in increasing access to patented medicines owned by a “North”-based entity in “South” countries. Their model shows, among others, that: (i) when the patent holder does not work the patent domestically, then compulsory licensing threats result to access by South countries of the patented medicine, albeit of lesser quality, and (ii) the two access strategies are “[m]utually reinforcing” (Bond and Saggi 2014). Using economic supply and demand analysis, Flynn, Hollis and Palmedo (2009) analysed the effect of patent monopolies and income inequality in countries on medicine prices and argued that compulsory licensing allowing “open licenses” is an effective and legitimate means to lower medicine prices (Flynn, Hollis, and Palmedo 2009). Bird and Cahoy (2008) investigated the relationship between compulsory license and FDI. They developed an economic model to minimize potential FDI losses while preserving access in compulsory licensing negotiations (Bird and Cahoy 2008).

## 11. Useful Resources

1. The Medicines Law and Policy developed the TRIPS Flexibilities Database available at this link: <http://tripsflexibilities.medicineslawandpolicy.org/>. It

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

documents cases wherein countries have used, proposed to use or been requested to use TRIPS flexibilities, including instances invoking Article 31, for public health interests. Among others, it includes pieces of information about the country involved, the subject product, royalty rates, whether or not the flexibility was implemented and if not, the corresponding reason for non-implementation.

2. The World Intellectual Property Organization created the Database on Flexibilities in the Intellectual Property System available at this link: <https://www.wipo.int/ip-development/en/agenda/flexibilities/database.html>. This database compiles national legal provisions pertaining to intellectual property flexibilities, including compulsory licenses and government-use licenses.

## Research Gaps

1. Lack of data on the impact of compulsory license on innovation activities of affected originator companies
2. Limited data on broader economic impacts of compulsory licensing, such as in terms of effect on: (i) the issuing country's foreign direct investment flows, and (ii) the accessibility to patients of resulting medicine prices in the context of private medicine procurement settings (especially in countries where medicine expenditures are largely out-of-pocket expenses)
3. Limited information on compulsory licensing timeframes, i.e., length of time involved in negotiating a voluntary license before an application for compulsory license is pursued, the length of time involved from submission of such application to the grant or refusal of a compulsory license
4. Lack of information on costs involved in undertaking compulsory licensing applications, whether significant, reasonable, or negligible
5. Lack of information on terms and conditions included in voluntary licensing and other agreements that arose out of compulsory licensing threats
6. Lack of information on the likelihood of litigation (risk involved) with respect to compulsory licensing applications, particularly if made by generic manufacturers, including duration, grounds invoked and costs of litigation, whether significant, reasonable, or negligible

## References with abstracts

Abbott, Frederick, Sean Flynn, Carlos Correa, Jonathan Berger, and Natasha Nyak. 2014. *Using Competition Law to Promote Access to Health Technologies: A Guidebook for Low- and Middle-Income Countries*. New York, U.S.A.: United Nations Development Programme. <https://www.undp.org/content/undp/en/home/librarypage/hiv-aids/using-competition-law-to-promote-access-to-medicine.html>.

Abstract: Not available

Abbott, Frederick M., and Rudolf V. Van Puymbroeck. 2005. *Compulsory Licensing for Public Health: A Guide and Model Documents for Implementation of the Doha Declaration Paragraph 6 Decision*. World Bank Working Papers. The World Bank. <https://doi.org/10.1596/978-0-8213-6292-1>.

Abstract: The Doha Declaration on the TRIPS Agreement and Public Health (in its Paragraph 6) recognized that developing countries with insufficient or no manufacturing capacity in the pharmaceutical sector could face difficulties in

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



making effective use of compulsory licensing under the TRIPS Agreement. The WTO's decision of August 30, 2003 set up a system intended to overcome these difficulties. The present work is a guide to the implementation of that system. The first part gives the reader an understanding of the issues involved; the second part provides model documents for use by governments. Four model instruments of notification are included: three for notification of the WTO as required by the Decision and one for notification of the patent or right holder pursuant to Article 31 of the TRIPS Agreement. Because most countries will have to amend their legislation (typically their patent law) to implement the system, model amendment provisions have been provided both for exporting countries and for importing countries. All model documents contain their own detailed commentary

Access to Medicines Ireland, Asociacion por un Acceso Justo al Medicamento, AIDES, ARAS – the Romanian Association Against AIDS, Asociación por un Acceso Justo al Medicamento, BEUC (Bureau Européen des Unions de Consommateurs), Consumer Action, et al. 2020. "Open Letter to Governments of Australia, Canada, Iceland, Japan, New Zealand, Norway, Switzerland, the United Kingdom, United States, and the European Union, Including the Following Member States: Austria, Belgium, Bulgaria, Croatia, Cyprus, Czechia, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Netherlands, Poland, Portugal, Romania, Slovakia, Slovenia, Spain, Sweden," April 7, 2020. <https://www.keionline.org/32707>.

Abstract: Not available

Accoto, Dario. 2011. "Compulsory Licensing of Pharmaceuticals in Emerging Economies Explaining Variance between Brazil and Argentina." Master's Thesis, Geneva: Graduate Institute of International and Development Studies. <https://repository.graduateinstitute.ch/record/13842?ln=en>.

Abstract: The WTO's TRIPS Agreement provoked conflict between developed and developing countries over intellectual property rights' role in limiting access to medicines. To assuage developing countries, TRIPS contains several flexibilities. This study focuses on compulsory licenses - breaking patents and manufacturing medicines locally - as one option for middle-income countries with a domestic drug industry. To understand the limited use of compulsory licenses, Brazil's and Argentina's experiences will be contrasted in a case study based on five conjectures derived from prior research. The study finds that rising costs for Brazil's universal antiretroviral treatment program required drastic savings through compulsory licensing. Brazil's early TRIPS compliance through a retroactive mechanism had increased prices for newer antiretrovirals, while Argentina had enacted a transition period. Moreover, Brazil's patent and health authorities have mandates referring to social development and access to healthcare, while Argentina's have narrower mandates. Finally, Argentina's access-to-medicines program was partially foreign-funded, reducing its incentive for cost-cutting.

Andia, Tatiana. 2015. "The Inverse Boomerang Pattern: The Global Kaletra Campaign and Access to Antiretroviral Drugs in Colombia and Ecuador." *Studies in Comparative International Development* 50 (2): 203–27. <https://doi.org/10.1007/s12116-015-9185-3>.

Abstract: This paper examines a global campaign in which transnational advocacy networks challenged the monopoly rights of Abbott Laboratories over the antiretroviral drug Kaletra. It focuses on the cases of Colombia and Ecuador and

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

analyzes the different trajectories of the campaign in the two countries and how each trajectory contributed differently to the global outcome. In both of these cases, I show that activism operated in an “inverse boomerang” pattern, by which an international NGO reached out to local allies to expand its global coalition, prioritizing its agenda over other domestic considerations. I argue that in cases where transnational campaigns are initiated globally, there is a potential mismatch between global and domestic goals and that the campaigns’ contribution to global norm-making depends on the type of relationship established between international advocates and domestic actors. Such relationships are in turn influenced by the political and economic context and the institutional arrangements of each country.

**Baker, Brook.** 2018. “Don’t Be Afraid of Compulsory Licenses Despite US Threats: Special 301 Reports 1998-2017 - Listing Concerns but Taking Little Action.” WordPress. *InfoJustice* (blog). February 20, 2018. <http://infojustice.org/archives/39594>.

Abstract: Not available

**Balasubramaniam, Thiru.** 2020. “Israel Issues Compulsory License to Allow the Government to Import Generic Versions of Kaletra.” Knowledge Ecology International. March 23, 2020. <https://www.keionline.org/32503>.

Abstract: Not available

**Balasubramaniam, Thiru, and Andrew S. Goldman.** 2017. “Submission of Knowledge Ecology International to the WIPO SCP: Constraints Faced by Developing Countries and Least Developing Countries (LDCs) in Making Full Use of Patent Flexibilities and Their Impacts on the Access to Affordable Especially Essential Medicines for Public Health Purposes in Developing Countries and LDCs.” [https://www.wipo.int/export/sites/www/scp/en/meetings/session\\_27/3rdparty\\_comments/kei.pdf](https://www.wipo.int/export/sites/www/scp/en/meetings/session_27/3rdparty_comments/kei.pdf).

Abstract: Not available

**Beall, Reed F., Randall Kuhn, and Amir Attaran.** 2015. “Compulsory Licensing Often Did Not Produce Lower Prices For Antiretrovirals Compared To International Procurement.” *Health Affairs* 34 (3): 493–501. <https://doi.org/10.1377/hlthaff.2014.0658>.

Abstract: Compulsory licensing has been widely suggested as a legal mechanism for bypassing patents to introduce lower-cost generic antiretrovirals for HIV/AIDS in developing countries. Previous studies found that compulsory licensing can reduce procurement prices for drugs, but it is unknown how the resulting prices compare to procurements through the Global Fund to Fight AIDS, Tuberculosis, and Malaria; UNICEF; and other international channels. For this study we systematically constructed a case-study database of compulsory licensing activity for antiretrovirals and compared compulsory license prices to those in the World Health Organization’s (WHO’s) Global Price Reporting Mechanism and the Global Fund’s Price and Quality Reporting Tool. Thirty compulsory license cases were analyzed with 673 comparable procurements from WHO and Global Fund data. Compulsory license prices exceeded the median international procurement prices in nineteen of the thirty case studies, often with a price gap of more than 25 percent. Compulsory licensing often delivered suboptimal value when compared to the alternative of international procurement, especially when used by low-income

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

countries to manufacture medicines locally. There is an ongoing need for multilateral and charitable actors to work collectively with governments and medicine suppliers on policy options.

Beall, Reed, and Randall Kuhn. 2012. "Trends in Compulsory Licensing of Pharmaceuticals Since the Doha Declaration: A Database Analysis." Edited by Nathan Ford. *PLoS Medicine* 9 (1): e1001154. <https://doi.org/10.1371/journal.pmed.1001154>.

**Abstract:** Background: It is now a decade since the World Trade Organization (WTO) adopted the "Declaration on the TRIPS Agreement and Public Health" at its 4th Ministerial Conference in Doha. Many anticipated that these actions would lead nations to claim compulsory licenses (CLs) for pharmaceutical products with greater regularity. A CL is the use of a patented innovation that has been licensed by a state without the permission of the patent title holder. Skeptics doubted that many CLs would occur, given political pressure against CL activity and continued health system weakness in poor countries. The subsequent decade has seen little systematic assessment of the Doha Declaration's impact.

**Methods and Findings:** We assembled a database of all episodes in which a CL was publically entertained or announced by a WTO member state since 1995. Broad searches of CL activity were conducted using media, academic, and legal databases, yielding 34 potential CL episodes in 26 countries. Country- and product-specific searches were used to verify government participation, resulting in a final database of 24 verified CLs in 17 nations. We coded CL episodes in terms of outcome, national income, and disease group over three distinct periods of CL activity. Most CL episodes occurred between 2003 and 2005, involved drugs for HIV/AIDS, and occurred in upper-middle-income countries (UMICs). Aside from HIV/AIDS, few CL episodes involved communicable disease, and none occurred in least-developed or low-income countries.

**Conclusions:** Given skepticism about the Doha Declaration's likely impact, we note the relatively high occurrence of CLs, yet CL activity has diminished markedly since 2006. While UMICs have high CL activity and strong incentives to use CLs compared to other countries, we note considerable countervailing pressures against CL use even in UMICs. We conclude that there is a low probability of continued CL activity. We highlight the need for further systematic evaluation of global health governance actions.

Bird, Robert, and Daniel R. Cahoy. 2008. "The Impact of Compulsory Licensing on Foreign Direct Investment: A Collective Bargaining Approach." *American Business Law Journal* 45 (2): 283–330. <https://doi.org/10.1111/j.1744-1714.2008.00056.x>.

**Abstract:** The innovation impact of intellectual property compulsory licenses - government-imposed access without the authorization of the property owner - has generated great interest in the academic literature. Moreover, recent measures by the governments of Thailand and Brazil have generated increased international awareness of the issue. Equally significant, but receiving less attention is the impact of compulsory licenses on flows of foreign direct investment (FDI) to the granting nation. It is quite likely that FDI mechanisms provide an important attenuating factor that influences a country's compulsory license strategy. This paper investigates the compulsory license-FDI relationship, using essential medicines as a context. It explores the potential for collective action and bargaining on the part of licensing nations to minimize FDI losses while preserving access. Middle-developed countries (MDC) such as Egypt and Brazil are highlighted to demonstrate the extent to which nations with differing abilities to resist political pressure can

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#### CONTACT

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

influence FDI losses. The paper concludes by demonstrating optimal negotiating strategies using a unique game theory framework that models real-world licensing decisions.

**Bond, Eric W., and Kamal Saggi. 2014. "Compulsory Licensing, Price Controls, and Access to Patented Foreign Products." *Journal of Development Economics* 109 (July): 217–28. <https://doi.org/10.1016/j.jdeveco.2014.04.001>.**

**Abstract:** We analyze how a price control and the threat of compulsory licensing (CL) affect consumer access in a developing country (South) to a patented foreign product. In the model, the Southern government sets the level of the price control on a Northern patent-holder who chooses between entry and voluntary licensing (VL). While entry incurs a higher fixed cost, licensed production is of lower quality. If the patent-holder does not work its patent locally, the South is free to use CL. The threat of CL: ensures that consumers have access to (a lower quality version of) the patented good when the patent-holder chooses not to work its patent locally; improves the terms at which VL occurs; can cause the patent-holder to switch from VL to entry; and can delay consumer access when CL replaces VL or entry. We also show that a price control and CL are mutually reinforcing instruments.

**Cherian, Neil George. 2016. "Using Compulsory Licenses to Access Pharmaceuticals: A Cross Case Analysis on Outcomes." University of Oslo. [https://www.duo.uio.no/bitstream/handle/10852/54054/Cherian\\_Thesis\\_Nov2016.pdf?sequence=1](https://www.duo.uio.no/bitstream/handle/10852/54054/Cherian_Thesis_Nov2016.pdf?sequence=1).**

**Abstract:** Patents pose a significant barrier to accessing innovative medicines, due to exclusivity granted to inventors by the Trade Related Agreement on Intellectual Property Rights (TRIPS), which sets the basis for protection of intellectual property at the international level. The founding of the World Trade Organization and adoption of TRIPS in 1994 brought harmonized intellectual property standards to member states. Compulsory licenses are exemptions to patent exclusivity, allowing a government or a third party to use patented subject matter for commercial, public or emergency use provided certain requirements are fulfilled.

**Objective:** To evaluate outcomes and policy approaches used by different countries for compulsory licenses under the Article 31 framework of TRIPS, and identify shortfalls and best practices in order to inform policy changes on national, and multilateral levels.

**Methods:** This retrospective study is comprised of a cross-case comparison of compulsory licensing in varying countries, including Low, Middle and High Income Countries to enable access to generic medications. Each case has been driven by varying contexts and scenarios. After a detailed search for all compulsory licenses threatened and issued after 1994, a database was developed and focus cases selected. Specifics of license and outcomes associated with use were then recorded and compared. Among aspects evaluated were national legislation and delivery instruments for procured generics.

**Findings:** Following the Doha ministerial declaration on Public health in 2001, there has been more frequent use of compulsory licenses (CL) to procure HIV medications, and increasingly, non-essential medicines such as oncologic agents, anti-inflammatory agents, and prophylactic drugs for heart disease. Approaches taken by countries include an official Government-use policy to compulsory license drugs, use of CLs as a threat, an emergency use for pandemic preparedness, and anti-competitive tool to promote parallel trade. Each case has unique motivators and reveals context specific outcomes.

**Conclusions:** While use of compulsory licenses is controversial, countries have traditionally used them in case of exceptionally expensive medicines (Cancer drugs,

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and 2nd line ARV medication), often after failed negotiations (Brazil, Thailand, and Taiwan). The TRIPS Article 31 framework allows significant liberty in issue and use of compulsory licenses, but requires further clarifications of certain provisions to clarify ambiguities passed down from the Paris convention of 1885. Some further policy clarifications are also prudent given the evolving nature of the patent landscape, and current global discussion on impending need for change to the innovation framework has been motivated by conflicting goals between Human rights and Inventors rights.

Chien, Colleen. 2003. "Cheap Drugs at What Price to Innovation: Does the Compulsory Licensing of Pharmaceuticals Hurt Innovation?" *Berkeley Technology Law Journal* 18 (3): 853–907.  
<https://www.jstor.org/stable/24116860?seq=1>

Abstract: The patent system is built on the premise that patents provide an incentive for innovation by offering a limited monopoly to patentees. The inverse assumption that removing patent protection will hurt innovation has largely prevented the widespread use of compulsory licensing—the practice of allowing third parties to use patented inventions without patentee permission. In this Article, I empirically test this assumption. I compare rates of patenting and other measures of inventive activity before and after six compulsory licenses over drug patents issued in the 1980s and 1990s. As reported below, I observe no uniform decline in innovation by companies affected by compulsory licenses and find very little evidence of a negative impact, which is consistent with earlier empirical work. While anecdotal, these findings suggest that the assertion that licensing categorically harms innovation is probably wrong. Based on the data, I comment on the use of compulsory licensing to reduce the price of AIDS and other drugs for developing countries. I suggest that, based on past experience, compulsory licenses need not result in a decline in innovation and that this policy option for increasing access to medicines deserves greater exploration.

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Correa, Carlos M. 1999. "Intellectual Property Rights and the Use of Compulsory Licenses: Options for Developing Countries." T.R.A.D.E Working Papers 5. Geneva: South Centre.  
[https://www.iatp.org/sites/default/files/Intellectual\\_Property\\_Rights\\_and\\_the\\_Use\\_of\\_Co.pdf](https://www.iatp.org/sites/default/files/Intellectual_Property_Rights_and_the_Use_of_Co.pdf).

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<https://repository.law.umich.edu/cgi/viewcontent.cgi?article=1223&context=mjil>

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Correa, Carlos M. 2019. "Will the Amendment to the TRIPS Agreement Enhance Access to Medicines?" Policy Brief No. 57. South Centre. [https://www.southcentre.int/wp-content/uploads/2019/01/PB57\\_Will-the-Amendment-to-the-TRIPS-Agreement-Enhance-Access-to-Medicines\\_EN-1.pdf](https://www.southcentre.int/wp-content/uploads/2019/01/PB57_Will-the-Amendment-to-the-TRIPS-Agreement-Enhance-Access-to-Medicines_EN-1.pdf).

Abstract: An amendment to the TRIPS Agreement by incorporation of the text of the decision of the WTO General Council on 30 August 2003 (as article 31bis) has been made in response to the problem identified in paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health. This paragraph sought a solution to situations where patented pharmaceuticals which are not available in a country with no or insufficient manufacturing capacity can be supplied by a foreign provider. As originally adopted, the TRIPS Agreement did not allow the grant of compulsory licenses for exports only, thereby preventing generic manufacturers from exporting the required products to countries unable to produce them. While the new article 31bis is a step forward as it reflects public health concerns, it would be necessary to streamline the procedures to effectively ensure broader access to pharmaceutical products at low cost and in a timely manner.

———. 2020a. "Guide for the Granting of Compulsory Licenses and Government Use of Pharmaceutical Patents - Research Paper 107." South Centre. <https://www.southcentre.int/research-paper-107-april-2020/>.

Abstract: Like other rights, patent rights are not absolute. There are situations in which their exercise can be limited to protect public interests. Such situations may arise, for instance, when access to needed pharmaceutical products must be ensured. Compulsory licenses and government use for non-commercial purposes are tools, provided for under most laws worldwide, that can specifically be used to address public health needs. This document is intended to provide legal guidance for the effective use of such tools, consistently with the international law.

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Abstract: The continuous application of Special Section 301 by the Office of the United States Trade Representative (USTR) undermines the rule of law as a fundamental principle of a multilateral system based on the sovereign equality of states and the respect for international law. Interference with foreign countries' national intellectual property (IP) policies—which have significant socio-economic effects—negates their right to determine independently the level and modalities of protection of such property within the framework and policy space allowed by the international law. This paper examines the patent-related claims made by the USTR in relation to the developing countries on the USTR Priority Watch List. It argues that the regulations and practices identified by the USTR show a legitimate use of the flexibilities provided for by the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS), and that the ignorance of the public interests of the countries concerned (for instance, with regard to access to affordable medicines) has contributed to the discredit (and ineffectiveness) of the Special

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Section 301.

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Abstract: This South Centre research paper discusses first, the limitations of the current research and development (R&D) model and its implications for access to medicines. Second, it considers the tension between intellectual property rights applied to medicines and States' observance of the fundamental right to health. Third, it examines the case of access to medicines for the treatment of Hepatitis C, illustrating the barriers to access created by intellectual property and the high prices normally associated with its exercise. Fourth, it presents the background, main aspects and obstacles to the achievement of the objectives of the Doha Declaration on the TRIPS Agreement and Public Health (2001). To conclude, this paper examines the experiences of compulsory licensing and government use of patents in Latin America (particularly in Ecuador, Peru and Colombia).

Correa, Carlos, and World Health Organization. 2009. "Guide for the Application and Granting of Compulsory Licences and Authorization of Government Use of Pharmaceutical Patents." World Health Organization. <https://apps.who.int/iris/handle/10665/70096>.

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Engelberg, Alfred B, and Aaron S Kesselheim. 2016. "Opinion: Use the Bayh-Dole Act to Lower Drug Prices for Government Healthcare Programs." *Nature Medicine* 22 (6): 576–576. <https://doi.org/10.1038/nm0616-576>.

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Flanagan, William, and Gail Whiteman. 2007. "'AIDS Is Not a Business': A Study in Global Corporate Responsibility – Securing Access to Low-Cost HIV Medications." *Journal of Business Ethics* 73 (1): 65–75. <https://doi.org/10.1007/s10551-006-9198-y>.

Abstract: At the end of the 1990s, Brazil was faced with a potentially explosive HIV/AIDS epidemic. Through an innovative and multifaceted campaign, and despite initial resistance from multinational pharmaceutical companies, the government of Brazil was able to negotiate price reductions for HIV medications and develop local production capacity, thereby averting a public health disaster. Using interview data and document analysis, the authors show that the exercise of corporate social responsibility can be viewed in practice as a dynamic negotiation and an interaction between multiple actors. Action undertaken in terms of voluntary CSR alone may be insufficient. This finding highlights the importance of a strong role for national governments and international organizations to pressure companies to perform better.

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*Journal of Law, Medicine & Ethics* 37 (2): 184–208. <https://doi.org/10.1111/j.1748-720X.2009.00365.x>.

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Goyal, Yugank. 2015. "Economic and Procedural Constraints of Compulsory Licenses for Medicines." In *Compulsory Licensing: Practical Experiences and Ways Forward*, edited by Reto M. Hilty and Kung-Chung Liu. Vol. 22. MPI Studies on Intellectual Property and Competition Law. Berlin, Heidelberg: Springer Berlin Heidelberg. <https://doi.org/10.1007/978-3-642-54704-1>.

Abstract: The chapter argues that since there is no conclusive evidence for a causal relationship between the issuance of compulsory licences (CL) for medicines and any fall in innovation or foreign direct investment (FDI) inflow, various other factors like predictability and market potential need to be taken into account for understanding the after-effects of a grant of CL. The chapter examines the trends in CLs after the Doha Declaration and carves out a case for adhering to transparent procedures for imparting some predictability to the process in order to mitigate losses from possible repercussions.

Haile, Lisa A. 2020. "A Balance Between the Government, the Private Sector and the Needs of the People: Invocation of Rarely Used Provisions to Ensure Public Safety During the COVID-19 Pandemic." DLA Piper. April 6, 2020. <https://www.dlapiper.com/de/austria/insights/publications/2020/04/invocation-of-rarely-used-provisions-to-ensure-public-safety-during-the-covid19-pandemic/>.

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Hein, Wolfgang, and Suerie Moon. 2016. *Informal Norms in Global Governance: Human Rights, Intellectual Property Rules and Access to Medicines*. London: Routledge. <https://www.taylorfrancis.com/books/e/9781315588483>.

Abstract: Not available

Hemel, Daniel J., and Lisa Larrimore Ouellette. 2017. "Bayh–Dole beyond Borders." *Journal of Law and the Biosciences* 4 (2): 282–310. <https://doi.org/10.1093/jlb/lxx011>.

Abstract: The Bayh-Dole Act, which encourages patents on federally funded inventions, has been criticized for forcing consumers to 'pay twice' for patented products—first through the tax system and again when the patentee charges a

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supracompetitive price. Supporters counter that patents promote commercialization, but it is doubtful that this benefit can justify the Act's present scope. One important feature of Bayh-Dole, however, has been overlooked in this debate—a feature that arises from the global-public-good nature of knowledge. Without patents on US taxpayer-funded inventions, the United States would have no practical way of internalizing the positive externalities these inventions confer on consumers in other countries. Put differently, the charge that Bayh-Dole forces US consumers to 'pay twice' misses the point that eliminating some Bayh-Dole patents would permit non-U.S. consumers to avoid paying at all. To be sure, this 'internalization theory' was not the rationale upon which sponsors of the Act relied. And like commercialization theory, it cannot justify the Act's present scope. Rather than relying on internalization theory to defend Bayh-Dole, we highlight ways in which this novel theory can inform Bayh-Dole debates.

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**Hoehn, Ellen F. M. 't, Pascale Boulet, and Brook K. Baker. 2017. "Data Exclusivity Exceptions and Compulsory Licensing to Promote Generic Medicines in the European Union: A Proposal for Greater Coherence in European Pharmaceutical Legislation." *Journal of Pharmaceutical Policy and Practice* 10 (1): 19. <https://doi.org/10.1186/s40545-017-0107-9>.**

Abstract: The challenge of providing access to high-priced patented medicines is a global problem affecting all countries. A decade and a half ago the use of flexibilities contained in the World Trade Organization Agreement on Trade Related Aspects of Intellectual Property Rights, in particular compulsory licensing, was seen as a mechanism to respond to high-price medicines for the treatment of HIV/AIDS in low- and middle-income countries. Today a number of upper-income European Union (EU) Member States are contemplating the use of compulsory licensing in their efforts to reduce expenditure on pharmaceutical products. EU regulation of clinical test data protection and the granting of market exclusivity interfere with the effective use of compulsory licensing by EU Member States and can even prevent access to off-patent medicines because they prohibit registration of generic equivalents. EU pharmaceutical legislation should be amended to allow waivers to data and market exclusivity in cases of public health need and when a compulsory or government use license has been issued. Such an amendment can be modelled after existing waivers in the EU Regulation on compulsory licensing of patents for the manufacture of pharmaceutical products for export to countries with public health problems outside the EU. Allowing a public health/ compulsory license exception to data and market exclusivity would bring greater coherence between EC regulation of medicinal products and national provisions on

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compulsory licensing and ensure that Member States can take measures to protect public health and promote access to medicines for all.

Hoehn, Ellen 't. 2020. "Covid-19 and the Comeback of Compulsory Licensing." *Medicines Law & Policy*. March 23, 2020. <https://medicineslawandpolicy.org/2020/03/covid-19-and-the-come-back-of-compulsory-licensing/>.

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Hoehn, Ellen 't, and Jorge Bermudez. 2015. "Letters to the Editor: Compulsory Licenses For Medicines." *Health Affairs* 34 (6): 1068–1068. <https://doi.org/10.1377/hlthaff.2015.0452>

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Khor, Martin. 2014. *Compulsory License and "Government Use" to Promote Access to Medicines: Some Examples*. Third World Network. <https://www.twn.my/title2/books/pdf/CompulsoryLicense.pdf>.

Description: In this book, the experiences of Brazil, Ecuador, Ghana, India, Indonesia, Malaysia, Thailand and Zimbabwe are described. In addition, some recent cases from the United States and Italy on compulsory licenses for non-ARVs show that this important tool for public health is also used in developed countries. Copies of the actual compulsory licenses of developing countries are also included for reference.

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Abstract: Objectives: To assess the budget impact of the government use licenses policy, a form of compulsory licensing used by the government, on seven patented drugs, namely, efavirenz, lopinavir/ritonavir combination, clopidogrel, letrozole, docetaxel, erlotinib, and imatinib, in Thailand between 2006 and 2008.

Methods: By using government's perspective, budget impact was estimated within a 5-year period after the introduction of the policy. The number of patients who need treatment with each drug and the costs of treatments by both original and generic versions were obtained from Thai government agencies. Probabilistic sensitivity analysis was used to determine the impact of uncertainty surrounding parameters such as the numbers of patients and the health-care costs.

Results: The study indicated that the use of generic drugs under the policy could

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

save the government budget approximately \$370 million over 5 years. It was also found that each drug had a different effect on budget saving depending on the number of patients treated, the difference in drug costs between original and generic drugs, and the lag time from the introduction of the policy to the availability of the generic drugs on the market.

Conclusion: The study showed that the introduction of the government use licenses policy in Thailand would provide significant benefits for the study timeframe; however, there are several issues that should be taken into account when the government use licenses policy is adopted.

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Rahman, Fifa, and Chee Yoke Ling. 2017. "Intellectual Property and HCV: Barriers & Solutions." In *At the Edge of a Miracle: The Hepatitis C Virus (HCV) Epidemic in Malaysia - A Situational Report*, edited by Fifa Rahman. Kuala Lumpur: Malaysian AIDS Council. [https://www.mac.org.my/v3/wp-content/uploads/2017/07/HCV\\_Report\\_A4\\_FA\\_23052017-web.pdf](https://www.mac.org.my/v3/wp-content/uploads/2017/07/HCV_Report_A4_FA_23052017-web.pdf).

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Reichman, Jerome H. 2009. "Comment: Compulsory Licensing of Patented Pharmaceutical Inventions: Evaluating the Options." *The Journal of Law, Medicine & Ethics* 37 (2): 247–63. <https://doi.org/10.1111/j.1748-720X.2009.00369.x>.

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Reichman, Jerome H, and Catherine Hasenzahl. 2003. *Non-Voluntary Licensing of Patented Inventions: Historical Perspective, Legal Framework under TRIPS, and an Overview of the Practice in Canada and the USA*. Geneva: International Centre for Trade and Sustainable Development, United Nations Conference on Trade and Development. [https://unctad.org/system/files/official-document/ictsd2003ipd5\\_en.pdf](https://unctad.org/system/files/official-document/ictsd2003ipd5_en.pdf).

Abstract: Not available

Scopel, Carolinne Thays, and Gabriela Costa Chaves. 2016. "Iniciativas de Enfrentamento Da Barreira Patentária e a Relação Com o Preço de Medicamentos Adquiridos Pelo Sistema Único de Saúde." *Cadernos de Saúde Pública* 32 (11). <https://doi.org/10.1590/0102-311x00113815>.

Abstract: Since 1996, when antiretroviral (ARV) treatments started being guaranteed to people living with HIV in Brazil, the government has faced the challenge of ensuring sustainability of this policy within a context of incorporating patented medicines. This article sought to analyze the historical series of the price of lopinavir/ritonavir (LPV/r) in Brazil and in the international market also

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considering the initiatives to challenge patent barriers between 2001 and 2012. The methods used were mapping initiatives to challenge LPV/r patent barriers and the analysis of historical series of its price in Brazil and in the international market. Results show that, between 2001 and 2003, there were efforts to use compulsory licensing as a threat. From 2005 to 2007, initiatives by different stakeholders were identified: declaration of public interest, pre-grant opposition ("support to examination") and civil action. From 2006 to 2008, compulsory licensing initiatives in other countries resulted in a price reduction in Brazil. Between 2009 and 2012, there was a 30% reduction in the Brazilian purchasing price.

Senra de Morais, Rafael Pinho. 2017. "Compulsory Licensing of Pharmaceuticals by the Developing South." *Economics Letters* 161 (December): 74–77. <https://doi.org/10.1016/j.econlet.2017.09.011>

Abstract: Compulsory licensing (CL) of medicines by a developing South unambiguously improves access to treatments by its population. Its impact on profits and thus innovation rates and welfare is a more controversial issue in the literature. This paper proposes a North–South model dealing with parallel trade, price controls and compulsory license (if the South is not served). Our results challenge the literature claiming that parallel trade leads to higher innovation and welfare. Moreover, conditions apply for CL to be used; in particular, it should never be used for neglected diseases, as malaria and tuberculosis. When the South issues CLs, it is compensated for the welfare losses caused by the North allowing parallel trade, and innovation and northern welfare do not decrease. The best outcome, however, is market segmentation, i.e. no parallel trade in the first place.

"Several March-In and Royalty Free Rights Cases, under the Bayh-Dole Act." n.d. Knowledge Ecology International. <https://www.keionline.org/cl/march-in-royalty-free>.

Abstract: Not available

Silva, Francisco Viegas Neves da, Ronaldo Hallal, and André Guimarães. 2012. "Compulsory License and Access to Medicines: Economic Savings of Efavirenz in Brazil." Presented at the XIX - International AIDS Conference, Washington, July. <https://www.youtube.com/watch?v=FlwhjANOUvo>.

Abstract: Not available

Son, Kyung-Bok, and Tae-Jin Lee. 2018. "Compulsory Licensing of Pharmaceuticals Reconsidered: Current Situation and Implications for Access to Medicines." *Global Public Health* 13 (10): 1430–40. <https://doi.org/10.1080/17441692.2017.1407811>.

Abstract: To examine patterns and trends in attempts, distinguished from issuance, to issue compulsory licensing of pharmaceuticals and to assess related implications in the era of high-cost medicines. Documents from various civil society organisations were primarily used to search attempts, as well as published literature. The identified attempts were analysed by pharmaceutical level, national level, claimers, and the outcomes of the attempts. There have been 108 attempts to issue compulsory licensing for 40 pharmaceuticals in 27 countries since 1995. Most of the attempts were in Asian, Latin American, and African countries and mainly for HIV/AIDS medicines. Moreover, when the claimer was the government, the likelihood of approval and positive outcomes increased. Compulsory licensing, which was devised to cope with the HIV/AIDS pandemic in low-income countries, became a practical measure in several Asian and Latin American countries, even for

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non-HIV/AIDS medicines. Resurgent compulsory licensing in 2012 and 2014, influenced by the global justice movement, might represent a policy window in the near future as the Doha Declaration did in the 2000s. In this context, various experiences should be circulated and analysed at the global level to better understand the circumstances under which successful issuance has been achieved at the country level.

South Centre. 2021. "Scope of Compulsory License and Government Use of Patented Medicines in the Context of the COVID-19 Pandemic." <https://www.southcentre.int/wp-content/uploads/2021/03/Compulsory-licenses-table-Covid-19-2-March.pdf>.

Abstract: Not available.

't Hoen, Ellen FM, Jacquelyn Veraldi, Brigit Toebes, and Hans V Hogerzeil. 2018. "Medicine Procurement and the Use of Flexibilities in the Agreement on Trade-Related Aspects of Intellectual Property Rights, 2001–2016." *Bulletin of the World Health Organization* 96 (3): 185–93. <https://doi.org/10.2471/BLT.17.199364>.

Abstract: Millions of people, particularly in low- and middle-income countries, lack access to effective pharmaceuticals, often because they are unaffordable. The 2001 Ministerial Conference of the World Trade Organization (WTO) adopted the Doha Declaration on the TRIPS (Trade-Related Aspects of Intellectual Property Rights) Agreement and Public Health. The declaration recognized the implications of intellectual property rights for both new medicine development and the price of medicines. The declaration outlined measures, known as TRIPS flexibilities, that WTO Members can take to ensure access to medicines for all. These measures include compulsory licensing of medicines patents and the least-developed countries pharmaceutical transition measure. The aim of this study was to document the use of TRIPS flexibilities to access lower-priced generic medicines between 2001 and 2016. Overall, 176 instances of the possible use of TRIPS flexibilities by 89 countries were identified: 100 (56.8%) involved compulsory licences or public noncommercial use licences and 40 (22.7%) involved the least-developed countries pharmaceutical transition measure. The remainder were: 1 case of parallel importation; 3 research exceptions; and 32 non-patent-related measures. Of the 176 instances, 152 (86.4%) were implemented. They covered products for treating 14 different diseases. However, 137 (77.8%) concerned medicines for human immunodeficiency virus infection and acquired immune deficiency syndrome or related diseases. The use of TRIPS flexibilities was found to be more frequent than is commonly assumed. Given the problems faced by countries today in procuring high-priced, patented medicines, the practical, legal pathway provided by TRIPS flexibilities for accessing lower-cost generic equivalents is increasingly important.

Tantivess, Sripen, Nusaraporn Kessomboon, and Chotiros Laongbua. 2008. "Introducing Government Use of Patents on Essential Medicines in Thailand, 2006-2007: Policy Analysis with Key Lessons Learned and Recommendations." International Health Policy Program, Ministry of Public Health, Thailand. <http://164.115.27.97/digital/files/original/80f0bb35df6675f9fb5429194be268e3.pdf>.

Abstract: In late 2006 and early 2007, Thailand's administration announced its intention to introduce the government use of patents for 3 pharmaceutical products, including 2 antiretrovirals (ARVs): efavirenz and lopinavir/ritonavir combination and drug for heart disease: clopidogrel. According to the Ministry of Public Health (MOPH), this action, with the aim to ensure access to affordable medicines in the public sector, complied with the flexibilities of the Agreement on Trade-related Aspects of Intellectual Property Rights (TRIPS). The Thai move

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prompted rigorous protests and pressure from multinational drug companies and their national governments. At the same time, the use of public health safeguards was praised by international agencies and non-governmental organisations (NGOs). This study assesses the roles of key actors and contextual elements that shaped the processes of policy making and implementation.

This analysis suggests that despite continual advocacy by civil society organizations, the idea of enforcing TRIPS flexibilities for essential medicines in Thailand was heightened on the governmental agenda and adopted as a public policy when the new administration took office after a military coup in September 2006. To deal with the opposition from powerful parties, the Thai government sought collaboration with existing alliances of domestic and international NGOs, many of which had experienced campaigning for expansion of HIV/AIDS treatment, including those to encourage the use of TRIPS safeguards for public interests. Diverse strategies were employed by responsible government agencies and civic networks in order to alleviate political pressures and avoid trade retaliations. It could be observed that the government use policy often moved back and forth between the formulation and implementation stage, while limited groups of key stakeholders were involved. While international authorities, such as the World Health Organization (WHO), seemed to be reluctant to participate in the disputes between Thailand and the opponents to the government use policy, global concerns about the unaffordable costs of patented drugs that hampered access to essential health care in the South was beneficial to the Thai action. The potential diffusion of this policy from Thailand to other developing countries triggered substantial tensions between the supporters and opponents of the government use enforcement.

The introduction of TRIPS flexibility for medicines in Thailand offers several lessons which may be helpful for resource-poor settings and health advocates coalitions, for example, the roles of public civic networks, relentless advocacy and collective learning among partners, as key factors of success. Policy recommendations derived from this study emphasize the needs for the commitment and leadership of the WHO, in collaboration with other parties, to bridge the gaps between the demands for and access to health products, by fostering intellectual property management frameworks which do not undermine health of the underprivileged.

“The TRIPS Flexibilities Database.” n.d. Medicines Law & Policy. Accessed December 6, 2020. <http://tripsflexibilities.medicineslawandpolicy.org/>.

Abstract: Not available

Urias, Eduardo, and Shyama V. Ramani. 2020. “Access to Medicines after TRIPS: Is Compulsory Licensing an Effective Mechanism to Lower Drug Prices? A Review of the Existing Evidence.” *Journal of International Business Policy*, September. <https://doi.org/10.1057/s42214-020-00068-4>.

Abstract: While Trade-Related Aspects of Intellectual Property Rights (TRIPS) was expected to hike up prices of patented medicines, there was no consensus on its likely final impact on access, because the agreement housed instruments to address this challenge. For instance, compulsory licensing, through the facilitation of price reductions, was considered to be an important countermeasure. However, little is known about the extent to which compulsory licensing has actually been effective in reducing prices of much-needed patented drugs. To fill this gap, this paper undertakes a systematic-review of the existing evidence on the impact of compulsory licensing on drug prices. Retrieval and analysis of 51 observations of pre- and post-compulsory licensing prices indicate that a compulsory licensing event is likely to reduce the price of a patented drug, albeit with some caveats.

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Moreover, compulsory licensing procurement from the international market is likely to be more effective in reducing drug prices than contracts to local companies. These findings are reconfirmed in the race to improve access to Remdesivir for hospitalized COVID-19 patients. Clearly, the future incidence and impact of compulsory licensing will depend on further possible procedural refinements to ease its implementation, the development of technological and manufacturing capabilities in developing countries, and the importance of biologics among life-saving drugs.

Vawda, Yousuf A. 2018. "Compulsory Licensing Jurisprudence in South Africa: Do We Have Our Priorities Right? - Research Paper No. 90." South Centre. [https://www.southcentre.int/wp-content/uploads/2018/12/RP90\\_Compulsory-Licensing-Jurisprudence-in-South-Africa-Do-We-Have-Our-Priorities-Right\\_EN-1.pdf](https://www.southcentre.int/wp-content/uploads/2018/12/RP90_Compulsory-Licensing-Jurisprudence-in-South-Africa-Do-We-Have-Our-Priorities-Right_EN-1.pdf).

Abstract: Compulsory licences are generally available on a variety of grounds, most notably on patents where the patentee is found to have abused its rights in one manner or another. This research paper attempts to review South African case law on applications for compulsory licences since the inception of the current legislation, analyse the interpretations placed on the relevant sections, and draw conclusions about judicial reasoning, impediments to the grant of such licences, and generally the courts' approach to disputes relating to patents.

Vawda, Yousuf A, and Bonginkosi Shozi. 2020. "Eighteen Years After Doha: An Analysis of the Use of Public Health TRIPS Flexibilities in Africa (Research Paper 103)." South Centre. <https://www.southcentre.int/research-paper-103-february-2020/>.

Abstract: As we observe the 18<sup>th</sup> anniversary of the Doha Declaration on the TRIPS Agreement (Agreement on Trade-Related Aspects of Intellectual Property Rights) and Public Health, it is appropriate to take stock of intellectual property developments and endeavour to present a comprehensive account of the situation in the African continent in respect of the implementation of TRIPS flexibilities, specifically those regarding access to medicines. This research paper provides an overview of the extent to which selected African countries have adopted legal and policy frameworks with regard to TRIPS flexibilities, examines the actual use of these flexibilities in enabling access to medicines in those countries, and suggests some recommendations for optimising the use of the flexibilities in pursuing public health imperatives.

Velásquez, Germán, and Tido von Schoen-Angerer. 2015. "Response: Unfair Attack to Developing Countries' Efforts to Use Compulsory Licenses." IP-Health Listservs, Knowledge Ecology International. March 6, 2015. [http://lists.keionline.org/pipermail/ip-health\\_lists.keionline.org/2015-March/004915.html](http://lists.keionline.org/pipermail/ip-health_lists.keionline.org/2015-March/004915.html).

Abstract: Not available

Vieira, Marcela, Felipe Fonseca, Pedro Villardi, and Clara Alves. 2017. "A Promoção Do Acesso a Medicamentos Por Meio Da Produção Local: Estudo de Caso Da Experiência Brasileira Sobre o Uso de Licença Compulsória e Licença Voluntária Do Ponto de Vista Da Sociedade Civil." In *Políticas de Produção Local de Medicamentos No Brasil: Elementos Para o Debate*, edited by Pedro Villardi, Felipe Fonseca, and Carolinne (Org.) Scopel, 85–127. Rio de Janeiro: ABIA - Associação Brasileira Interdisciplinar de AIDS. <http://deolhonaspateentes.org/wp->

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World Health Organization. 2018. "Progress Report on Access to Hepatitis C Treatment: Focus on Overcoming Barriers in Low- and Middle-Income Countries." Switzerland: World Health Organization. <https://apps.who.int/iris/handle/10665/260445>

Abstract: Not available

World Health Organization Regional Office for South-East Asia. 2017. "Country Experiences in Using TRIPS Safeguards: Part I." World Health Organization Regional Office for South-East Asia. <https://apps.who.int/iris/handle/10665/272977>.

Abstract: Not available

World Health Organization, World Intellectual Property Organization, and World Trade Organization. 2020. *Promoting Access to Medical Technologies and Innovation: Intersections between Public Health, Intellectual Property and Trade*. Second Edition. Switzerland: World Health Organization, World Intellectual Property Organization and World Trade Organization. <https://www.who.int/publications/i/item/9789240008267>.

Abstract: Not available

World Intellectual Property Organization, Secretariat. 2010. "Patent Related Flexibilities in the Multilateral Legal Framework and Their Legislative Implementation at the National and Regional Levels." World Intellectual Property Organization. [https://www.wipo.int/meetings/en/doc\\_details.jsp?doc\\_id=131629](https://www.wipo.int/meetings/en/doc_details.jsp?doc_id=131629).

Abstract: Not available

———. 2011. "Survey on Compulsory Licenses Granted by WIPO Member States to Address Anti-Competitive Uses of Intellectual Property Rights." World Intellectual Property Organization. [https://www.wipo.int/meetings/en/doc\\_details.jsp?doc\\_id=187423](https://www.wipo.int/meetings/en/doc_details.jsp?doc_id=187423).

Abstract: Not available

———. 2019. "Draft Reference Document on the Exception Regarding Compulsory Licensing SCP/30/3." [https://www.wipo.int/meetings/en/doc\\_details.jsp?doc\\_id=437425](https://www.wipo.int/meetings/en/doc_details.jsp?doc_id=437425).

Abstract: Not available

Yamabhai, Inthira, Adun Mohara, Sripen Tantivess, Kakanang Chaisiri, and Yot Teerawattananon. 2011. "Government Use Licenses in Thailand: An Assessment of the Health and Economic Impacts." *Globalization and Health* 7 (1): 28. <https://doi.org/10.1186/1744-8603-7-28>.

Abstract: BACKGROUND: Between 2006 and 2008, Thailand's Ministry of Public Health (MOPH) granted government use licenses for seven patented drugs in order to improve access to these essential treatments. The decision to grant the

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government use licenses was contentious both within and beyond the country. In particular, concerns were highlighted that the negative consequences might outweigh the expected benefits of the policy. This study conducted assessments of the health and economic implications of these government use licenses.

**METHODS:** The health and health-related economic impacts were quantified in terms of i) Quality Adjusted Life Years (QALYs) gained and ii) increased productivity in US dollars (USD) as a result of the increased access to drugs. The study adopted a five-year timeframe for the assessment, commencing from the time of the grant of the government use licenses. Empirical evidence gathered from national databases was used to assess the changes in volume of exports after US Generalized System of Preferences (GSP) withdrawal and level of foreign direct investment (FDI).

**RESULTS:** As a result of the granting of the government use licenses, an additional 84,158 patients were estimated to have received access to the seven drugs over five years. Health gains from the use of the seven drugs compared to their best alternative accounted for 12,493 QALYs gained, which translates into quantifiable incremental benefits to society of USD132.4 million. The government use license on efavirenz was found to have the greatest benefit. In respect of the country's economy, the study found that Thailand's overall exports increased overtime, although exports of the three US GSP withdrawal products to the US did decline. There was also found to be no relationship between the government use licenses and the level of foreign investment over the period 2002 to 2008.

**CONCLUSIONS:** The public health benefits of the government use licenses were generally positive. Specifically, the policy helped to increase access to patented drugs, while the impact of the US GSP withdrawal did not adversely affect the overall export status. Because the levels of benefit gained from the government use licenses varied widely between the seven drugs, depending on several factors, this study makes recommendations for the future implementation of the policy in order to maximise benefits.

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

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