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# Report on Compulsory Licensing Provisions in the National Patent Legislation of 15 Middle-Income Countries:

# A Content Analysis and Recommendations

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# A Content Analysis and Recommendations

A Report of the Global Economic Governance Initiative of the
Boston University Global Development Policy Center [*]

## Table of Contents



[*] The Global Economic Governance Initiative of the Boston University Global Development Policy Center advances policy-oriented research to enable the international financial architecture to foster financial stability, human well-being and environmental sustainability across the globe.


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## Executive Summary

The access to medicines discourse over the past 30 years has highlighted the myriad of obstacles to access experienced by low- and middle-income countries (LMICs). Already plagued by over-taxed health services systems, a limited health care workforce, and other resource constraints, in the mid-1990s these countries faced a new constraint in the form of the World Trade Organization's (WTO) Agreement on Trade-Related Aspects of Intellectual Property Rights (hereafter referred to as the TRIPS Agreement or TRIPS). The TRIPS Agreement raised the global baseline of protection for intellectual property rights (IPRs) including patents. As a result, countries struggled to gain access to medicines for major infectious and non-communicable diseases. This was especially visible in the lack of access to HIV antiretroviral (ARV) therapies in LMICs. The COVID-19 pandemic brought into even sharper focus the impact of intellectual property (IP) protection (particularly patents and trade secrets) on sufficiency of supply, price affordability, and equitable distribution of medicines and other health countermeasures. As a result, efforts to expand supply and distribution mainly relied on voluntary measures by pharmaceutical firms, and resulted in what some called "vaccine apartheid", such that high-income countries (HICs) had rapid access while LMICs did not.

The TRIPS Agreement, however, does provide for certain exceptions and limitations to exclusive IPRs, often referred to as TRIPS flexibilities. The principal flexibility is a provision allowing for compulsory licenses (CLs), authorizations granted by governments to allow themselves or others to work a patent without the consent of the patent holder. Under Article 31 of TRIPS, Member States are free to determine the grounds for issuing CLs as inclusively and broadly as they wish, as long as they comply with the procedural rules set out therein.

Although WTO members have a clear right to adopt and use TRIPS-compliant compulsory licensing mechanisms, their initial attempts to do so were met by strident opposition from industry and rich countries, especially the United States. Political pressure against the lawful use of flexibilities by South Africa led the Africa Group at the WTO to demand a clarification of TRIPS flexibilities. This ultimately resulted in the Doha Declaration on the TRIPS Agreement and Public Health in November of 2001, as well as a temporary waiver of the limitations on export of licensed medicines under Article 31(f), now codified as Article 31*bis*. These additional interpretations and revisions of Article 31 were made to ensure that countries have additional flexibility to manufacture, export and import pharmaceutical products for countries with insufficient capacity to manufacture domestically.

From 2003 to 2008, CLs were frequently deployed, especially to access generic supplies of HIV drugs. In 2010, however, following the creation of the Medicines Patent Pool (MPP), reliance on CLs dropped in favor of voluntary licensing mechanisms. Unfortunately, many upper-middle income countries (UMICs) are often excluded from voluntary licenses, including those negotiated with the MPP. Even during the early days of the COVID-19 pandemic, it was mostly HICs that rushed to allow inventors and manufacturers to override patent rights to address COVID-19 pandemic needs. Indeed, the US deployed the most widespread use of government use licenses (GULs), a special kind of CL for the purpose of securing "public, non-commercial use", "by or for" the government, during the COVID-19 pandemic.

This study examines the national legislation supporting the granting of CLs by middle-income countries (MICs). Given HIC willingness to override traditional patent rights during the pandemic, and an increasingly positive public discourse around the use of CLs in the aftermath

of the pandemic as seen in the European Union, there are strong reasons for MICs to adopt robust and easy-to-use compulsory and government use licensing laws. These laws make legal space for them to overcome the risks of delayed and insufficient supply, unaffordable prices, and inequitable distribution. This rationale informs our research question, which explores the extent to which our study countries (all of which have been historically excluded from MPP voluntary licensing programs and most of which are MICs) have adopted such provisions in their domestic laws. Building on previous studies, this paper assesses existing domestic legal provisions against a more detailed matrix of potential CL law components that are likely to maximize the effectiveness and useability of these laws, specifically with the goal of protecting public health. As such, the study is both a content analysis of the CL laws of 15 countries and a comparison between those laws and a set of "best practices", identified by experts in the area of access to medicines and IP, to maximize the policy space that countries have to issue effective compulsory licenses.

We drew a sub-sample of study countries from a list of all the MICs excluded from Gilead's 2014 licenses for medicines to treat the hepatitis C virus. We downloaded and reviewed all relevant legal texts related to compulsory licensing for each country from WIPOLex database, identifying the presence or absence of those best practices. In order to compare laws across countries, as indicated above, we divided the best practices into three categories: (1) the breadth of the grounds allowed for issuing compulsory and government use licenses, (2) the procedural flexibilities (measuring general ease-of-use for the compulsory licensing law) and (3) the scope of application (measuring ability to issue CLs on pending patents and product components and to import and export the patented product under the law). We then developed a quantitative scoring system to allocate points based on the degree to which best practices were incorporated into the countries' laws. To explore what additional, non-legal factors might also play a role in the effectiveness and useability of a country's CL laws, we explored in more detail the cases of two of our study countries: Thailand and Colombia.

All 15 countries in our sample have established CL laws, which is unsurprising given that all of the countries are WTO members, except for Algeria, which has "Observer" status. These laws allow for at least some bases for issuing CLs, usually at the request of an interested party. The national legislation of all 15 countries applies the basic procedural rules for compulsory licensing in the TRIPS Agreement, often including prior negotiation requirements with the IP right holder, requiring remuneration, which must be "adequate" or "reasonable", and which allow for the CL to be revoked if the circumstances that gave rise to it no longer exist. Most importantly, none of the subject countries have maximized their CL policy space. There is significant variation in the degree to which, and the ways in which, flexibilities provided for by TRIPS Article 31 and 31*bis* have been incorporated into countries' national CL laws, which is consistent with the findings of previous studies. Given the diverse types and degrees of implementation of TRIPS flexibilities, as well as the diverse experiences with issuing compulsory licenses, the two case studies (Thailand and Colombia) highlight the other factors that impact a country's experience with compulsory licensing.

While expanding policy space by reforming CL laws would make issuing CLs easier, it is clear also that the issuance of CLs does not depend on the quality of legislation alone. There is a complex interplay between other factors in the environment that shape the prospects for a successful CL, including the patent and trade secret landscape, political will and pressure, regulatory requirements, technical and financial capacity and market size. In other words, having workable CL legislation is necessary but not sufficient – whether governments are able to issue CLs may be more related to legal, economic, resource, and political factors aside from

the technical aspects of their laws. Removing barriers within the TRIPS Agreement and other trade agreements through reform and relieving the political pressure on UMICs not to issue CLs may turn out to be as important for improving access to medicines as the specific features of their national CL mechanisms.

In light of these findings and conclusions, the report makes six core recommendations:

1. **National law reform**. Countries should, as much as possible, fully adopt the TRIPS flexibilities for more effective and easier use of CLs for access to medicines.

2. **Technical Support for countries excluded from voluntary licenses.** Given the limited incorporation of TRIPS flexibilities across the board in MICs, additional technical support and guidance should be provided by key international organizations with relevant mandates like the World Health Organization (WHO) or the United Nations Development Programme (UNDP).

3. **Middle-income country cooperation and coordination**. MICs should cooperate in sharing best practices with respect to law reforms and coordinate the granting of CLs in order to create aggregate markets and generate economies of scale for generic manufacturers.

4. **Increasing attention to and adoption of supportive and enabling companion policies**. Countries should harmonize their regulatory requirements to reduce the complexity, cost, and delay of seeking regulatory approval. Other recommended enabling policies include clinical guidance required in workforce training, adding more medicines to the essential medicines lists, and more.

5. **Reform of TRIPS and other trade agreements**. Ideally, TRIPS should be reformed to remove the specific obstacles in Article 31(f) and 31*bis* that keep countries from effectively aggregating purchasing and production markets, and to provide greater clarity around the other flexibilities available. Moreover, countries should avoid negotiating TRIPS-plus provisions and investment clauses that allow IP-related claims; and trade agreements that contain these types of provisions should be renegotiated.

6. **Further research**. There is a need for further research to identify better examples of full implementation of CL-related TRIPS flexibilities in national laws.

## I. Background of the Project

The access to medicines discourse over the past 30 years, most famously with respect to access to HIV antiretroviral therapies (ART), has highlighted the myriad obstacles to access experienced by low- and middle-income countries (LMICs). These countries, already plagued by deficient health service delivery systems, a limited health care workforce, and public and private resource constraints, found themselves newly constrained from the mid-1990s by global intellectual property (IP) standards. The creation of the World Trade Organization (WTO) and its TRIPS Agreement raised the global baseline of protection for intellectual property rights (IPRs). It granted originators newly expanded rights to exclude competition, and to determine if and when to bring their products to market and what prices to charge.

These international legal changes confounded efforts to tackle major infectious and chronic diseases. While the U.S. and the E.U. had access to highly active ART starting in 1996, expanded access in Africa was delayed for more than a decade, in part because of IP barriers. However, the COVID-19 pandemic brought into even sharper focus the impact of IP protection (particularly patents and trade secrets protection) on sufficiency of supply, price affordability, and equitable distribution of life-saving medical countermeasures. Protected by exclusive patent rights that prevent competitors from "working" a patented product or process, and protected further by laws permitting trade secrets and other commercially valuable information to be kept confidential, COVID-19 medical countermeasures were distributed largely according to commercial interests and demand of rich country instead of global public health needs (Baker and Thrasher 2023, 2–3). The predictable results were IP-related supply bottlenecks that were exacerbated by domestic hoarding by rich countries via bloated preferential advance purchase agreements This further resulted in delayed and insufficient, or non-existent, access for LMICs – developments described respectively as vaccine nationalism and vaccine apartheid (Riaz et al. 2021; Forman, Jackson, and Fajber 2023).

Although the need for expanded supplies, affordable prices, and globally equitable distribution was recognized early, the biopharmaceutical industry maintained control over supply, price, and distribution in part because of an interlocking system of patents, called "patent thickets", held in countries around the world that cemented its monopolies (Baker 2021a; Gardner 2021). Prominent pharmaceutical firms entered into more than 450 voluntary agreements with other suppliers (Airfinity 2023), but virtually all of those agreements were in the form of contract manufacturing agreements (mostly fill-and-finish) tightly controlled by the originator (Baker 2021b). Despite multiple requests that companies license and transfer their medical technologies to independent qualified producers in LMICs, most large pharmaceutical companies declined (Baker and Thrasher 2023, 24–26). Indeed, Pfizer/BioNTec and Moderna refused to license and transfer know-how on their platform messenger RNA (mRNA) vaccine, despite an explicit request from the WHO mRNA Technology Transfer Programme, which involved prospective manufacturers in South Africa and 14 other LMICs (Baker and Thrasher 2023). They presumably did so because of their desire to avoid future competition as they explored highly profitable new uses of the mRNA platform, including to prevent or treat cancer (Shi et al. 2024).

Even in the wake of a pandemic that caused nearly 25 million excess COVID-related deaths, massive social disruptions, and trillions of dollars in economic losses, global leaders debated at length in the WHO Pandemic Treaty negotiations whether to rely solely on voluntary, mutually agreed commercial measures to provide access to countermeasures in future pandemics or whether involuntary measures might also be needed (The Economist 2022;

Reuters 2022; Report by the Director General 2024; Love 2024). Negotiations proved difficult and protracted (Gleeson et al. 2024), with key equitable access provisions progressively watered down to achieve consensus. The text finally agreed in April 2025 to be put to the 78th World Health Assembly reportedly struck a compromise on the language related to technology transfer, referring to it as "mutually agreed", defined in a footnote as "willingly undertaken and on mutually agreed terms, without prejudice to the rights and obligations of the Parties under other international agreements" (Cullinan 2025). While this language carefully retains the right for Parties to use compulsory measures (while not committing them to do so), the extent to which this was a sticky point illustrates the ongoing tensions over technology transfer, which are not likely to resolve any time soon.

Fortunately, patent and competition law provides for certain exceptions and limitations to exclusive rights under existing global IP rules thereby allowing countries to retain policy space[1] to find alternative producers. The principal safeguard in this regard is compulsory licenses (CLs), authorizations granted by governments to allow themselves or others to work a patent without the consent of the patent holder, conditioned only by procedural requirements and the payment of adequate remuneration (WTO 2024). Regrettably, CLs were not widely used during the COVID-19 pandemic for a variety of reasons discussed further below.

***Compulsory licenses, a history***

CLs, also known as involuntary licenses, have been a feature of international patent law since the Paris Convention for the Protection of Industrial Property Conference of the Parties in 1925 (Correa 1999). In lieu of providing for revocation or forfeiture of patent rights in the event of abuse, including failure to use or "work" the invention such that the public could benefit from the innovation, CLs were identified as the preferred international remedy in Article 5A of the Paris Convention. By issuing a CL when the patent holder was abusing its rights, countries were permitted to authorize use of the patent by other entities who could then manufacture and commercialize the patented subject matter.

Despite the existence of the Paris Convention, during much of the twentieth century patent law was globally a feature of domestic not international law. Accordingly, there was wide variation in how countries protected patents and other IP rights. Even though patent regimes in many LMICs had been imposed by colonial masters, countries varied considerably in defining patentable subject matter, patentability criteria, exceptions and limitations, and how long patents lasted (Drahos 2002, 766–67). Mid-century, exactly half the countries who were signatories to the Paris Convention, including many in Europe, did not allow patents on pharmaceutical products and/or agricultural technologies (Drahos 2002, 768).

Given the slow and late development of the pharmaceutical industry in the mid-century, agitation for broader IP protection only started in earnest in the 1960s and 70s when high-income countries (HICs) argued for IP harmonization at WIPO (Drahos 2002, 768–69; Drahos and Braithwaite 2002). At the same time, newly independent LMICs were campaigning for technology transfer without strict IP rights, the right to copy, and other flexibilities to support industrial development – in other words, IP-avoiding mechanisms used by many countries historically to support their own industrial development. Because HICs and LMICs had

[1] For the purpose of this paper, we adopt the definition of policy space by Koivusalo et al (2009, p. 105) as "the freedom, scope, and mechanisms that governments have to choose, design and implement public policies to fulfil their aims".

divergent interests (HICs desiring to protect their existing IP-intensive industries and LMICs desiring to build new ones), WIPO reforms stalled (Chang 2002).

The impasse at WIPO led pharmaceutical and other IP-intensive industries, through the HICs that supported them, to redouble their efforts to globalize and harmonize IP protections during the Uruguay Round of negotiations on the General Agreement on Tariffs and Trade (GATT) (Drahos 2002, 769–76). The negotiations, which concluded in 1994, established the WTO and included a new chapter, the TRIPS Agreement (WTO 1994). The TRIPS Agreement established minimum standards and enforcement obligations across a range of IPRs including patents, confidential information, trademarks, copyright, industrial design, geographical indications, and topographies of integrated circuits.

***Changes wrought by the TRIPS Agreement***

Protection of patents and confidential information, including data submitted to regulatory authorities to obtain marketing approval for pharmaceuticals, were the most consequential sections affecting innovation and access to health technologies. With respect to patents, Article 27.1 of the TRIPS Agreement requires that product and process patents be granted "without discrimination as to the place of invention, the field of technology and whether products are imported or locally produced" for a minimum of 20 years and with remedies for infringement, including the possibility of injunctive relief (WTO 1994). Beyond patents, commercially valuable confidential information must be protected from dishonest commercial use, and certain undisclosed pharmaceutical test and other data submitted for marketing approval must also be protected against unfair commercial use and unwarranted disclosure. Although the TRIPS Agreement codified new and stronger IP protections, it also provided for key flexibilities including: (1) transition periods for least developed country Members, developing countries, and countries that had not previously provided patent protection for pharmaceuticals products; (2) exclusions, exceptions, and limitations to patent rights; (3) allowance for international exhaustion or parallel importation;[2] and (4) a waiver from IP enforcement obligations to address essential security interests.

For the purposes of this paper, the most important flexibility is found in Article 31 of the TRIPS Agreement, which provides guidelines for granting CLs. Under Article 31, countries are free to establish self-determined grounds for issuing CLs as inclusively and broadly as they wish, as long as they comply with the procedural rules encoded in the Agreement. In 2003, WTO members negotiated a waiver (WTO 2003) and eventually an addition to the TRIPS Agreement, Article 31*bis*, which allows for additional flexibilities for manufacture, export and import of pharmaceutical products for countries with insufficient capacity to manufacture domestically (WTO 2024).

Under Article 31, CLs can be granted to domestic or foreign entities for production or import of the patented product, though foreign entities (producers) will then need a second CL for export if the product is patented in their home State. In addition, under Article 31(f) of the TRIPS Agreement, the foreign producer who requires a CL from its own country, is often

[2] Allowing a country to adopt a system of "international exhaustion" means that once a patented product is first sold in any market in the world, the patent right is "exhausted" and the patented product may be re-sold into a new market. This effectively allows "parallel importation", where a patented product enters the domestic market from two sources: from the originator, and from another country where the originator had sold it at a prior time. This theoretically allows a country to enjoy cheaper access to the patented products because of competition, and because prices negotiated by originators often differ between countries (Williams 2020).

limited with respect to the quantity of a patented product it can export – namely non-predominant quantities, meaning that the majority of what is produced must be for domestic use.

The prototypical CL permits manufacture, sale, use, and importing of a patented invention upon request by any applicant that jumps through all the procedural hoops. Most countries also include alternative license rules for the purpose of securing "public, non-commercial use" "by or for" the government – also known as government (or crown) use – to authorize the government or its subcontractor to exploit the patent. In the medical context, government-use licenses (GULs) allow supply to public sector health care systems or government-financed health programs. Other CLs are permitted (1) as a remedy for anti-competitive behavior (Art. 31(k)) and (2) for secondary or "dependent" patents where infringement of the "first" patent is necessary to exploit a second patented invention. In the latter context, the second patent must represent a significant technical advance with considerable economic significance, and a cross license must be granted to the first patent holder (Art. 31(l).[3]

In addition to these rules, certain procedural requirements must be met:

1) Authorizations must be considered on their individual merits (Art. 31(a)), though class-based merits and presumptions in favor of issuance can be allowed;[4]
2) The scope and duration of use granted should be limited to the purposes for which the use was authorized (Art. 31(c));
3) The use should be non-exclusive and non-assignable (Art. 31(d) and (e));
4) Continued use may be revoked when the grounds for the use have ended and are not likely to recur, as long as the legitimate interests of the licensee are adequately protected (Art. 31(g)); and
5) The legality of the license and the amount of remuneration must be reviewable judicially or by a distinct, higher authority (Art. 31 (i) and (j)).

Under the TRIPS Agreement, ordinary CLs require prior negotiation with the patent holder for a voluntary license on reasonable commercial terms for a reasonable period of time whereas government-use, emergency, and competition-based licenses do not (Art. 31(b) & (k)). When there are multiple patents on a product, as there often are for pharmaceuticals, a CL must be issued with respect to each patent (Art. 31(b)). In the context of emergencies or matters of "extreme urgency", CLs may be granted on final products and their subcomponents without any need for prior negotiation, but all relevant patent holders are entitled to a notification as soon as reasonably practicable (Art. 31(b)). In contrast, typical government use licenses do not require a patent search or identification of all relevant patents before or after issuance, allowing such licenses to be issued on final products and their subcomponents. TRIPS requires "adequate remuneration" to all rightsholders "taking into account the economic value of the authorization" (Art. 31(g)). In the case of GULs, however, the rightsholder might have to identify itself and compensation can be reduced or even eliminated for competition-based licenses (Art. 31(k)). Finally, while CLs may be granted to domestic or foreign entities, the

[3] A "cross-license" in this case would allow the first patent holder to also use or exploit the second patent. It is considered a quid pro quo, since using the second patent is dependent on the use of the first.

[4] Requiring license authorizations to be made on the basis of individual merits means that each petition for a CL will be assessed individually as to whether it is justified by the substantive grounds legally recognized under the law. In some instances a CL may be granted based on the "class" (or type of CL) to which it is a part.

majority of what is produced under the license must be for supply of the domestic market (of the CL granting jurisdiction) (Art. 31(f)) (WTO 1994).

Within these rules, countries have broad discretion to define many features of their CL law. They may establish many grounds for issuing CLs, such as the need to promote national development priorities, assure affordability, protect nutrition and health, and simply meet the domestic demand for a particular product. Countries are also free to determine what constitutes "commercially reasonable terms" and the amount of time given to concluding prior negotiations. Countries can and have established remuneration guidelines, frequently calculated as a small percentage of the wholesale price (Love 2005).

In many respects, the most problematic requirement in Article 31 is found in subsection (f), which requires that "use shall be authorized predominantly for the supply of the domestic market of the Member authorizing such use." Although big, rich countries like the US can issue CLs domestically that are potentially profitable to licensees and do not run afoul of 31(f), smaller and poorer countries with insufficient domestic manufacturing capacity might find themselves without a supplier if that supplier can only export non-predominant quantities. In the pre-TRIPS era, Canada was uniquely aware of this problem, and, during a period of its wide-spread issuance of CLs, Canada allowed its licensees to export without restriction to other countries with no patent barriers so that economies of scale might be reached (Reichman and Hasenzahl 2003).

***Early political obstacles to compulsory licenses***

Although WTO members had a clear right to adopt and use TRIPS-compliant compulsory licensing mechanisms and other TRIPS flexibilities, including transition periods and parallel importation, their attempt to do so was met by strident opposition from industry and rich countries, especially the US For example, when South Africa passed a law permitting parallel importation, 39 drug companies and trade associations sued the Mandela Government in what ultimately became a four-year, but unsuccessful, legal battle (Oxfam 2001). Simultaneously, the US threatened trade sanctions against South Africa and made similar moves to restrict the use of TRIPS flexibilities against Brazil (for allowing CLs for non-local working), Thailand (for threatening issuance of a CL), Argentina (for the absence of data exclusivity), and other LMICs through use of its Special 301 Watch List and other means (Bond 1999; Attaran and Champ 2002; Markandya 2001; Yu 2018). These political constraints on the use of lawful flexibilities led the Africa Group at the WTO to call for a clarification of TRIPS flexibilities, which ultimately resulted in the Doha Declaration on the TRIPS Agreement and Public Health in November of 2001 (Sun 2004; WTO 2001).

In addition to reasserting members' rights to determine their own grounds for issuing CLs and what health problems were emergencies or matters of extreme urgency, and members' rights to allow parallel importation, the Doha Declaration clarified members' right to ensure access to medicines for all as long as TRIPS procedural minimums were met. Special attention was given to relaxing the requirements of Article 31(f) to allow export to countries with insufficient domestic manufacturing capacity. Paragraph 6 of the Doha Declaration charged the TRIPS Council to come up with an expeditious solution to the production-for-export problem.

Unfortunately, the resulting solution, initially a waiver and now Article 31*bis* of the TRIPS Agreement, was neither expeditious nor effective (WTO General Council 2003; WTO 1994; Vincent 2020). Instead of an easy-to-use mechanism to allow adequate supplies to all non-

producing countries, Article 31*bis* requires labyrinthine procedures requiring country-by-country, product-by-product, and possibly quantity-by-quantity CLs (Baker 2004). The process is also overladen with multiple notifications from importing and exporting countries and exporting entities, and imposes obligations both to differentiate the commercial image of the licensed product and take other measures to prevent diversion to unauthorized markets. Despite the adoption of the original Paragraph 6 waiver 21 years ago, the production-for-export to non-producing countries mechanism has been used only once (Weber and Mills 2010; Houston 2021).

***Ongoing obstacles to issuing compulsory licenses: fits and starts***

For a while post-Doha Declaration, CLs were frequently deployed, especially to access generic supplies of ARVs to treat HIV. Ellen 't Hoen has documented 100 CL applications between 2001 and 2016, 81 percent of which were implemented and 78 percent of which involved HIV medicines.[5] However, CLs were used for 13 other diseases as well, including cancer. The use of CLs was highest in the 2004-2008 period, until voluntary licenses became more common ('t Hoen 2023). In 2010, the Medicines Patent Pool (MPP) (supported by Unitaid) was created, leading to even more widespread voluntary licensing not just of ARVs, but of treatments for TB, hepatitis C, and other medicines (MPP 2020; Baker 2018). The voluntary licenses would then be issued to an exclusive list of firms for manufacture and exported to a fixed list of countries authorized by the originator pharmaceutical firm – a list that frequently excluded many commercially attractive upper-middle-income countries (UMICs).

One would have expected that unanimous approval of the Doha Declaration would have prompted countries to amend their laws to take full advantage of TRIPS flexibilities relevant to CLs and GULs. Although some countries and self-governing States certainly did pass at least partial reforms, including India, Zanzibar, Uganda, Indonesia, and the Philippines, many others who were frequently excluded from voluntary licenses did not. Moreover, some of these same countries have negotiated free trade agreements (FTAs) with the US and EU that require even greater IP protections and remedies. While those other treaties largely leave Article 31 rules intact, they frequently limit other flexibilities, for example through requiring data exclusivity periods that make CLs more difficult to issue effectively (El Said 2022).[6]

In the absence of a CL, in order to gain access to those same medicines, countries excluded from MPP licenses must negotiate with a highly concentrated pharmaceutical industry incentivized to maintain strict protection over patents and trade secrets, as well as to maximize commercial returns through public-private market segmentation and confidential tiered-pricing practices. These countries, typically UMICs, face the added problems of delayed regulatory approval and market entry as biopharmaceutical companies concentrate on more profitable sales in European and US markets (Wouters and Kuha 2024). After 2010, reliance on CLs declined and did not pick back up even during the draconian days of the COVID pandemic.

[5] The TRIPS Flexibilities database does not differentiate between compulsory licenses and government use licenses. As such, these CLs which were requested and granted includes GULS as well.

[6] By extending data exclusivity periods, these treaty commitments make it difficult or impossible for CL petitioners to rely on the original clinical trial data to support their own market and regulatory approval applications.

### *Expanded use of and political space for CLs during the COVID-19 pandemic*

Paradoxically, it was mostly rich countries that rushed to enact and use laws allowing override of patent rights to address COVID-19 pandemic needs (WTO, WHO, and WIPO 2023). Such countries included Canada, Germany, France, Italy, and Hungary. Israel issued a government use license on lopinavir/ritonavir (which ultimately proved ineffective against SARS-CoV-2), and Russia and Hungary issued CLs on Gilead's remdesivir. On the other hand, Canada thwarted an effort by Bolivia, Antigua and Barbuda to access a COVID vaccine through Canada's Article 31bis export scheme by refusing to add COVID-19 pharmaceutical products to its authorized list. India likewise declined to issue CLs despite invitations to do so by Delhi High Court and the Supreme Court of India (WTO, WHO, and WIPO 2023, pp. 12–13).

The most widespread use of government use licensing during the COVID-19 pandemic was by the U.S. which issued contractual authority under 28 U.S.C. sec. 1498[7] to dozens of its COVID-countermeasure contractors to infringe patent rights with impunity, subject only to the government's duty to compensate the infringed party for the government's "use" of the patent (WTO, WHO, and WIPO 2023, p. 12). In addition, during discussions of South Africa and India's temporary TRIPS waiver proposal, the European Commission championed use of CLs to address unmet countermeasure needs and the US dropped all opposition to the adoption and use of CLs in its Special 301 reports (European Commission 2021; USTR 2024a). Although the European Commission did not move with alacrity to address uneven and delayed access to COVID-19 countermeasures in poorer regions of the EU, it is currently considering a proposal to establish a regional compulsory licensing mechanism to address future health emergencies (WTO, WHO, and WIPO 2023; Vidal and Beck 2024; 't Hoen 2024).[8] In all, the pandemic re-engaged the interest and increased the political will to expand CL policy space for access to medicines in emergencies, even if primarily in the United States and Europe.

### *Rationale for this study*

Given their routine exclusion from voluntary licenses,[9] the evolving practice by HICs of embracing CLs, and increasingly positive public discourse around the use of CLs, there is little question that MICs and particularly UMICs, should adopt robust and easy-to-use compulsory, government-use, and competition-based licensing laws to make legal space for them to overcome the risks of delayed and insufficient supply, unaffordable prices, and inequitable distribution. For this reason, we explore the extent to which MICs that have been historically excluded from voluntary licensing programs have adopted such provisions in their domestic laws. Following that, we propose concrete policy recommendations for how they might improve their opportunities for increasing access to medicines through these measures.

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[7] 28 U.S.C. sec. 1498 allows an originator to sue the US in federal court for violations of their patent rights where the use of the patented invention is "by or for" the US. It allows, however, for the US to argue that its use was "substantially justified" or that "special circumstances" make a remedy awarded to the originator "unjust". This gives the US Government freedom to permit subcontractors to use patented inventions in their production under "special circumstances" such as a pandemic. 28 U.S.C. sec. 1498(a).

[8] In the absence of a regional mechanism, individual European countries would have to take their own initiative to issue CLs in a health emergency. The lack of coordinated action could not only delay access to medical countermeasures but could lead to more transborder transmission and undermine an effective regional response..

[9] While there are many commercial voluntary licenses (as mentioned above in this section), including contract manufacturing agreements, granted to pharmaceutical firms in these countries, here and elsewhere we use the term "voluntary license" to specifically refer to what are generally referred to as bilateral "access" licenses and MPP licenses.

There are clear normative bases for this move. In the first place, maximizing policy space makes sense to keep CL opportunities open, even if a subsequent decision (about the need for a particular CL, or the most effective way to gain access to particular product) is needed before granting a CL. In other words, countries should keep all the tools in their policy toolkit even if they don't need them all of the time. Second, CL flexibilities may be critical to the newly energized movement to develop biopharmaceutical research and manufacturing capacity in LMIC regions (UNITAID 2023). This effort to decentralize pharmaceutical manufacturing can help fulfill global public health and human rights norms such as the right to health, as articulated in sustainable development goal 3 (SDG3) (UN General Assembly 2015).[10] Finally, there have been multiple international initiatives led by global institutions that have all included proposals or final text recommending adoption and use of TRIPS flexibilities, including CLs.[11]

This study was undertaken to assess to what extent countries typically excluded from voluntary licenses have adopted TRIPS-compliant flexibilities in their domestic CL laws such that they are as effective and easy to use, as permitted under the global rules. There have been earlier studies of compulsory licensing provisions globally and in particular regions, but those studies have often lacked granularity or might not be up to date. McGivern (2023) analyzed domestic patent legislation in 187 countries with domestic or regional patent laws. Of those, 176 (94.1%) had CL provisions and only 11 did not (McGivern 2023). However, only 72 (38.5%) provided for CL for import or export of pharmaceuticals specifically (i.e., implemented TRIPS Article 31*bis*). McGivern acknowledges that her study has limitations as due to the large number of countries included, it did not analyze the CL laws in depth.

McGivern's study was only one of the more recent in a series of studies exploring CLs in various contexts. Musungu (2007) had previously examined and briefly summarized national and regional patent legislation affecting 39 African countries finding that all of them had compulsory licensing rules and that most, but not all had government use provisions. WIPO also undertook a comprehensive and detailed study of compulsory licensing provisions, including grounds for such licenses, in 2010, but it has not since been updated (Committee on Development and Intellectual Property (CDIP) 2010). Khor and contributors (2014) studied CLs and government use provisions in Malaysia, Indonesia, Thailand, Zimbabwe, Ghana, Brazil, United States, and India (Khor 2014). Another study by Correa and Lamping (2024) looked in detail at patent laws, including CL provisions, in a selection of Latin American countries while Krikorian (2017) examined IP legislative landscapes in Egypt, Morocco, and Tunisia. Vawda & Shozi (2020) updated a review of TRIPS flexibilities in Africa, including reporting on and making recommendations concerning CLs. Mitchell and Taubman (2023) examined CL laws in ten countries in the Asia-Pacific as part of a study of how TRIPS flexibilities could be utilized to increase vaccine production in this region.

The current study is designed to update these and other previous studies and to assess existing legal provisions against a more detailed matrix of domestic CL components that are likely to maximize the effectiveness and useability of these laws, specifically with the goal of protecting

[10] SDG 3 explicitly supports "healthy lives and promote well-being for all at all ages".

[11] The international initiatives include (the Global Commission on HIV and the Law, the High Level Panel on Access to Medicines, the WHO Commission on Intellectual Property Rights, Innovation, and Public Health, and most recently the WHO negotiations on a Pandemic Prevention, Preparedness and Response Treaty). For a description and critique of some efforts to energize local/regional production, see (Chaudhuri 2023).

public health. It is hoped that this analysis will provide a more comprehensive legal landscape and understanding for policymakers as they make decisions about changes to their domestic laws. It may also prove useful for civil society organizations as they advocate for compulsory licensing to address public health needs.

The objective is to study the text of the compulsory licensing legislation in a sample of largely UMIC excluded from Gilead's original hepatitis voluntary license and assess the scope and alignment with the best practices. The study explores the extent to which representative countries that have been excluded from voluntary licenses have legal rules that facilitate or obstruct the effective deployment of CLs to address emergencies and other public health needs. Following this observational analysis, it compares country laws, identifying differences and similarities along regional and other country group lines.

## II. Study Design and Methodology

### *Study design*

This study is a content analysis of the compulsory licensing laws of 15 middle-income countries, and a comparison between those laws and a set of "best practices" identified by experts in the area of access to medicines and IP. Generally speaking, those "best practices" are identified as components or characteristics of compulsory licensing laws which make them both (1) effective in increasing access to affordable health technologies and (2) easy (for both the government and petitioners) to use. The best practices identified and relied on for comparison in this study were identified by the authors based on analyses by the Max Planck Institute, Carlos Correa, and their own work (Hilty and Lamping 2014; Correa 2000, 2013a; Baker 2019, 26–35). The practices generally fall into three distinct categories: (1) the breadth of the grounds allowed for issuing compulsory and government use licensing, (2) the procedural ease-of-use of each country's laws, and (3) the scope of application of these licenses. Each of these categories is described in more detail below.

### *Selection of countries*

There are many MICs that have been commonly excluded from large scale voluntary licensing by large pharmaceutical firms (Baker 2023; MSF 2020). Although the lists of excluded countries vary across licenses, we drew our sub-sample from a list of all the MICs excluded from Gilead's 2014 licenses for medicines to treat hepatitis C virus (HCV) (MSF 2015a). These countries were verified against the list of included territories in Gilead's 2014 license (Gilead Sciences 2014). We found this list to be illustrative of the countries that would benefit the most from improving their CL legislation to improve effectiveness and ease of use.

From among those countries, we selected a sample of 15 countries which were middle-income at the time, geographically diverse, and consistent with the language capacity of our principal researchers and research assistants, including countries with laws in English, Spanish, Arabic and French. Our final selection of countries included Algeria, Argentina, China, Colombia, Ecuador, Jordan, Malaysia, Mexico, Panama, Peru, Philippines, Romania, Thailand, Turkey and Ukraine.[12]

Gilead's voluntary HCV license was amended and restated in 2017 (see Gilead Sciences 2017) to add a further 14 countries, including five of our study countries: Algeria, Malaysia, Philippines, Thailand, and Ukraine). This occurred after Malaysia issued a CL for Sofosbuvir (MSF 2020). While five of the countries in our sample were added to the license in 2017, their omission from the 2014 license suggests that they remain vulnerable to exclusion from other voluntary licensing arrangements. Thailand, for instance, remains excluded from MPP licenses for other hepatitis C drugs (Tenni et al, 2024).

### *Sources of legal texts, data extraction and search strategy*

To evaluate the content of the laws, we downloaded relevant legal texts from the WIPO legal database (WIPO 2024b), supplementing these documents with texts from additional official sources publicly available online as needed. Within the WIPO Lex database, we selected the

[12] While these countries were MICs when excluded from the voluntary licensing programs, not all were classified as middle-income by the time of the current study.

following options from the "Subject Matter" menu: Enforcement of IP and related laws, IP regulatory body, Patents (Inventions), Transfer of Technology and Undisclosed Information (Trade Secrets). We further narrowed the search in the "Type of Text" menu to search only: Implementing Rules/Regulations, IP-related Laws and Main IP Laws. We used Python Web Scraping code to download all those documents for each of the study countries (see Appendix C).

We then created a search strategy that allowed us to identify within each legal text those sections and provisions which were most relevant to assessing a country's ability to fully implement CL flexibilities as allowed by the TRIPS Agreement. We engaged four research assistants to review the documents and identify the relevant provisions. We assigned two research assistants to each country's laws to increase the likelihood that we did not misidentify the legal language. Following this data gathering stage, we reviewed that data for inconsistencies between research assistant responses and resolved those inconsistencies through further document review by legal experts in the research team. We also checked the findings for specific countries (China, Thailand and Ukraine with external researchers with expertise in those countries.

***Data analysis and comparison***

In order to compare laws across countries, as indicated above, we divided the best practices into three categories: (1) the breadth of the grounds allowed for issuing CLs and GULs, (2) the procedural flexibilities (measuring general ease-of-use for the compulsory licensing law) and (3) the scope of application (measuring the ability to issue CLs on pending patents and product components and to import and export). We then developed a quantitative scoring system (described below) to allocate points based on the degree to which best practices were incorporated into the countries' laws.

*Assessing the breadth of grounds allowed for issuing compulsory and government use licenses*

One way to improve both effectiveness and ease-of-use for compulsory and government use licensing is for countries to build into their laws multiple and broad grounds for issuing these licenses. Allowing national decision makers to determine when it is in the interests of the government or the public to expand production of a patented product through licensing is a fundamental flexibility built into the TRIPS Agreement.

In order to quantify the expression of this flexibility in the CL laws, we identified each unique basis ("ground") for issuing a license under each larger CL category (see Table 2). For example, where the law allows CLs to be issued for general exploitation (as a CL category), usually in the case of non-use or insufficient use of a patented invention, it may also include other grounds like suspension of use of the patent, excessive pricing of the product, refusal to license the rights to other parties, or failure to work the patent locally.[13] In another example, where the law allows CLs to be issued in the public interest (as a CL category), sometimes only the broad term "public interest" is used as a basis for issuing a CL, while in other cases, multiple specific public interest grounds are listed, such as public health, excessive pharmaceutical pricing,

[13] As provided for in TRIPS Article 31(l), countries may also grant compulsory licenses on patents that are necessary to use in order to exploit a secondary patent, provided the secondary patent represents an important technical advance and [other requirements] and that the secondary patent holder offers a cross license to the prior patent holder.

protecting the environment, or pursuing economic development. Other broad and specific grounds can be found in Table 2.

For the individual grounds under each category, we generally assigned 1 point, except in the case of very broad grounds (public interest, emergency, public non-commercial use) or in the case where the grounds are particularly important for access to medicines (public health, epidemics, pharmaceuticals, etc.). In the latter cases, we assigned 3 points per ground to weigh these more heavily given their significance. Scores were calculated for each country by adding the points per available ground and calculating a percentage of the total points available if all possible grounds were reflected in the country's law. Thus, if a given country receives a score of 7 in the general exploitation category, its percentage for that category is 100 percent. Receiving 100 percent across all categories is considered a "full" adoption of TRIPS flexibilities with respect to adopting expansive bases for issuing CLs and GULs (Table 1).

Table 1.
**Grounds for issuing Compulsory or Government Use licenses, possible grounds for each category of CL and points assigned for each ground**

| ***Categories of CLs*** | ***General Exploitation*** | ***Anti-competitive Remedy*** | ***Public Interest[14]*** | ***Emergency*** | ***Government-use[15]*** |
|---|---|---|---|---|---|
| Possible broad and specific grounds for issuing a CL in each category | non-use | anti-competitive practices | general public interest* | general emergency, extreme urgency* | general emergency, extreme urgency* |
| | insufficient use/not meeting domestic demand | abuse of dominant position of the market | public health* | national security | general public interest* |
| | suspension of use | patent worked in a manner harmful to public | economic or industrial development | epidemics or serious illnesses* | general non-commercial use* |
| | excessive pricing | refusal to license | product not put on the market in quantities/quality sufficient for | other | public health, pharmaceuticals, serious illnesses* |

[14] The category of CLs that we identify as "public interest" are those where the grounds are not expressly for emergencies or government use, but where other (more general) concerns of public interest are included as possible grounds for issuing a CL. Not all experts have separated out CLs for general (non-emergency) public interest purposes as an independent category, as in Correa and Lamping (2024), where they identified national security, national emergency, public health emergencies, declarations of serious diseases, and economic, social and technological development grounds all as falling into the public interest category (J. Correa and Lamping 2024, 78–80). The term "public interest" can be broadly inclusive and used as grounds for a range of CLs differentiated under the TRIPS Agreement. We elected to separate out the open-ended category of "public interest" from the emergency or government use contexts, primarily because countries could include that language to allow CLs for a broad spectrum of causes or justifications.

[15] For purposes of this paper, the category of CLs that we identify as "government-use" are those where a public entity (or its subcontractor) is a licensee or where the use is designated as "public, non-commercial use". The study countries exhibit a variety of procedural differences in how both CLs and GULs are granted, some of which we attempt to capture in our section on "procedural flexibilities".

| | | | | | |
|---|---|---|---|---|---|
| | | | normal consumption | | |
| | refusal to license | excessive pricing | excessive pricing | | national security |
| | failure to work locally | | ecology or environmental grounds | | economic or industrial development |
| | dependent patents | | | | ecological or environmental grounds |
| ***Total possible points for each category*** | ***7*** | ***5*** | ***10*** | ***8*** | ***15*** |

Note: Grounds with an *asterisk* are worth 3 points under our scoring system due to their importance for the purpose of access to medicines. The remaining grounds were assigned one point each.

*Assessing the extent of countries' incorporation of procedural flexibilities*

The procedural flexibilities are provisions which make compulsory and government use licenses generally easier to grant and maintain (see Table 2). Some of the provisions identified as contributing to the ease-of-use include those related to (1) petitioning and granting procedures, (2) shifting the burden of proof and (3) procedures for review or challenge (Baker 2023). In the first place, at a minimum, countries can ease the petition process consistent with the TRIPS Agreement by not requiring prior negotiation with a patent holder in the context of anti-competitive remedies, emergency licenses and GULs. This possibility is clearly spelled out in TRIPS Article 31(b) and (k). Where a prior negotiation with a patent holder is required, countries could place timelines and substantive guidelines around what constitutes a sufficient effort at prior negotiations for other categories like general exploitation and public interest licenses. This ensures that the requirement for a prior negotiation does not provide the patent holder with an indefinite opportunity to halt the process. Countries may also place guidelines or caps on what constitutes reasonable or adequate remuneration under a CL or government use license. This can limit the scope of remuneration negotiations and increase transparency in the CL granting process.

Another way to increase ease-of-use for CL laws is to make it clear that the patent holder bears the burden of proof that a CL is not justified in the case where a petitioner makes a *prima facie* case that it is. A law may also state directly that there is a rebuttable presumption that such licenses will be granted. In some cases, countries may want to include the option of mandatory licenses,[16] especially where it is in the public interest or in the case of emergency or government use licenses.

Finally, a country may introduce measures that make review of a granted CL less costly to the CL holder. First, countries may keep any review outside of the court system and in the administrative system, which is bound to be more efficient. Second, countries may prohibit

[16] A "mandatory" license is a special type of CL that allows the government to subject a patented product to licensing such that all applications for CLs on that patent are automatically granted. The language of the law often states that "the competent authority shall grant such licenses as may be applied for."

preliminary injunctions against a licensee who has been granted a CL when that CL is challenged. Third, a country may preserve the right of continued use for the CL holder in the case that revoking the license would harm their legitimate interest.

For each country, we assigned 1 point or 2 points for each license category to which a given procedural flexibility would apply.[17] In that way, the maximum points for any country on all flexibilities except prior negotiation was either 5 or 10. For flexibilities specifically related to the negotiating stage we divided the points into two sections. Where TRIPS does not require prior negotiations, we assigned two points per license category. Where prior negotiations are required, we assigned one point per license category each for limited negotiating timelines and for laws that contain guidelines for commercially reasonable terms. A given country with 100 percent the listed procedural flexibilities would have a total score of 50.

Table 2.
**Procedural Flexibilities (ease-of-use) and points assigned for each**

| **Type of procedural flexibility** | | **Points per flexibility (max)** | **Categories** | **Total points** |
|---|---|---|---|---|
| Petitioning/granting procedures | No prior negotiation with patent holder required | 2 | - Emergency<br>- Government Use<br>- Anti-competitive Remedy | 6 |
| | Limited negotiation timeline | 1 | - General exploitation<br>- Public Interest | 2 |
| | Guidelines for commercially reasonable terms in negotiations | 1 | - General Exploitation<br>- Public Interest | 2 |
| | Remuneration guidelines | 1 | All | 5 |
| Burden of proof | Burden of proof to prevent the CL on the patent holder/Presumptive licenses | 1 | All | 5 |
| | Option for mandatory CLs | 1 | All | 5 |
| Review & challenge procedures | Administrative review, in lieu of judicial review, available where permitted | 2 | All | 10 |
| | Challenges to the grant of a CL do not allow injunctive | 2 | All | 10 |

[17] We assigned two points per license category for a flexibility that we assessed as highly important for access to medicines and one point per license category for the rest of the flexibilities.

| | | | | |
|---|---|---|---|---|
| | relief (or have "no suspensive effect") | | | |
| | Right of continuation based on the interest of the licensee | 1 | All | 5 |

*Assessing countries' scope of application flexibilities*

The scope of application flexibilities we identified in this study relate to both improving the ease-of-use and increasing the effectiveness of the CL law by broadening the scope of a potential license and expanding purposes for which it is used (see Table 3). Countries have the right to broaden the scope of their CLs by allowing licenses on pending patents as well as those that have been granted.[18] Another way to expand the scope of CLs is to allow licenses on all patented components of a patented final product. A third way to expand the scope is to provide for import and export CLs. At the very least, a country may include importation as a kind of "use" allowed under licenses. Countries may also want to specifically state that CLs may be granted to foreign licensees, especially if that country does not have domestic manufacturing capacity for pharmaceuticals (Baker 2023). Furthermore, a country's law may expand the possibility for export of licensed products beyond non-predominate quantities by including that flexibility for anti-competitive remedy licenses and making specific reference to the export of pharmaceuticals to countries that lack manufacturing capacity, as specifically allowed under TRIPS Article 31*bis*.

We assigned 1 to 3 points for each license category to which a given scope of application flexibility would apply.[19] In the areas of import and export flexibilities, we identified a "baseline" standard as well as two additional levels of import/export flexibilities which progressively improve the effectiveness of a CL to increase access to medicines. For import, the baseline standard is that the country includes importation in its general definition of "use" or "exploitation" of a patented product or process. Since license holders generally have the same rights as patent holders, importation would then be permitted under a CL unless otherwise stated. If a CL law specifically notes the right to import under a license, then the country received additional points, and if there is a reference to importing pharmaceuticals according to TRIPS Article 31*bis*, the country received 3 additional points. For export, the baseline standard is that the country allows the export of "non-predominant quantities". Usually this takes the form of a requirement in CLs that they be "predominantly" or "mainly" for the supply of the domestic market. Beyond the baseline, countries may permit exports beyond "non-predominant quantities" in the context of anti-competitive remedy CLs (increasing their score by 2 points) and (most importantly for our study), in the context of pharmaceuticals as permitted under TRIPS Article 31*bis* (adding 3 additional points). Thus, a country whose score

[18] It is important to note that CLs on pending patents, while possibly helpful in terms of initiating the process of granting the greatest number of CLs, especially under emergency conditions like those of the COVID-19 Pandemic, has also been subject to some disagreement among experts. There is some advantage to be able to authorize alternative producers without risking infringement claims even before the granting of the final patent. At the same time, licensees should not have to pay upfront royalties for CLs on pending patents given that the patent holder does not even hold a legally recognized property right at the time. Some experts are also concerned that a CL on a pending patent may incentivize ultimately granting that patent. Even if it does not have this effect, it may reduce the licensed generic producer's incentive to pursue patent oppositions.

[19] We assigned three points per license category for a flexibility that has a direct impact on access to medicines, two points for flexibilities that the authors assessed as important for access to medicines and one point per license category for the rest of the flexibilities.

was 37 would have incorporated into their CL law 100 percent of the scope of application flexibilities specified Table 3.

Table 3.
**Scope of application flexibilities**

| **Type of substantive flexibility** | | **Points per flexibility** | **Categories** | **Total points** |
|---|---|---|---|---|
| Scope of CLs | License can be granted for all patents related to a final product | 2 | - Emergency<br>- Government Use | 4 |
| | Licenses can be granted on filed patent applications, pending and granted patents | 1 | All | 5 |
| Export Use | License allows export of non-predominant quantities | 2 | All | 10 |
| | License allows export beyond non-predominant quantities for anti-competition remedy | 2 | Anti-competitive Remedy | 2 |
| | License allows export beyond non-predominant quantities under Article 31*bis* | 3 | Health/ Medicines | 3 |
| Import Use | IPR law has general inclusion of importation as a right of exploitation | 1 | All | 5 |
| | Compulsory License provision specifically mentions importation[20] | 1 | All | 5 |
| | Allows for Article 31*bis* importation | 3 | Health/ Medicines | 3 |

Note: Although we did not categorize CLs granted for the purposes of public health or medicines as a distinct type of license in our study (they are usually grounds for issuing government use, Emergency and/or Public Interest licenses), the presence of flexibilities for export and import under Article 31*bis* is only allowed for pharmaceutical products. For that reason, we assign 3 points only once for that specific context.

Upon assessing the extent of the study countries' adoption of TRIPS CL flexibilities, we drew upon published reviews of the CL literature and Ellen 't Hoen's TRIPS Flexibilities Database (Son and Lee 2018; Urias and Ramani 2020; Yamabhai et al. 2011; Mohara et al. 2012; 't Hoen 2023) to determine which of these countries had been most active with respect to issuing and announcing the intention to issue compulsory and government use licenses. We explored whether a particular type of flexibility was associated with greater use of CL laws. Finally, in order to explore additional bottlenecks or obstacles to granting CLs, we examined in detail the political, economic and historical contexts of two of our study countries: Thailand and Colombia. These case studies begin to uncover the broader context within which countries grant CLs and GULs.

[20] Although the right to import is generally understood as an intellectual property right that would automatically transfer to any license holder, there are some countries where that has not been well understood in the past, and in the interest of clarity, our recommended practice is that the legal text be exquisitely clear on that point.

## III. Findings

The focus of the study was on the incorporation of key TRIPS-related flexibilities in the national compulsory licensing and government use laws of the included countries. We specifically quantified and depicted the policy space each country has retained for issuing compulsory and government use licenses, a relative measure of how easy their laws are to use, both for the government issuing the license and for petitioners of that license, and a relative measure of how broad the scope there is in each country for granting and using the license.

All 15 countries in our sample have established laws that allow for at least some mechanisms for issuing CLs, usually at the request of an interested party (see Appendix C for a list of the relevant laws). The national legislation of all 15 countries apply the basic procedural rules for compulsory licensing in the TRIPS Agreement, often including prior negotiation requirements with the IP right holder, requiring remuneration, which must be "adequate" or "reasonable", and which allow for the CL to be revoked if the circumstances that gave rise to it no longer exist.

The degree to which the flexibilities provided for in TRIPS Article 31 and 31*bis* have been incorporated into the national law of these UMICS varied significantly, with respect to each of the three categories of flexibilities we examined.

### *Findings related to the breadth of grounds available for each country*

Drawing from the scoring method laid out in Table 1, Table 4 shows the scores that each country received for the 5 different categories of licenses. Table 1 in Appendix E shows how these scores were calculated.

Table 4.
**Country Scores for breadth of 5 categories of compulsory and government use licenses** (percent of total possible grounds expressed in the country's law)

| | AL | AR | CH | CO | EC | JO | MA | ME | PA | PE | PH | RO | TH | TU | UK |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| General exploitation license | 42.9 | 42.9 | 57.1 | 85.7 | 71.4 | 28.6 | 71.4 | 14.3 | 14.3 | 42.9 | 28.6 | 42.9 | 57.1 | 42.9 | 57.1 |
| Anti-competitive remedy | 20.0 | 80.0 | 20.0 | 40.0 | 40.0 | 20.0 | 20.0 | 0.0 | 20.0 | 40.0 | 20.0 | 20.0 | 0.0 | 20.0 | 0.0 |
| Public interest license | 80.0 | 0.0 | 60.0 | 90.0 | 60.0 | 0.0 | 70.0 | 0.0 | 0.0 | 30.0 | 70.0 | 0.0 | 90.0 | 70.0 | 70.0 |
| Emergency license | 12.5 | 50 | 37.5 | 50.0 | 50.0 | 87.5 | 62.5 | 87.5 | 87.5 | 50.0 | 87.5 | 37.5 | 50.0 | 12.5 | 100.0 |
| Government use license | 53.3 | 46.7 | 20.0 | 66.7 | 86.7 | 66.7 | 73.3 | 46.7 | 20.0 | 20.0 | 93.3 | 40.0 | 100.0 | 53.3 | 20.0 |

Legend: AL = Algeria; AR = Argentia; CH = China; CO = Colombia; EC = Ecuador; JO = Jordan; MA = Malaysia; ME = Mexico; PA = Panama; PE = Peru; PH = Philippines; RO = Romania; TH = Thailand; TU = Turkey; UK = Ukraine.

TRIPS allows significant flexibility for countries to establish their own grounds for issuing CLs. The broader the grounds under which a license can be issued, the more options that country can have to issue CLs. All of the countries in our sample took advantage of at least some of the grounds allowable under TRIPS and just over half (9 of the 15) provided at least one ground within each of the license categories. All 15 countries allowed for CLs for either public interest or for emergencies or matters of extreme urgency, although public interest

grounds were more often omitted than in any other category. Fourteen of the 15 countries allowed CLs to be granted where the patented product or process has not been worked (or imported) in the granting jurisdiction (only Panama did not allow this). Twelve out of 15 (excluding Mexico, Thailand and Ukraine) allow CLs as a remedy for anti-competitive behavior. Despite the overall breadth of coverage, no single country provided for the full range of possible grounds in each category.

Using the scores presented in Table 4, we created spiderweb diagrams to compare the policy space available to each country in terms of the possible breadth of grounds to issue a CL (see Figures 1a-1c). For example, the score of 100 for Ukraine with regard to "emergency use" means that Ukraine's law incorporated all the emergency use grounds listed in Table 1. At the same time, it includes less than half of the grounds for CLs based on "general exploitation" grounds, slightly more than half of the "public interest" grounds and no grounds based on 'anti-competitive' activity.

Figure 1a.
**Policy Space for granting compulsory licenses**: Eastern Europe, Northern Africa & West Asia

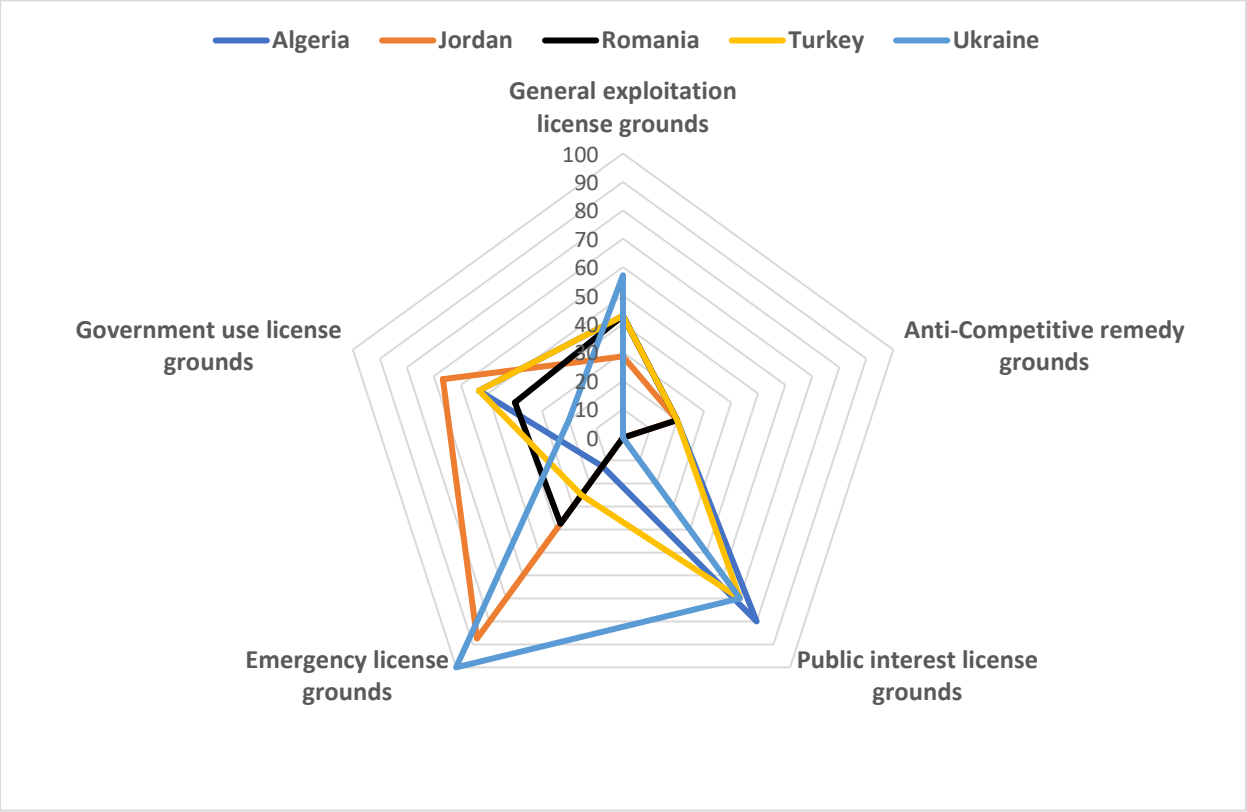


Figure 1b.
**Latin America**

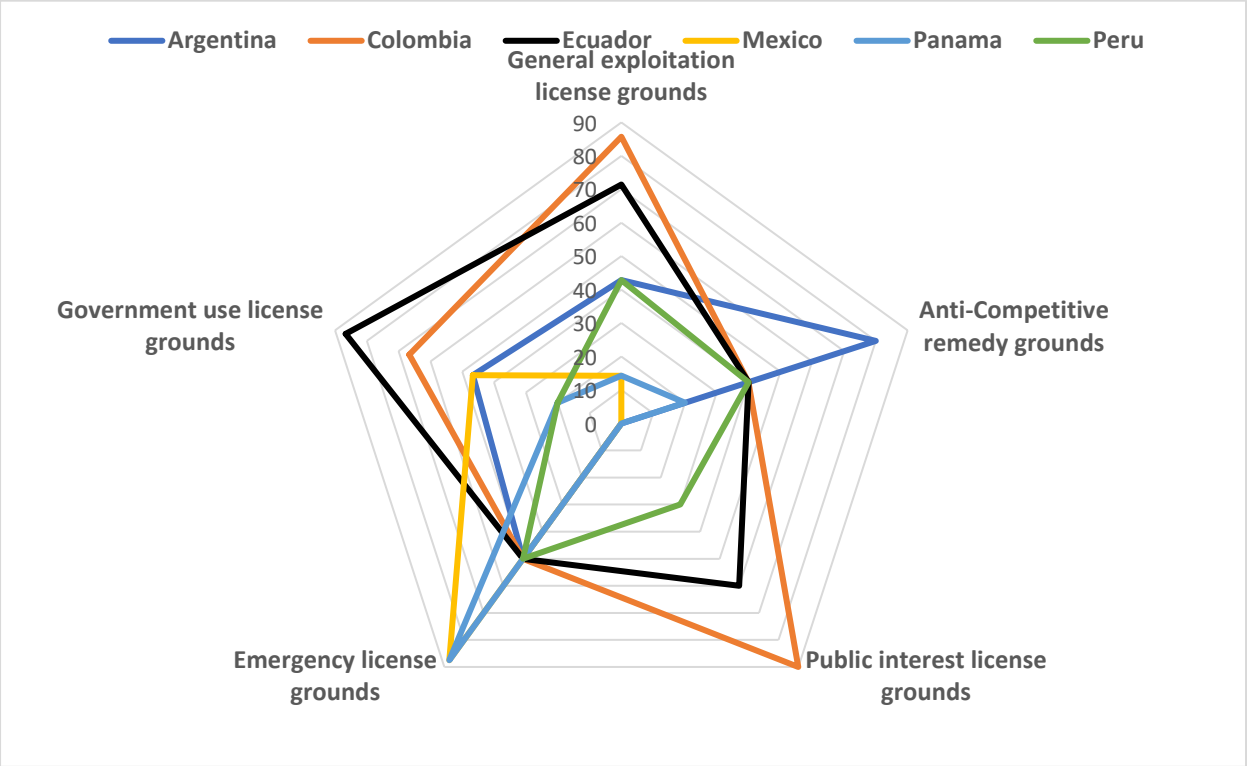
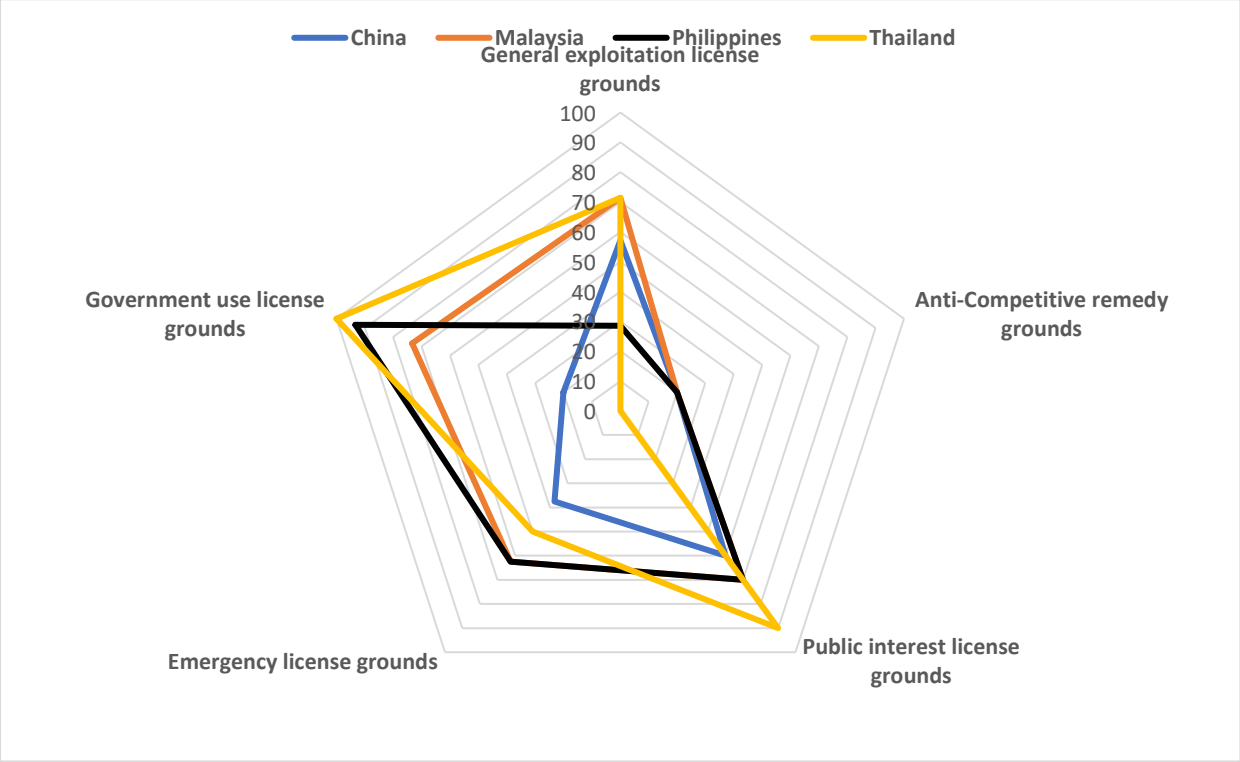



Figure 1c.
**Asia**



Thus, the broader the grounds for issuing licenses, the higher the score (see Table 1), which is represented by how far out it intersects on the spiderweb. Consequently, the broader the grounds for issuing such licenses overall, the larger the area within the web for each country. The scores have been expressed as a percentage of total possible score for each type of license in order to be able to compare a country's policy space across license types.

For example, Figure 1b demonstrates that Mexico lists a large number of broad and specific grounds for issuing emergency CLs (87.5 % of the total possible) but does not allow CLs to be issued at all as a remedy for anti-competitive actions, nor does it mention CLs for the public interest. Colombia, by contrast, includes a wide range of broad and specific grounds within its public interest license (90 % of the total possible) but has fewer grounds that count as "emergencies" (only 2/3 of the total possible). Some countries exhibit more expansive grounds for issuing licenses in certain categories. Thailand (Figure 1c), for instance, has the highest score under the "government use license" category and it seems to have been able to utilize this policy space to issue seven GULs between 2006 and 2008 (Yamabhai et al. 2011).

In general, the countries in our study tended to have more expansive Emergency Use grounds. Panama, Mexico, Jordan and Ukraine all have scores in that category that are 87.5% or higher (Ukraine is 100%). The top three scores for public interest grounds were Thailand (90), Colombia (90) and Algeria (80). By contrast, there were five countries with no public interest grounds at all: Argentina, Jordan, Mexico, Panama, Romania. By taking an average of all the scores across the different types of grounds for issuing compulsory or government use licenses, we find that Colombia (66.5) is the highest, followed by Thailand (62.3), Ecuador (61.6), and Malaysia (59.5).

Importantly, 13 out of 15 study countries include some reference to epidemics, serious illnesses, pharmaceuticals, public health as a legitimate ground for a CL or government use license (Table 5).

Table 5.
**Presence of health-related CL grounds in study countries**

| | AL | AR | CH | CO | EC | JO | MA | ME | PA | PE | PH | RO | TH | TU | UK |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Public interest license – public health | X | | X | X | X | | X | | | | X | | X | X | X |
| Emergency license – epidemics or serious illnesses | | X | | | | X | | X | X | | X | | | | X |
| Government use license grounds – public health, pharmaceuticals and serious illnesses | X | X | | X | X | X | X | X | X | | X | | X | X | |

Legend: AL = Algeria; AR = Argentia; CH = China; CO = Colombia; EC = Ecuador; JO = Jordan; MA = Malaysia; ME = Mexico; PA = Panama; PE = Peru; PH = Philippines; RO = Romania; TH = Thailand; TU = Turkey; UK = Ukraine.

***Findings related to procedural flexibilities and ease of use***

The second set of flexibilities are those which increase the likelihood of a CL or GUL being granted, and improve the ease-of-use of the process. These generally include provisions that (1) lay out limited timelines and clear guidelines for negotiations, contractual terms and remuneration, (2) increase the likelihood of granting a license by shifting the burden of proof to the patent holder and by allowing presumptive and mandatory licenses, and (3) allow non-judicial, administrative review of compulsory licensing decisions and eliminate right of injunctive relief while a CL is being challenged.

For this second set of findings, we assigned a number to each procedural flexibility according to how many of the five categories of CLs or GULs would allow for this kind of flexibility. The higher the total score, the easier it should be for CL petitioners to request, be granted and maintain rights under a license. In our study only the four highest scorers in procedural ease-of-use (Argentina, Colombia, Ecuador, and Peru) included even one-half of the possible flexibilities allowed under the TRIPS Agreement. The full table of individual flexibility scores can be found in Appendix E, Table 2. Figure 2 (below) highlights the wide variety of flexibility differences available within our study countries.

In the area of petitioning and granting flexibilities, all countries in our study have some licenses which do not require prior negotiations – specifically emergency licenses and GULs. Notably in some countries, public interest licenses do not require prior negotiation either.[21] Outside of that, however, very few countries have introduced petitioning and granting guidelines that make the process easier for the petitioner. Argentina and Ecuador are the only countries to include a limited timeline for prior negotiations and provide remuneration guidelines for the licenses. Ukraine provides remuneration guidelines only in the case of CLs involving medicines. No country in our study includes guidelines for what might be considered "commercially reasonable" terms within a prior negotiation.

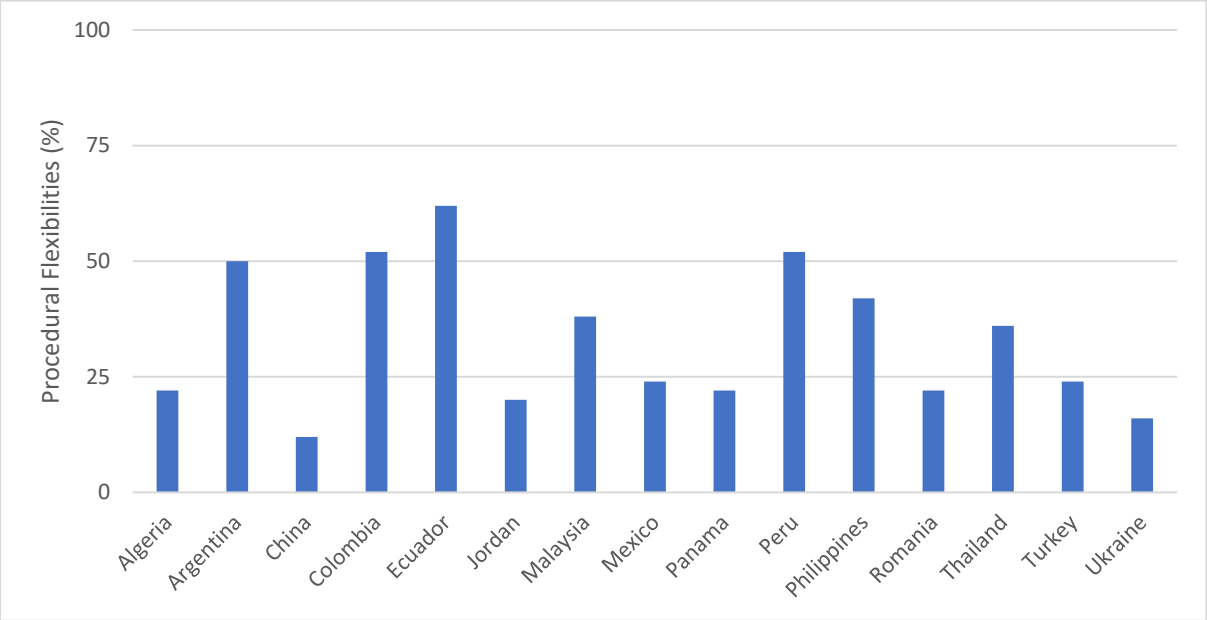
In the area of shifting the burden of proof in a CL petition procedure, the majority of study countries have legal provisions for some types of licenses which place the burden of proof on the patent holder or otherwise create a presumption in favor of the license petitioner. Of those countries, three (Ecuador, Peru, and Turkey) also have provisions for "mandatory" licenses for limited categories of licenses (e.g., public interest, emergency, or anti-competitive behavior).

In the area of maintaining and defending compulsory and government use licenses, only three of the study countries (Malaysia, Mexico, and Thailand) limit review to an administrative process and five countries prohibit injunctive relief against the CL holder in the case of a challenge (Panama, Peru, Philippines, Romania and Thailand). By contrast, almost all countries reserved some right of continued use for licenses, or at least a consideration of the licensee's interest, in determining whether to revoke a CL.

Once more, it is notable that countries that embody a greater amount of flexibility in one area may not incorporate flexibilities in the other areas. In fact, aside from Ecuador, no country stands out as exceptional in more than one of the three procedural flexibility categories.

[21] These countries are Algeria, China, Colombia, Ecuador, Malaysia, Peru and Romania. There is some ambiguity about whether "public health" public interest licenses require prior negotiation under the TRIPS Agreement if they are not also (simultaneously) based on an emergency or public non-commercial use.

Figure 2.
**Ease-of-Use in Compulsory licensing laws in each country**




***Findings related to scope of application, including import and export***

The substantive flexibilities we identified in this study relate to the scope of application of a potential license. For purposes of this study, the "scope of application" of the license means (1) whether a license may be granted for pending as well as granted patents, (2) whether a single license may be granted for patented components as well as the final product at once, and (3) whether CL legislation allows for both import and export. Under this definition, there was very little variation in the scope of application of the potential licenses granted in the study countries.

Only one country (Algeria) allows CLs on pending as well as granted patents. Additionally, only one study country (Argentina) includes a provision that explicitly allows CLs to cover all patented components as well as the final product. Two other countries adopted a sort of "due diligence" standard for GULs, whereby the laws relieve the government of having to do a patent search unless they have a reason to believe that a patent may be violated. This implicitly allows some GULs to cover both components and final products together. Otherwise, for purposes of expanding the scope of application to pending patents or patented components, few countries stand out.

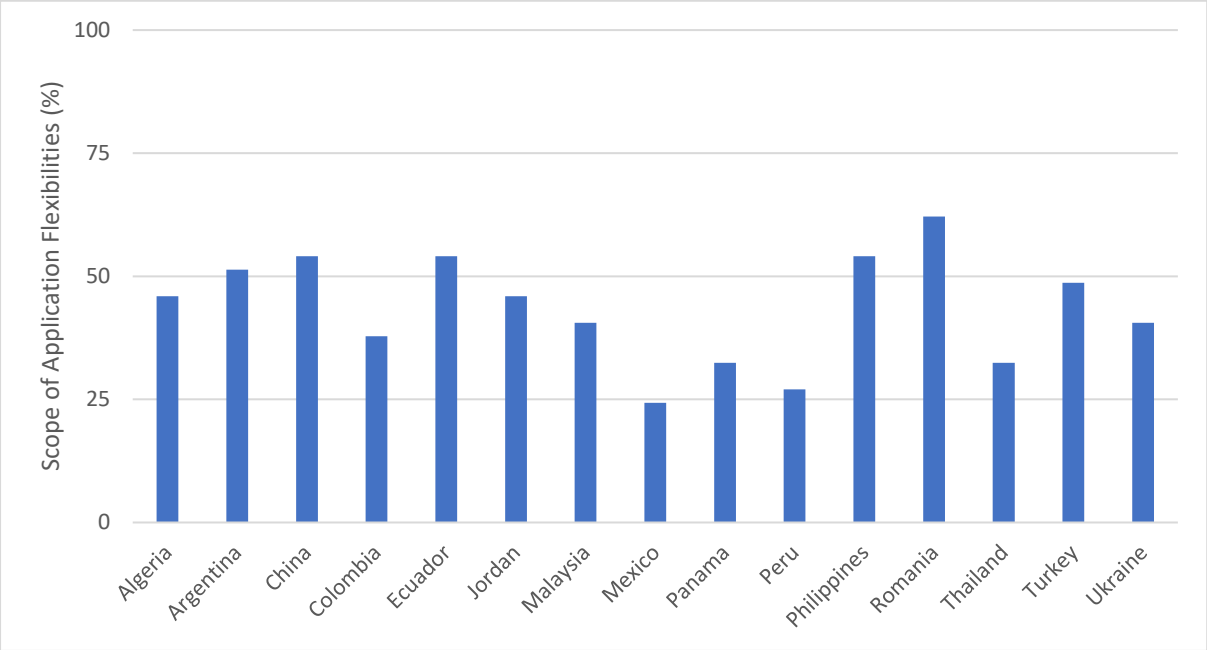
In terms of import flexibilities, most study countries' legislation implicitly or explicitly include importation as one of the rights granted to license holders, as it is one of the explicit patent rights of patentees recognized in most jurisdictions. The main outliers here are Peru and the Philippines, which exclude importation as an authorized used under CLs or GULs. Colombia, likewise, does not allow importation under a general exploitation CL (but does for emergency, public interest, anti-competitive remedy and government use licenses), and Turkey, **only** allows importation under a license if it is in the public interest and a special import licenses is then granted. On the other hand, the Philippines' law specifically allows importation in the context of pharmaceuticals, making it highly useful for access to medicines. Ukraine also has some unique flexibility here. Rather than issue licenses for government use, its law **defines**

non-commercial use as a non-violation of patent rights so that no license is needed (thus importation as well as exportation is implicitly permitted).

When it comes to export use, all study countries allow export of non-predominant quantities for compulsory and government use licenses. Beyond that basic right, several study countries permit exports beyond those quantities in the context of anti-competitive remedy CLs and (most importantly for our study), in the context of pharmaceuticals (as permitted under TRIPS Article 31*bis*). These countries which have more comprehensively adopted the TRIPS Article 31*bis* standard include Argentina, China, Ecuador, Jordan, Philippines and Turkey.

Once more, there is great diversity in terms of the adoption of these scope of application flexibilities and no single country stands out in all categories, although the study countries did have more similarities than in the procedural set. Nevertheless, even the highest scorers only barely exceeded adoption of 50 percent of TRIPS-related scope-of-application flexibilities.

Figure 3.
**Scope-of-Application Flexibility Scores**




***Findings related to the use of compulsory and government use laws***

In addition to assessing study countries' adoption of key TRIPS-compliant CL flexibilities, we also attempted to ascertain whether the subject countries had in fact issued or attempted to issue CLs since 2000. We found, despite the diversity of applicable law and the failure of any country to maximize its CL flexibilities, that many of the study countries had indeed attempted or succeeded in issuing CLs, 33 in total as detailed in Table 6 below.

Table 6.

**Compulsory licenses issued and attempts to issue**

| Country | Date | Product | Licensee/ applicant | Disease/ Indication | Executed | Reason if not executed |
|---|---|---|---|---|---|---|
| Argentina | 2005 | Oseltamivir | Unknown | Avian flu | No | No patent |
| China | 2005 | 3TC/D4T/NVP | Civil society | HIV/AIDS | Yes | |
| | 2007 | 3TC/D4T/NVP, LPV/r | Civil society | HIV/AIDS | Yes | |
| Colombia | 2014 | Imatinib | Civil society | Cancer | No | |
| | 2017 | Direct Acting Antivirals | Civil Society | Hepatitis C | No | |
| | 2022 | Nirmatrelvir/ritonavir | Civil society | COVID-19 | Pending | |
| | 2024 | Dolutegravir (2024) | Government | HIV/AIDS | Yes | |
| Ecuador | 2003 | 3TC/AZT | Acromax Laboratorio | HIV/AIDS | No | Price discount |
| | 2010 | RTV | Eskegroup SA (Cipla importer) | HIV/AIDS | Yes | |
| | 2012 | ABC/3TC | Acromax Laboratorio, Quimico Farmaceutico SA | HIV/AIDS | Yes | |
| | 2013 | ABC/3TC | Ginsberg Ecuador S.A. | HIV/AIDS | Yes | |
| | 2013 | Gemcitabine | Ginsberg Ecuador S.A. | Cancer | Unclear | |
| | 2013 | RTV | Acromax Laboratorio, Quimico Farmaceutico SA | HIV/AIDS | Yes | |
| | 2014 | Etoricoxib | Acromax Laboratorio, Quimico Farmaceutico SA | Rheumatoid arthritis | Yes | |
| | 2014 | Mycophenolic acid | Ginsberg Ecuador S.A. | Kidney transplants | Yes | |
| | 2014 | Sunitinib | ENFARMA Empresa Publica | Cancer | Yes | |
| | 2014 | Certolizumab | ENFARMA Empresa Publica | Rheumatoid arthritis | Yes | |
| Malaysia | 2003 | AZT, 3TC+AZT | Syarikat Megah Pharma & Vaccines/Cipla | HIV/AIDS | Yes | |
| | 2017 | Sofosbuvir | Pharmaniaga Logistics Sdn. Bhd. | Hepatitis C | Yes | |
| Peru | 2014 | ATV | Civil society | HIV/AIDS | Pending | |
| | 2022 | Nirmatrelvir/ritonavir | Civil society | COVID-19 | Pending | |

| | | | | | | |
|---|---|---|---|---|---|---|
| Philippines | 2005 | Multiple ARVs | Procurement agent | HIV/AIDS | Yes | |
| | 2008 | Multiple ARVs | Procurement agent | HIV/AIDS | Yes | |
| Romania | 2015 | HCV medicines | Civil society | Hepatitis C | No | Data exclusivity barrier |
| Thailand | 2006 | EFV | Government Pharmaceutical Organization (GPO) | HIV/AIDS | Yes | |
| | 2007 | LPVr | GPO | HIV/AIDS | Yes | |
| | 2007 | Clopidogrel | GPO | Cardiovascular disease | | |
| | 2008 | Letrozole | GPO | Cancer | Yes | |
| | 2008 | Docetaxel | GPO | Cancer | Yes | |
| | 2008 | Imatinib | Government | Cancer | No | Donation |
| Ukraine | 2004 | ARVs | Civil society | HIV/AIDS | Yes | |
| | 2023 | Elexacaftor/ivacaftor/tezacaftor | Civil society | Cystic fibrosis | Pending | |
| Albania<br>Algeria<br>Jordan<br>Mexico<br>Panama<br>Turkey | No records of compulsory licenses issued or sought | | | | | |

*Sources*: (Son and Lee 2018; Urias and Ramani 2020; Yamabhai et al. 2011; Mohara et al. 2012; 't Hoen 2023; Thai Ministry of Public Health 2008) with some updating by the authors.

Ecuador is among the most successful adopters of TRIPS flexibilities in all three areas of our study and has been actively engaged in issuing CLs on key medicines. Since 2014 however, Ecuador has not taken the same ambitious approach. Thailand also has fairly expansive TRIPS flexibilities in certain areas (allowing broad grounds for government use and public interest licenses). However, while it was an active user of CLs 2006-2008, it has certainly slowed down in more recent years. This trend, as noted above, is the same for all countries; but it also shows that the law itself is not the only factor indicating whether a country will be actively issuing CLs.

The countries that have the highest amount of procedural flexibilities (Argentina, Colombia, Ecuador and Peru) have all had at least some experience with filed or granted CLs. On the other hand, of those, only Argentina and Ecuador also have high levels of scope of application flexibilities compared to the other countries in our study. This demonstrates that flexibility by one measure (breadth of grounds, procedural or scope of application) is not closely correlated to flexibility in another.

Additionally, the levels of flexibility and breadth of any given law as a whole sometimes align with its use in practice, and sometimes does not. Romania, for instance, has very narrow grounds for issuing a license, no public health grounds for licenses, low procedural flexibilities and moderate substantive flexibilities. It is not surprising then that the only effort to apply for a CL in Romania failed. Thailand also does not seem to have high-level incorporation of flexibilities overall but did have an extensive successful experience with CLs from 2006-2008.

Colombia on the other hand has broad grounds for issuing a license, two of three possible public health grounds and high levels of procedural flexibility, but has only had one successful attempt to issue a CL – and that only in 2024.

As the following case studies demonstrate, while the legal language is important in making it possible for countries to issue compulsory and government use licenses for the purposes of protecting public health, there are many other factors that come into play.

## IV. Case Studies

Given the diverse kinds and levels of implementation of TRIPS flexibilities, as well as the diverse experiences with issuing compulsory licenses, the two case studies below highlight the other factors that impact a country's experience with compulsory licensing. Thailand and Colombia represent two countries that have attempted several times to issue these licenses, with varying degrees of success. Their stories unveil the national and international complexities involved in adopting and relying on TRIPS flexibilities in the real world.

### *Thailand*

Thailand is an UMIC of more than 71 million people (WHO 2024). In 2002, Thailand became one of the first MICs to implement universal health coverage (UHC). It currently covers 53 million people or 74 percent of the population (Damrongplasit and Melnick 2024). This scheme relies heavily on locally produced and imported generic medicines to contain costs. Thailand has an established generic pharmaceutical industry which includes the Government Pharmaceutical Organization (GPO), a wholly government-owned enterprise that supplies many of the generic medicines used in Thailand's national treatment programs (Siraprapasiri et al. 2016). Challenges to the sustainability of Thailand's UHC include its aging population, rising rates of non-communicable disease and the large number of people living with HIV (PLHIV) requiring lifelong treatment with ARVs (Sumriddetchkajorn et al. 2019).

*Compulsory license laws and policies*

The Thai Patent Act allows for compulsory licensing as detailed in Articles 45-52. Articles 46, 47 and 47bis allow for the granting of a CL to a private entity and are designed to facilitate local working and improve competition. Articles 51 and 52 authorize the government to use a patented product for public non-commercial use (Supakankunti et al. 2001). The Thai Patent Act does not include compulsory licensing for export as it is defined in Paragraph 6 of the Doha Declaration and the decisions of the WTO General Council of 2003 and 2005 (Kuanpoth 2008). Thailand's patent law includes a fairly broad set of grounds on which the government may issue a compulsory or government use license. Thailand has general exploitation CLs that include a ground for failure to work the patent locally. Grounds on which a public interest or GUL may be issued include "(1) any service for public consumption, (2) any service which is of vital importance to the defense of the country, (3) any service for the preservation or realization of natural resources or the environment, (4) to prevent or relieve a severe shortage of food, medicines or other consumption items, or (5) for any other public service." This language is as broad as possible to allow the Thai Government to increase domestic access to almost any patented product or process that is in the interests of the public. Thai law does not, however, allow for CLs as a remedy for anti-competitive behavior.

In terms of TRIPS flexibilities that encourage broad and easy execution of CLs, Thailand does not require prior negotiation with patent holders for public interest and emergency licenses, and GULs. For all CLs and GULs, it places the burden of proof on patent holders to disprove the need for a license and allows only administrative review of CLs once they are granted. Moreover, for general exploitation licenses, the law makes a reference to the preservation of the rights of a CL holder in the case where the license might otherwise be terminated (as when the circumstances which gave rise to it have ceased). In contrast with the breadth of grounds by which the Thai Government can issue CLs, Thailand's law does not go beyond the usual

allowance for export of non-predominant quantities and import as an implied right of use under a license.

*Thailand's experience of CLs*

Thailand has been among the countries in Asia with the highest HIV prevalence since its first HIV case was detected in 1984. By the late 90s, Thailand had an estimated 930,000 PLHIV (UNAIDS 2023). Highly active antiretroviral therapy (HAART) or triple-drug therapy became available in 1996 (NIAID 2024), however treatment coverage in Thailand was initially very low due to the high price of ARV caused by patents (Kuanpoth 2014). Many PLHIV died before they were able to access treatment. Highly active antiretroviral therapy was also not initially included in the UHC package in part due to its cost. When the price could be reduced, however, the government shifted priorities and committed to include it (Kuanpoth 2014). A coalition of civil society groups and NGOs that included the Thai Network of People Living with HIV (TNP+) and Médecins Sans Frontières (MSF) advocated strongly for greater access to affordable ARV and urged the government to challenge the patent barriers that hindered access (Kuanpoth 2014). Supported by this access to medicines coalition, the GPO submitted a request for a GUL for a tablet form of the ARV didanosine to the Thai Department of Intellectual Property in November 1999 (Ford et al. 2004). This request was denied, and the GPO was limited to the production of a non-patented, powdered formulation of didanosine which had more side effects and was more difficult to consume (Yamey 2000).

After years of sustained advocacy, the Thai Ministry of Public Health issued a GUL for the ARV efavirenz (marketed as Stocrin by Merck) in November 2006. This was followed by GULs for the second line ARV lopinavir/ritonavir, marketed as Kaletra by Abbott Laboratories (Abbott) (Thai Dept Disease Control 2007), and for clopidogrel, an anti-clotting medication marketed as Plavix by Bristol-Myers Squibb (Thai Ministry of Public Health 2007) in January 2007. This was the first time an LMIC had issued a CL for a medicine other than an ARV (Kuanpoth 2014). In 2008, Thailand issued an additional four GULs for letrozole (for the treatment of breast cancer), docetaxel (for the treatment of multiple cancers), erlotinib (for the treatment of lung and pancreatic cancer) and imatinib (for the treatment of leukemia) (Mohara et al, 2012).

Thailand's Minister of Public Health, Dr Mongkol na Songkhla, immediately came under pressure from the Thai Pharmaceutical Research and Manufacturers' Association (PReMA) and the US Government to withdraw the initial three GULs (Kuanpoth 2014). Abbott responded to the granting of the GULs by withdrawing its medicines awaiting registration and refusing to register any new pharmaceutical products in Thailand (Oh and Kim 2012). The patent holders of the medicines subject to 2006 and 2007 GULs accused Thailand of violating TRIPS rules. Their arguments included that:

- The Thai Government did not negotiate with the patent holders before granting a GUL;
- Thailand had not declared an emergency before granting the GULs;
- As the GULs were issued to the GPO, a state enterprise under the Ministry of Public Health, they were not for "public non-commercial use";
- The royalty rate was too low; and
- The licenses would reduce patent holders' profits, thereby decreasing incentives to invest in research and development (Kuanpoth 2014).

In response, the Thai Government published a series of White Papers to outline the rationale and legality of the initial 2006 and 2007 GULs and its compliance with Thai law and WTO rules. It refuted the above arguments of the patent holders and outlined how Thailand has no legal requirement to negotiate with patent holders or declare a prior emergency given it was a GUL. Additionally, the White Papers detailed how the Thai Government held many meetings with patent holders over a two-year period that failed to achieve any price reductions. The royalty renumeration rate offered by Thailand was compliant with Thai patent laws and policies and comparable to previous GULs issued by other LMICs (Thai Ministry of Public Health and Thai National Health Security Office 2007).

Despite US Government and pharmaceutical company protestations, no case was brought against Thailand in the WTO presumably because the GULs were deemed to be TRIPS compliant. Dr. Margaret Chan, the Director General of the WHO at the time, confirmed the legality of the GULs in a letter to the Thai Public Health Minister. Despite this, the Office of United States Trade Representative (USTR) placed Thailand on the Priority Watch List (PWL) in the 2007 and 2008 annual USTR Special 301 Reports that provide a review of the global state of IP rights protection and enforcement (USTR 2007, USTR 2008). These reports made specific reference to Thailand's issuance of GULs as a rationale for the PWL rating. Countries placed on the PWL are the focus of increased bilateral attention and subject to an action plan to address the perceived IP-related issues. The Pharmaceutical Research and Manufacturers of America (PhRMA) submissions to these USTR reports also referenced Thailand's GULs and urged the USTR to designate Thailand a USTR Priority Foreign Country (USTR 2008). Designation as a Priority Foreign Country initiates an investigation and possible sanctions and is reserved for countries deemed by the USTR to have the most onerous or egregious IP legislation, policies, or practices.

In total, Thailand's CLs are estimated to have saved the government approximately $370 million and allowed an additional 84,158 patients to access these medicines over 5 years (Mohara et al. 2012; Yamabhai et al. 2011). Of the seven GULs, efavirenz (EFV) was found to have the greatest health-related economic benefits to society and saved the Thai Government up to USD 118 million over five years (Yamabhai et al. 2011).

Together with Ecuador, Thailand has been the most frequent user of compulsory licensing for pharmaceuticals (Vawda 2022). Thailand's CLs and the associated controversies and challenges have been well documented. The Thai Patent Law, however, has not been highlighted in the published literature as an obvious impediment to compulsory licensing. In contrast, several studies have underscored the political, economic and trade pressures that have posed significant challenges to the successful implementation of Thailand's CLs (Wibulpolprasert et al. 2011; Kuanpoth 2014; Tenni et al. 2024). A recent study found that it was only when the problem, policy, and politics briefly aligned that Thailand issued a number of GULs and that a similar window of opportunity has not arisen since (Tenni et al, 2024). It has been surmised that Thailand's apparent reluctance to issue GULs since 2008 is attributable to government concerns about reprisals from pharmaceutical companies, greater willingness of pharmaceutical companies to negotiate medicine prices; and a policy shift to voluntary licensing (Tenni et al. 2024; Thammatacharee et al. 2020).

As our quantitative findings indicate, Thailand has only moderately adopted the full range of TRIPS flexibilities to date. The Thai Government could make several changes to expand the breadth of grounds for issuing licenses, make it easier to apply for and grant those licenses and to increase the scope of use for both CLs and GULs. However, the Thai experience with CLs

and GULs makes it clear that legislative change is only the beginning. In addition to adopting a more useable and effective CL law, Thailand must overcome domestic and international political pressure as well as changing realities in the global pharmaceutical market.

***Colombia***

Colombia, with a population of 53 million, has been an UMIC since 2007. In 2021, it spent about 9 percent of its GDP on health expenditures (The Global Economy 2021; Brun Vergara, Garcia Ruiz, and Guzman 2023). Colombia provides "nearly universal healthcare coverage" via a mixed public-private healthcare system and, as of 2015, nearly 97 percent of the population had access to insurance (OECD 2015). This percentage is nearer 100 percent in the larger cities.

Colombia is a member of the WTO and the Andean Community (with Peru, Bolivia and Ecuador), and is a party to the Colombia-US Trade Promotion Agreement (TPA) since 2012. Colombia's compulsory licensing law is governed primarily by the Cartagena Agreement – Decision 486 on Common Provisions on Industrial Property for the Andean Community (2000), articles 61-69. The most relevant provisions of its domestic law are Decree 410 (1971) Articles 558-565 and Decree 4302 (2008) which lays out the procedure for the process of declaring the existence of a public interest. The TPA also permits compulsory licensing according to the TRIPS Agreement and subsequent declarations and amendments (Article 16.13). The TPA further notes that if there is any additional amendment the parties will consult to adapt the treaty to the new amendment.

Colombia's patent law includes a fairly broad set of grounds on which the government may issue a compulsory license. In fact, Colombia's law represents the broadest set of public interest and general exploitation license grounds of the whole study sample. In addition to the usual non-use and insufficient use grounds, Colombia allows petitioners to request a CL in circumstances of suspension of use of the patent for at least one year, the patented product or process not being used locally, where exploitation has not satisfied the national market demand in reasonable quantity, quality or price, or that the patent holder has refused to license on reasonable terms. Public interest licenses can be issued when (1) the patents are of interest for public health, (2) when they are necessary for economic development (3) when the product has not been put on the market in quantities and qualities sufficient for normal consumption or (4) when prices are excessive. These government-initiated licenses can be granted to private or public entities. If they are granted to public entities, they are in essence government-use licenses but with procedural requirements, including prior judicial authorization, that go beyond what is required by Art. 31 of the TRIPS Agreement for public, non-commercial-use licenses.

The TRIPS flexibilities that Colombia has adopted are (1) no prior negotiation for anti-competitive remedy, emergency use, government use and public interest licenses, (2) several options for mandatory compulsory licenses – in which the government makes a patent "subject to license" and thus any petitioners who request the license (and show that they can exploit it or are a public entity) will be granted that license. There are also protections for CL holders – such that (3) challenges do not result in injunctive relief and (4) they may continue to use the patent even when the original circumstances that gave rise to the CL have ceased, subject to their legitimate expectations. By contrast with this expansiveness, Colombia includes very few flexibilities that are related to the scope of application of the patent. For import and export, only the baseline standards apply – that import is generally considered a legitimate way to

exploit the patent, and that export of non-predominant quantities is permitted. Even further, Colombia does not allow import at all for CL holders of general exploitation licenses – they must manufacture the product within Colombia's territory.

Civil society organizations (CSOs) in Colombia have spent decades advocating for CLs to be granted for essential medicines related to HIV, cancer and hepatitis C. In all three instances, the CSOs petitioned first for a declaration of public interest – a necessary first step in order to grant a license on that basis. As noted above, excessive pricing does qualify as a sufficient ground for such a license. In the case of imatinib, a cancer treatment, the government declared the presence of a public interest given the rising prices that resulted from granting a patent to Novartis in 2012. Despite this acknowledgement, the government received pushback from Novartis, the domestic (Colombian) pharmaceutical industry, the US Congress, and even from voices within the Colombian government itself (Roa Ortiz 2021). They raised concerns (or issued threats) that the CL would hurt innovative investment, negatively impact the negotiations of the TPA, and possibly amount to an expropriation of private rights (Correa and Velasquez 2019). In the end, a new price limitation was negotiated for imatinib but no CL was issued.

In the case of Kaletra, Abbott Laboratories' ARV medication, CSOs failed to secure a declaration of public interest despite clear evidence of excessive pricing. In a separate proceeding, Abbott was required to pay fines for its pricing structure, but no CL was issued (Roa Ortiz 2021). Some have argued that "taking the price of generic alternatives into account, savings could have been 100% higher" if the CL had been granted (Correa 2013b). In the case of sofosbuvir and other direct-acting anti-virals (DAAs), the petition for a public interest declaration was not even reviewed by the Ministry of Health after 6 years of advocacy (Roa Ortiz 2021).

In 2024, the Colombian Government made dolutegravir, an ARV medication, the first to be "subject to compulsory license" such that all interested persons were invited to submit an application for a CL "in the form of government use" (Superintendence of Industry and Trade 2024). The declaration of the existence of public interest which made this possible was issued in 2023 (Ministry of Health and Social Protection 2023). By subjecting the patent for dolutegravir to government use license, this implied that anyone who applies is to be granted that license by the Superintendence of Industry and Trade (Commerce). Although the immediate impacts are difficult to assess, ex ante government assessments of the license's impact predict cost reductions of up to 90 percent (Public Citizen 2023). Patent holders GSK and ViiV have strenuously resisted the license, first opposing its issuance and subsequently filing an appeal challenging the legality of the license issued (Moeller 2025).

Colombia's experience with CLs reflects in some ways the greater ambition with which it has adopted the range of TRIPS flexibilities. The country has especially explored the expansive possibilities of its public interest license options. Although the success rate of such licenses is not high, even failures to grant the license have resulted in lower prices on essential medicines. Of course, Colombia could go further to expand its adoption of TRIPS flexibilities by lowering procedural hurdles for general exploitation licenses or expanding the possibilities for export under a license. Once more, however, legislative change is only a start. Colombia's most recent CL was highly dependent on continued advocacy by CSOs and perhaps the particular political moment with a progressive administration currently in office. As will be clear in the following discussion, the legal text of CL laws in any given country is one piece of a much larger puzzle that can be put together to increase access to medicines that country's population.

## V. Discussion

### *Failing to maximize CL flexibilities may forfeit price and health benefits*

This study has focused on national legislation in select MICs and the extent to which the legislation incorporates best practice provisions permitted by Articles 31 and 31bis of the TRIPS Agreement. The fundamental finding of this study is that the subject countries have not maximized their CL policy space and thus do not conform to what experts have deemed to be "best practices". Our most fundamental recommendation, therefore, is that they should maximize this space in order to fully enable the granting of CLs when they are needed. This finding is consistent with the findings of previous studies (McGivern, 2023; Mitchell & Taubman, 2023). Our study also investigates countries that are typically excluded from voluntary licenses and finds that these countries demonstrate a great deal of diversity spanning the many grounds for issuing CLs (and the pattern of possible grounds within each category), the procedural ease-of-use of the laws, and the scope of application of licenses. To sum up, no single country is a model for broad and specific grounds for issuing CLs, none incorporate all the possible ease-of-use flexibilities, and none apply the full scope of application that TRIPS allows.

Despite their importance, CLs in the post-TRIPS era have not been widely or systematically used and, when used, have mainly been restricted to HIV medicines and some medicines for non-communicable diseases (NCDs) (Beall and Kuhn 2012; 't Hoen et al. 2018). Son and Lee (2018) found 108 instances of attempts to issue CLs between 1995 and 2014, in 27 countries. There was significant number of attempts to obtain CLs between 2001-2008 followed by a lull between 2008-2011. Researchers attributed this lull to an increase in political opposition to CLs following Thailand's CL for clopidogrel, which raised the concerns of pharmaceutical companies about CLs being used for additional products beyond HIV ARVs. Despite a renewed use of CLs from 2012, (Son and Lee 2018) its use continues to remain limited and sporadic as confirmed by our tabulation of usage in the study countries.

Our review of CL implementation in the study countries found 33 attempts to issue CLs on a fairly wide range of medicines. Having CL laws that function as intended is particularly important for MICs that are typically excluded from voluntary licenses both because such countries can face delayed product introduction and relatively high originator prices, and because they are better able to take advantage of CLs than many low- and lower-middle-income nations. Beall and Kuhn (2012) observed that there was more CL activity in UMICs than in lower income countries; they speculated that this was due to domestic production capacity, greater ability to "withstand political pressure and threats of retaliatory action", and the double burden of infectious and NCDs. Similarly, Son and Lee (2018) found that 50.9 percent of CL attempts occurred in UMICs. Nevertheless, compared to need, the use of CLs remains limited in UMICs in general and in our study countries as well.

There may well be affordability and health costs that arise from countries having failed to maximize their CL policy space. A systematic review of IP protection and access to medicines found that CLs (and even the threat of issuing a CL) can lead to a range of important public health and economic outcomes including improving drug availability and treatment coverage, as well as reducing prices and costs to government (Tenni et al. 2022). A study of the effect of issued CLs on medicine prices found that the mean price reduction where pre- and post-CL price data was available ranged between 66.2-73.9 percent (n=24) (Urias and Ramani 2020). The most comprehensive country-specific empirical evidence comes from Thailand, where

retrospective analysis of the outcomes of its seven government use licenses issued from 2006-2008 has shown significant reductions in government health expenditure, increased patient access to treatment, health gains in terms of Quality of Life Years (QALYs) and improvements in national productivity (Mohara et al. 2012; Yamabhai et al. 2011). The potential for CLs to produce public health and economic gains means that countries should have workable CL laws and regulations enabling CLs to be issued when needed.

***Addressing contextual factors that complicate implementation of CLs***

Expanding policy space by reforming CL laws would make the substance and process of issuing CLs easier, but it is clear that the granting of CLs does not depend on the quality of legislation alone. There is a complex interplay between the following factors: (1) the realities of the patent and trade secret landscape, (2) the role of internal and external political will and pressure, (3) bottlenecks in regulatory requirements, and (4) the lack of technical and financial capacity and market size that structures the environment for successful CL implementation. We will explore each of these issues below.

*(1) Patent and trade secret landscapes*

Even where governments have fully implemented the TRIPS flexibilities and afforded themselves the broadest policy space for issuing CLs, the realities of the patent landscape and the increasing reliance on trade secrets to protect IP create additional obstacles to effective CLs. Biopharmaceutical companies tend to create patent thickets around successful and important medicines that not only protect the key active ingredients, but their optimized variations, dosages, methods of administration, disease indications, and methods of manufacture (Wu and Cheng 2019). Repeatedly filing for additional patents on variations, dosages and more (also called "evergreening") both extends the ultimate time period of patent protection, and complicates the search for all patents relevant to a final pharmaceutical product, which is often difficult in any case because of patent information accessibility barriers (WIPO 2024a, 17–20). This complexity can be exacerbated further by patent protections on key components to a medicine, such as the patents on lipid nanoparticles used in the production of mRNA COVID-19 vaccines. Moreover, patent applications need not identify the international non-proprietary name of final medical product to which they relate, making the task of identifying all relevant patents that much more difficult. As our study clarifies, the TRIPS Agreement does not require identifying all patents at the outset for GULs nor for emergency-use CLs, but complete identification is eventually required for emergency-use CLs to avoid the risk of successful infringement claims.

For more complex medicines, including biologics and vaccines, trade secrets may be a bigger barrier to generic entry than patents (WIPO 2024a, 22-23). Biopharmaceutical manufacturing processes that require multiple steps, stringent quality controls, complex information matrixes, specialized equipment, and use of secret biological resources are impossible to duplicate when such "know-how" and biological materials are fully protected by trade secret law and where rightsholders refuse to engage in voluntary technology transfer. In such cases, as has been true for the WHO mRNA Technology Transfer Programme, the requisite commercial know-how to produce good-manufacturing compliant products must be generated anew based on publicly available information and crowd-sourced expertise (Baker and Hassan, 2023). In our study, only Turkey has a provision that requires patent holders to share access to all information needed to effectuate a CL to a licensee.

*(2) The role of internal political will and external political pressure*

In addition, the patent and trade secret landscape, where governments have adopted the full policy space flexibilities allowed under the TRIPS Agreement, may still lack domestic political will to pursue CLs as a policy option, as well as experiencing external political pressure to not do so.

CLs are issued by governments, and, except when CLs are mandatory, the government must have sufficient political will to issue a CL. When a government seeks a GUL by and for its own use, political will is obviously present, though CL decision-makers can theoretically thwart government wishes. When a CL is sought by a potential licensee, however, the government is being petitioned to act and frequently has discretion to grant a license or not. The willingness of the government to act is impacted by the health need, the advocacy of patients and their allies and clinicians, costs savings that might be achieved, resource constraints, the absence or presence of donor assistance, right to health requirements in national law, and multiple other factors. While a basic premise of this study is that it will always be useful for countries to have the maximum policy space to issue CLs, it is a separate decision whether to grant one in a particular circumstance. That ultimate decision is likely to be impacted by differing opinions between different departments of government, with, for example, departments of trade and industry, intellectual property, and finance potentially at odds with departments of health (WIPO 2024a, 13).

As noted above, the health or epidemiological need of a population is an important factor influencing political will. For example, Thailand's large population of PLHIV requiring lifelong ARV treatment was a factor in Thailand's decision to issue GULs for two ARVs. These GULs enabled Thailand to import and ultimately produce cheaper generic ARVs that met the price threshold for inclusion in Thailand's UHC package (Tenni et al. 2024). The broader the health need, the more people affected, the higher the degree of morbidity and mortality, the greater the impact on economic productivity and community wellbeing, and the higher the risk of disease spread, the greater the likelihood of government action. These factors help to explain the United State's willingness to incorporate GULs into their government procurement contracts for COVID-19 countermeasures (KEI 2022). Along with the push of AIDS activism, epidemiological need also explains the historical willingness of countries to address the HIV pandemic as it impacted young and middle-aged people in their most productive years the hardest. Indeed, compulsory licensing has most commonly been implemented to facilitate greater access to ARV medication (Tenni et al, 2022).

Of course, epidemiological need does not always have the impact one would expect. It does not explain, for example, the relative neglect of CL use for chronic, non-infectious disease in most LMICs by donors and by countries themselves (see Table 6). Nor does it explain global and national disregard of neglected diseases where the problem much more centers on an inadequate R&D pipeline and the dearth of commercial incentives to treat the poor who suffer the most (Impact Global Health 2025).

Political will can also be affected by external factors including opposition by HIC trading partners that have historically acted to protect biopharmaceutical companies from CLs and by the companies themselves that can initiate costly legal challenges to compulsory licensing provisions and practice (WIPO 2024a, 13-14). Historically, countries that have attempted to use their CL laws have faced considerable pressure to abandon their efforts (McGivern 2023; Vawda 2022; Navarro and Vieira 2021). The US exerted pressure on Thailand after it invoked

a series of CLs in 2006–2007, as did Abbott Laboratories which threatened to withdraw all pending and new medicines applications because of Thailand's CL on lopinavir/ritonavir (Tenni et al. 2024). Similarly, India faced intense political and corporate pressure when it issued its first CL on a cancer medicine (Baker 2015), even triggering an out-of-cycle review by the USTR in 2012 (MSF Access Campaign 2015b). Colombia came under strong pressure from Switzerland and the US when it threatened to issue a CL on Novartis's anti-cancer medicine Glivec (Public Eye 2015). The US even threatened to withdraw financial support for Colombia's peace process (Silverman 2016).

As already discussed, Colombia has been challenged by GlaxoSmithKline and ViiV for issuing a CL on dolutegravir. Since 1989, the United States has employed regularly published reports to threaten trade retaliation against countries engaging in "unsatisfactory" IP practices based on the US Special Section 301 of the Trade Act. More recently, a similar strategy has also been pursued by the European Union (EU) through the European Commission's Counterfeit and Piracy Watch List and the Commission's regular reports on protection and enforcement of IPRs in third countries (Wong, Cole, and Kohler 2022).

Despite these historic pressures, it is important to acknowledge that in 2023 the Biden Administration announced a policy to support countries' use of TRIPS flexibilities including CLs. Specifically, the USTR adopted a policy of not "call[ing] out countries for exercising TRIPS flexibilities, including with respect to compulsory licenses, in a manner consistent with TRIPS obligations" (USTR 2024b). Moreover, the EU advocated expanded use of CLs during the COVID-19 pandemic and has been considering a proposal for a regionwide emergency compulsory licensing regime (European Commission 2023).

*(3) Regulatory requirements as obstacles*

In addition to overcoming patent barriers and political obstacles, all countries also require that there be emergency use authorization or registration/marketing approval of a candidate medicine based on its proven safety, efficacy, and assured quality (Baker 2018). Typically, a follow-on generic only needs to prove bioequivalence with the originator's reference medicine and commercial good manufacturing practices to secure marketing approval. However, if the originator has delayed marketing approval from the national regulatory authority, as is common in LMICs (Wouters and Kuha 2024), there is no previous determination of the safety and efficacy on record. In such cases, the generic manufacturer might have to prove safety and efficacy by conducting its own clinical trials which would be prohibitively time-consuming and expensive, and possibly even violate human subject research ethics given the presence of an existing effective treatment.[22] Alternatively, the regulatory authority might recognize registration by another regulator – typically a stringent regulatory authority or a Level 3 or 4 WHO authority – or reference regulatory approval or registration data held elsewhere. Fortunately, the WHO has established a Prequalification Programme that assesses safety, efficacy, and quality of many (but not all) medicines (WHO, n.d.-b). National regulatory authorities can (but do not always) expedite national registration based on WHO prequalification and can also rely on WHO Collaborative Registration procedures to view

[22] Exposing human subjects to the risk and inconvenience of clinical trials is only justified if the research could contribute to scientific knowledge. Duplicating a clinical trial to reestablish the known safety and efficacy of a medicine of a proven generic or biosimilar equivalent does not advance knowledge (Freedman 1987). Moreover, guidelines for human subject research projects prohibit giving a placebo to a human subject when an existing treatment exists (Gupta and Verma 2013).

WHO product assessment and inspection reports upon the condition that they finalize their own registration within 90 days (WHO, n.d.-a).

Both originators and generic and biosimilar manufacturers find registering medicines complicated, especially when documentation requirements and regulatory standards differ. Registration of biosimilar biologics and vaccines is even more complicated than small molecule medicines and historically has required clinical trials to establish therapeutic equivalence. Regulatory processes for biologics are being simplified globally to a certain extent, but unless the production method is exactly the same, proof of quality assurance will require extra steps (Congressional Research Service 2019; Domachowske 2024).

*(4) Lack of technical and financial capacity and market barriers*

Where governments have overcome the hurdles of patent landscapes, political will and regulatory obstacles, even all that may not be enough if they lack financial or technical resources to produce or purchase the licensed products. In the first place, compulsory licensing goals cannot be realized if a given country does not have the appropriate level of technical expertise to fully exploit a CL (McGivern 2023; Gurgula and McDonagh 2024; WIPO 2024a, 11–13, 17). Regrettably, many LMICs simply do not have the appropriate administrative and legal capacity to successfully manage CL issuance and implementation. In an effort to address this gap, and to respond to inequitable distribution of COVID-19 medical countermeasures and the lack of local manufacturing capacity (WIPO 2024a, 20-22), LMICs have increasingly turned their attention to the need to be more self-sufficient with respect to the supply of essential health technologies. Calls for regional production abound and have received strong support from many quarters including the United States, Europe, the African Union, PAHO, and multiple global health initiatives. Brazil has pursued industrial policy objective across a broad spectrum of medicines preferring to conclude technology transfer deals through voluntary licensing agreements in the long run even if that has meant higher short terms prices and an agreement not to pursue CLs in the short run. Politically, the importance of having local or regional biopharmaceutical manufacturing capacity is much more salient now, and provides strong policy support for relying on CLs when necessary to achieve reliable and affordable sources of medicines when they are excluded from voluntary licenses.

Another obstacle often faced by MICs is small domestic markets. Many of the countries in the study group do not necessarily have populations large enough to be economically attractive to one or more generic entrants on their own. Even if they have a sizeable population for a particular medical condition, they may not have one for orphan and rare diseases. If the market is too small, it will be difficult to incentivize a generic or biosimilar company to become a licensee. Afterall, as private entities, most generic and biosimilar companies need the promise of commercial reward to make the necessary investments in product development, regulatory approval, pursuit of a CL, and marketing and distribution worthwhile. On the other hand, if countries are able aggregate with one another into a sufficiently large market, the cost of pharmaceuticals is likely to fall as economies-of-scale are reached. If markets are of sufficient size, CLs can be granted to multiple producers who will thereafter compete on price ultimately resulting in lower prices. Médecins Sans Frontières has documented the dramatic impact generic competition has had on reductions in the cost of ARV medicines as more generics entered the market (MSF Access Campaign 2017).

As previously suggested, potential generic and biosimilar licensees have unique incentives and disincentives to market entry. One attractive possibility with respect to a medicine that is

already voluntarily licensed via the Medicines Patent Pool (MPP) is to seek a CL from an already authorized voluntary licensee. The MPP always includes a provision in its license agreements that MPP licensees can supply countries and territories excluded under a voluntary license where a country has issued a CL allowing such supply. However, if a potential licensee is being asked to sink all of the predictable capital into product development of a medical technology it is not yet producing, and thereafter conduct necessary bioequivalence studies, seek marketing approval, and set up distribution chains, it has much less incentive to do so unless the potential market returns are commensurate. To incentivize a potential generic licensee, governments can make commitments that reduce market risk like advance market agreements, quantity guarantees, pooled procurement, and other initiatives that expand and guarantee a viable market (WTO 2016; Mitchell and Taubman 2023; World Health Organization, World Intellectual Property Organization, and World Trade Organization 2020).[23]

For a CL to make sense, there also have to be resources for buying the medicine produced under the license. Domestically, those resources typically come from government coffers, private insurance, or out-of-pocket payments. But domestic purchasing power can also be augmented by donor assistance for health and resources from certain multilateral, multistakeholder, and charitable entities, including the Global Fund to Fight AIDS, TB, and Malaria, PEPFAR, UNICEF, GAVI, MSF, Unitaid, the Gates Foundation and others. When a CL is sought on a medical technology that will be safer and more efficacious than an existing technology, government will likely be more willing to issue a CL, especially if the technology will cost the same or less. If the technology is cost-saving for an existing health program, the government will be even more willing to grant a CL, as it will be if the health technology is subsidized with donor assistance. However, if the CL product is for a previously unmet need, the government will have to assess where new resources would come from or where other budget savings might be achieved. In conditions of constrained resources, governments may be reluctant to commit to meeting the health need through CLs and health system delivery costs.

The question of profitability and who can and will pay for the product produced under the CL will also be important to the potential licensee. If there is no prospective market or actual demand, the licensee would be making investments at risk. Few generic companies are willing to do so where LMIC governments are increasingly debt burdened, where tax collections are weak, and where fiscal restraints imposed by international financial institutions might constrain health sector spending (Yenet et al. 2023).

### *Continued insufficiency of TRIPS CL flexibility*

This paper and its findings have mainly focused on select countries' patent legislation to discern whether that legislation has fully incorporated CL flexibilities authorized by the TRIPS

[23] Reviewing this question, the Trilateral Study observed: "The special export license [under the TRIPS amendment] is one legal pathway that can be followed when it represents the optimal route to effective procurement, but, as for any compulsory license, it does not in itself make the production of a medicine economically viable. Sufficient scale and predictability of demand are prerequisites for making it practically and commercially viable for companies to undertake the regulatory, industrial and commercial steps required to produce and export a medicine under such a license. Regional approaches to procurement and joint notifications by countries with similar needs for accessible medicines may offer pathways to aggregating demand under the System, thus enabling an effective response to the needs identified." (World Health Organization, World Intellectual Property Organization, and World Trade Organization 2020).

Agreement. But working within the existing TRIPS rules still leaves countries vulnerable to inflexible provisions in Article 31 and 31*bis* that make CLs a much less effective strategy than they might otherwise be. In this regard, two existing TRIPS requirements and several additional missing considerations are especially consequential.

First, except with respect to government-use licenses, TRIPS requires compulsory licensees to identify all relevant patents on the finished medical product as well as its components before a CL can be properly issued (Art. 31(b)). As previously discussed, identifying all relevant patents is difficult because of the patent thickets that rightsholders file, because patent applications do not ordinarily require the identification of the commercial medical products to which they pertain, and because of difficulties in easily searching patents in patent offices, especially those that are not yet digitalized. A related problem is determining which patents are still valid and thus give rise to potential infringement and CL invalidity claims when the compulsory licensee manufactures the products or offers them for sale.

Second, as repeatedly addressed above, Article 31(f) of the TRIPS Agreement limits supply options for countries that cannot effectively work the licensed patent(s) locally. This may be due to lack of sufficient biopharmaceutical manufacturing capacity and/or insufficient market size to sustain a CL licensee and to achieve economies-of-scale for maximum cost savings. Article 31*bis* has proven to be totally inadequate to overcome the aggregated demand problem or to achieve any kind of procedural simplicity that would encourage its use.

Finally, the TRIPS Agreement lacks key components that would help to minimize the obstacles discussed above. TRIPS Articles 31 and 31*bis* do not generally make space for countries to prioritize self-reliance via local or regional production and aggregated markets. They also have little provision to ensure the continuing economic survival of a compulsory licensee who invests in commercial production but who might lose their status if the conditions warranting the CL change. Although the TRIPS Agreement does not require data exclusivity on its face, certain interpretations of the provision have made it seem ambiguous when it comes to whether countries need to provide some measure of data exclusivity under Article 39.3 or whether they may allow access to regulatory information and data, including with respect to manufacturing and quality assurance processes and assays (Owoeye 2015; Correa 2002; Solovy 2022). Moreover, the Agreement does not recognize the essential relationship between the protection of confidential information, trade secrets and CLs. It does not make it clear that countries are permitted to have public health and public interest exceptions to trade secrets (protection of confidential information under Article 39.2) and further have the right to issue CLs for access to such trade secrets and biologic resources needed to effectuate a CL. It likewise has a narrowly drafted national security exception to IPRs allowed in Article 72 which does not refer to public health emergencies and public health needs. In summation, the TRIPS Agreement in its entirety continues to facilitate monopoly ownership and control over the products of scientific progress. Thus, the most radical reform proposals involve dismantling TRIPS in major part and creating a new innovation and access regime that delinks the funding and market for R&D and the market for low-cost production and equitable distribution of health technologies based on need not gross national income (GNI) per capita.

Regrettably, reforming the TRIPS Agreement or even providing for meaningful waivers has proven to be extraordinarily difficult and has been opposed both by the biopharmaceutical industry and the HICs that protect it. Although it would be useful for LMIC Member States to consider strategies that might ultimately result in consequential TRIPS reform, their most promising strategies for the near- and mid-term are to focus on enactment and use of maximum

TRIPS flexibilities and to actively coordinate with other LMICs to establish new regimes for prioritizing biomedical R&D that addresses unmet needs and that guarantees equitable access to products produced at low cost and sold with minimum mark-ups.

Although this paper has mainly focused on CL constraints and flexibilities under the TRIPS Agreement, additional direct and indirect obstacles to issuing CLs can arise in free trade agreements and investment treaties. For example, there are knock-on effects on the need for CLs that arise from TRIPS-plus IPRs that ease patentability and disclosure requirements and extend patent terms for regulatory and patent-decision delays. Data exclusivity and patent-registration linkage can interfere with the ability to bring a CL-licensed medicine to market and trade secret rules can prevent information needed to work the patent, including manufacturing know-how and biologic resources, from reaching licensees. In addition, investment treaty rules might give rise to investor-state-dispute-settlement claims based on the issuance of a CL.[24]

*Limitations*

The best practices used to assess the CL laws in each country were developed by the authors based on work by author Baker, the Max Planck Institute, and Carlos Correa. However, these may not represent a complete or uniformly agreed list of best practices. They were not reviewed for completeness against other guides to designing CLs (Correa 1999; Navarro and Vieira 2021). Thus, there may have been additional ways that our study countries utilized TRIPS flexibilities that were not captured in the data because they were not envisaged in this list of "best practices."

We selected 15 countries for inclusion in the study from a list of 50 MICs that were excluded from the 2014 Gilead license (see MSF Access Campaign 2015a). These countries were selected because they were not high-income at the time, for geographic representativeness and because they had laws in English, Spanish, Arabic and French. However, this sub-sample may not be fully representative of the diversity of CL legislation in countries typically excluded from CLs, of which Brazil is a prime example. Also, four countries in our sample were added to Gilead's HCV license in 2017 (Algeria, Malaysia, Philippines, Thailand, and Ukraine), meaning there may be other countries among those excluded from the 2014 license that are more likely to benefit from useable CL laws.

The heterogeneity and degree of complexity in individual-country CL laws made it difficult to detect meaningful patterns in the data. Quantitative coding of the presence or absence of stipulated features the CL laws was used to reduce the complexity and identify patterns, however there is a risk that, for instance, the relative importance of different CL features was lost or miscalculated in this process.

While we did identify whether our study countries had deployed their CL laws, we did not examine the CLs themselves to correlate their features with the flexibilities in the respective countries' CL laws. Nor did our sampling strategy specifically select countries that had issued CLs and countries that had not, for comparison. This limited our ability to determine which flexibilities were useful in practice, and is an area where further research is needed (see below).

[24] Intellectual property measures have not frequently been assessed by investor-state arbitral tribunals. It is not unheard of, however, as evidenced by the case that Eli Lilly brought to challenge Canada's promise or utility doctrine. In many international investment agreements, IPRs are considered a "covered investment" whose value would be protected as an investor asset under the treaty (Baker and Geddes 2017; UNCTAD 2024).

In addition, we did not explore national practice, if any, with respect to provision for, or issuance of judicial licenses, the possibility of public interest exceptions to patent protection (allowable under TRIPS Article 30), nor CLs on trade secrets, though we did note that Turkey requires patent holders to disclose the information needed to operationalize a CL (Law No. 6769, Arts. 126, 137).

## VI. Conclusions

TRIPS allows significant policy space for countries to design their CL laws, so unsurprisingly there was a high degree of heterogeneity in the CL laws among the countries in our study. We observed considerable variation in the degree to which TRIPS flexibilities were incorporated into the CL laws and regulations of 15 countries, meaning that all countries we examined could more systematically exploit the TRIPS flexibilities in order to ensure their CL legislation is fit for purpose. All of the study countries have room to improve their incorporation of TRIPS-related flexibilities in terms of the number of possible grounds for issuing a CL, how easy their CL laws and regulations are to use, and the scope of application to cover pending patents, patents on components, and rights to export and import. No single country emerged as an example of best practice which other countries should emulate.

At the same time, it is unclear how much the incorporation of TRIPS flexibilities in national CL laws matters in terms of whether countries are able to successfully use CLs. Whether or not governments are able to issue CLs seems more likely to be related to legal, economics, resource, and political factors aside from the technical aspects of their laws – in other words, having workable CL legislation is **necessary but not sufficient**. Removing a range of other barriers including by relieving the political pressure on UMICs not to issue CLs may turn out to be as important as the specific features of their national CL mechanisms. In light of these findings, we make the following recommendations:

### *Recommendations*

### 1. National law reform

MICs and other countries which are frequently excluded from voluntary licenses should review and update their CL laws to take full advantage of flexibilities available under TRIPS if they wish to improve access to medicines. National CL laws should have:

- *All five categories of CLs and a broad range of grounds in each category, to maximize the options for issuing CLs.* While we were unable to identify any particular country that provides a "best practice" model for breadth of grounds, governments interested in reform should look at a range of different countries' legislation for best practice in relation to the different types of licenses (general exploitation, anti-competitive remedy, public interest, emergency, and government use). For example, Colombia includes a wide range of grounds for general exploitation licenses; Argentina for anti-competitive remedy licenses; Colombia and Thailand for public interest grounds; Ukraine for emergency license; and Thailand for government use licenses (and has successfully issued multiple GULs).

- *Full expression of TRIPS procedural flexibilities, to ensure ease-of-use*. This includes modifying provisions so that it is easier for governments to take action and issue government use and CLs on their own, as well as easier for petitioners to initiate the process. Other important procedural flexibilities act to shift the burden of proof onto the patent holder and make sure that challenges to the license do not undermine the effectiveness of the CL or contravene legitimate interests of the CL holder.

- *Full expression of flexibilities related to scope of application*. Finally, the scope of application should be expanded so that CLs are more effective once granted. This

includes allowing licenses for all patents related to a final product and for filed as well as granted patents. It also includes expanding the possibilities for import and export of licensed products. Most importantly, each country should make allowance for exporting pharmaceuticals to eligible countries under TRIPS Article 31*bis*, and importing pharmaceuticals when they themselves lack the pharmaceutical capacity.

For more details about how individual countries might reform their laws in accordance with the TRIPS Agreement, see Appendix D.

**2. Technical support for countries excluded from voluntary licenses**

Civil society groups and experts have historically provided technical support and guidance for countries seeking to change their laws (Baker 2019; Correa 2000). Given the limited incorporation of TRIPS flexibilities across board in MICs, international organizations like the World Health Organization, the United Nations Development Programme and others should do the same.

**3. Cooperation between middle-income countries**

There are a number of ways LMICs can cooperate to overcome obstacles to compulsory licensing. First, cooperation on law reform may assist countries to maximize their incorporation of TRIPS flexibilities. Mitchell and Taubman (2023) suggest, for example, that countries organize collaborative workshops to share best practice and areas for cooperation. Second, where market size in a particular country may be insufficient for commercially sustainable production, unlicensed countries with a need for a medicine might collaborate with others similarly situated counties to issue coordinated CLs that will attract generic entrants by pooling procurement needs to generate economies of scale for generic manufacturing. This could be done in a way that builds on existing regional and international mechanisms (Mitchell & Taubman, 2023). Collaborating on CLs or even making a commitment to collaborate would have the added benefit of lending weight to threats to issue CLs, making it easier to negotiate lower prices with originators (Ooms and Hanefeld 2019). Third, countries could collaborate in pressing for reform of TRIPS or pushing back against pressure not to use CLs (see Policy Recommendation 5).

**4. Attention to and adoption of supportive and enabling policies**

To help effectuate registration of medicines produced pursuant to a CL, countries should harmonize their regulatory requirements to reduce the complexity, cost, and delay of seeking regulatory approval. In addition, countries that have adopted a TRIPS-plus standard of data exclusivity (WIPO 2024a, 23-24) should provide for an exception to such exclusivity if a CL has been issued. For example, Chile, Colombia and Malaysia waive data exclusivity where necessary to protect public health. Chile and Malaysia specifically waive it if use of the patent is allowed under a CL. Meanwhile, Canada and the European Union waive data protection for medicines exported under Article 31*bis* compliant measures (WIPO 2024a, 24).

A number of other enabling policies would help smooth the way for implementation of CLs. The first would be to ensure that needed medical technologies under a CL are included in clinical guidance and that the health workforce is trained in their use. Second, it would be useful to ensure that important medicines made available through CLs be included on the country's essential medicines list. Finally, and as a signal of political will, countries that recognized the

need for a regular CL that could supply both public and private sectors could issue expressions of interest for generic applicants to seek a CL on an important health technology. Advocates in Latin America countries excluded from Gilead's voluntary license on lenacapavir are currently asking their governments to issue such expressions of interest.

## 5. Reform of TRIPS and other trade agreements

Each of the above policy recommendations seeks to provide countries with a way forward to promote access to medicines even in a world where the existing global governance institutions are not really set up to support their efforts. In the most desperate days of the COVID-19 pandemic, even very temporary, targeted reform efforts that were aimed at the TRIPS Agreement have fallen far short of what was needed. Nevertheless, no set of policy recommendations would be complete without an acknowledgement of the obstacles posed by such global IPR rules.

The reality of geopolitics today is that the money and political will to reform TRIPS are lacking. In our view, at this present moment and possibly for the foreseeable future, TRIPS is virtually un-negotiable. Nevertheless, ideally, TRIPS Article 31 and 31*bis* should be reformed to remove the specific obstacles in Article 31(f) and 31*bis* that make it more difficult for countries to effectively aggregate purchasing and production markets. Although at present, we suspect this will not happen soon, any new language should acknowledge the challenge that small market countries face in attempting to issue effective compulsory and government use licenses and provide for additional flexibilities. Second, WTO members should provide greater clarity around the other flexibilities that are available under the TRIPS Agreement either through reform of the text itself or, more realistically, the issuance of interpretive statements. For example, countries should be made aware of the option to rely on public interest grounds in order to waive confidential information protection. Finally, thought should be given to expanding legal exceptions to reduce administrative barriers to the issuance of licenses in the case of public health emergencies and related concerns.

Moreover, given renewed global focus on regional and bilateral free trade agreements, countries should avoid negotiating new TRIPS-plus rules and investment clauses that allow IP-related claims. They should also consider renegotiating troubling provisions, including use of exclusions and exceptions from rules that might create obstacles to CL use, or use interpretive ambiguity and gaps to adopt CL-enhancing measures.

## 6. Further research

Finally, there is a need for further research to identify better examples of full implementation of CL-related TRIPS flexibilities; conduct detailed case studies of countries where CLs have been sought and/or issued and exploring how these attempts and successes relate to the expression of TRIPS flexibilities in national law; and explore the contributing factors for poor or varied expression of the TRIPS flexibilities. In-depth case studies of specific countries, triangulating different data sources including interviews, would be beneficial for exploring the complex barriers to issuing CLs and generating context-specific recommendations for reform.

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**Appendix A. Table 1. TRIPS Agreement Article 31 Relevant Provisions**

| TRIPS Article 31 paragraph | Details |
|---|---|
| (a) | Authorization of use of the subject matter of a patent without permission of the right holder must be considered on individual merits |
| (b) | Proposed user must make effort to obtain authorization from right holder<br>• on reasonable terms and conditions<br>• and such efforts have not been successful within a reasonable period of time<br><br>This requirement can be waived in circumstances of<br>National emergency or other circumstance of extreme urgency<br>Or in cases of public non-commercial use<br>• If there is an emergency or other circumstance of extreme urgency, right holder must be notified as soon as reasonably practicable<br>• If for public non-commercial use, if the government or contractor, without making a patent search, knows or has demonstrable grounds to know that a valid patent is or will be used by or for the government, right holder shall be informed promptly |
| (c) | Scope and duration of such use is limited to the purpose for which it was authorized… |
| (d) | Such use is non-exclusive |
| (e) | Such use shall be non-assignable, except with that part of the enterprise or goodwill which enjoys such use |
| (f) | Any such use shall be authorized predominantly for the supply of the domestic market of the authorizing member |
| (g) | Authorization shall be terminated if and when the circumstances that led to it cease to exist and are unlikely to recur,<br>Subject to the legitimate interests of the persons so authorized (CL holder)<br>Competent authority has the authority to review requests to determine whether the circumstances have ceased to exist |
| (h) | Right holder is to be paid adequate remuneration in the circumstances of each case, taking into account the economic value of the authorization |
| (i) | The legal validity of any decision relating to the authorization of such use is subject to judicial review or other independent review |
| (j) | Any decision relating to the remuneration provided in respect of such use shall be subject to judicial review or other independent review |
| (k) | The obligations in (b) (prior negotiation) and (f) (use predominantly for the supply of the domestic market) do not |

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| | need to be applied in circumstances where a judicial or administrative process has found the right holder to be engaged in anti-competitive behavior<br>Also, remuneration in these cases may take into account the need to correct anti-competitive practices<br>Competent authorities have the authority to refuse termination of authorization if and when the conditions of anti-competitive practices are likely to recur. |
| (l) | Where the authorized use permits exploitation of a second patent which cannot be exploited without infringing on a first patent so long as<br>The second patent is for an invention that involves an important technical advance of considerable economic significance in relation to the first patent<br>The owner of the first patent shall be entitled to a cross-license on reasonable terms<br>The use authorized in respect of the first patent shall be non-assignable except with the assignment of the second patent |

## Appendix B. AMENDING PATENT LEGISLATION TO TAKE FULL ADVANTAGE OF TRIPS COMPLIANT FLEXIBILITIES WITH RESPECT TO COMPULSORY AND GOVERNMENT USE LICENSES

Professor Brook K. Baker
September 18, 2023

This analysis can be used to review existing compulsory license legislation and regulations in country legislation to ascertain whether countries have adopted all relevant TRIPS-compliant flexibilities with respect to compulsory and government use licenses. This analysis relies on an expert consensus by the Max Planck Institute, *Declaration on Patent Protection: Regulatory Sovereignty under TRIPS*[1] and also on the expertise of Carlos Correa.[2] The analysis concludes with a proposed checklist of compulsory license issues that would need assessment.

### 1. Compulsory licenses and government use

The TRIPS agreement allows involuntary use of patents as long as certain procedures are followed. It does not specify or otherwise limit the grounds upon which licenses can be granted. More specifically, Article 31 of TRIPS allows for the use of an invention covered by a patent without the patent holder's authorization subject to the following conditions:

- Each case must be considered on its individual merits (Art. 31(a));
- The proposed user has made a prior unsuccessful attempt to obtain a voluntary license from the right holder on commercially reasonable terms and such efforts have not been successful with a reasonable period of time (Art. 31(b);
    - Such requirement is waived in circumstances of national emergency or other circumstances of extreme urgency or in cases of public non-commercial use, though the right holder must be notified (Art. 31(b));
    - Such requirement is also waived where compulsory licenses have been granted to remedy anticompetitive practices (Art. 31(k));
- The scope and duration of use is limited for the purpose in which the use was authorized (Art. 31(c)) and the authorization for use shall be terminated if and when the circumstances which led to it cease to exist and are unlikely to reoccur, subject to the legitimate interests of the licensee being protected (Art. 31(g);
- The use is non-exclusive (Art. 31(c)) and non-assignable, except with that part of the enterprise or goodwill which enjoys such use (Art. 31(e));
- The use is "predominantly for the supply of the domestic market" except when issued to remedy anticompetitive practices (Art. 31(f) & (k));
- The patent holder is paid adequate remuneration for such use taking into account the economic value of the authorization (Art. 31(h)), though compensation may be adjusted downward in a compulsory license is issued to remedy anticompetitive practices (Art.

[1] Max Planck Institute, DECLARATION ON PATENT PROTECTION: REGULATORY SOVEREIGNTY UNDER TRIPS (2014), available at http://www.mpg.de/8133454/Patent-Declaration1.pdf.

[2] *See, e.g.,* Carlos Correa, INTEGRATING PUBLIC HEALTH CONCERNS INTO PATENT LEGISLATION IN DEVELOPING COUNTRIES (2000) (Correa, INTEGRATING PUBLIC HEALTH); Carlos Correa, GUIDELINES FOR THE EXAMINATION OF PHARMACEUTICAL PATENTS: DEVELOPING A PUBLIC HEALTH PERSPECTIVE, WHO-ICTSC-UNCTAD (2007) (Correa, GUIDELINES FOR EXAMINATION); Carlos Correa, INTELLECTUAL PROPERTY AND COMPETITION LAW: EXPLORING SOME ISSUES OF RELEVANCE TO DEVELOPING Countries (2007) (Correa, IP AND COMPETITION LAW; Carlos M. Correa, PHARMACEUTICAL INNOVATION, INCREMENTAL PATENTING AND COMPULSORY LICENSING, SOUTH CENTRE RESEARCH PAPER 41 (2011) (Correa, PHARMACEUTICAL INNOVATION).

31(k));
- The legal validity of any decision relating to the authorization of the use, as well as the amount of remuneration, is subject to judicial or other independent review by a "distinct higher authority" (Art. 31(g) & (j)); and
- The right holder of a second patent that cannot be exploited without infringing the first patent may receive a license if the second invention involves an important technical advance of considerable economic significance in relation to the first invention, the owner of the first patent receives a cross-license to the second invention on reasonable terms, and the use authorized in the license on the first inventions shall not be assigned without assignment of the second patent (Art. 31(l)).

The Doha Declaration on the TRIPS Agreement and Public Health clarified that "[e]ach Member has the right to grant compulsory licenses and the freedom to determine the grounds upon which such licenses are granted," and that "[e]ach Member has the right to determine what constitutes a national emergency or other circumstances of extreme urgency, it being understood that public health crises, including those relating to HIV/AIDS, tuberculosis, malaria, and other epidemics, can represent a national emergency or other circumstances of extreme urgency."[3]

Although the use of compulsory licensing procedures has not been as robust internationally as might be desired in light of compelling global health needs, multiple countries have issued compulsory or government-use licenses on medicines,[4] especially on AIDS medicines:

- In 2006-2008, Thailand issued compulsory licenses for key medicines related to HIV, heart disease and cancer.[5]
- In 2007, Brazil issued a compulsory license on efavirenz, an HIV medicine.[6] It renewed that compulsory license in 2012.[7]
- In 2010, Ecuador declared several medicines to be of public interest, announcing that it would examine each of these if they were appropriate for compulsory licensing. Ecuador subsequently issued a compulsory license for ritonavir, an HIV protease inhibitor booster (in 2010)[8] and for the paediatric form of abacavir/lamivudine, a

[3] World Trade Organization, Declaration on the TRIPS Agreement and Public Health (Doha Declaration), WT/MIN(01)/DEC/2, Ministerial Conference, Fourth Session, Doha, 9-14 November 2001, paragraph 5(b), (c), available at http://www.wto.org/english/thewto_e/minist_e/min01_e/mindecl_trips_e.htm.

[4] For an early compilation of compulsory licenses, see Knowledge Ecology International, Recent examples of the use of compulsory licenses on patents, KEI Research Note 2007:02, available at http://www.keionline.org/misc-docs/recent_cls.pdf.

[5] FACTS AND EVIDENCES ON THE 10 BURNING ISSUES RELATED TO THE GOVERNMENT USE OF PATENTS ON THREE PATENTED ESSENTIAL DRUGS IN THAILAND, Ministry of Public Health and The National Health Security Office, Thailand, February 2007, available at http://apps.who.int/medicinedocs/documents/s18718en/s18718en.pdf and THE 10 BURNING QUESTIONS ON THE GOVERNMENT USE OF PATENTS ON THE FOUR ANTI-CANCER DRUGS IN THAILAND, The Ministry of Public Health And The National Health Security Office, Thailand, February 2008, available at http://www.moph.go.th/hot/Second_white_paper_on_the_Thai_CL_%5BEN%5D.pdf.

[6] Press Release, *Ministry of Public Health, Brasil decreta licenciamento compulsório do Efavirenz*, Brazil's Ministry of Public Health (April 5, 2007), available at http://portal.saude.gov.br/portal/aplicacoes/noticias/noticias_detalhe.cfm?co_seq_noticia=29717.

[7] Brazil renews compulsory license for Efavirenz, May 2, 2012, available at http://www.aids.gov.br/en/en/noticia/2012/brazil_renews_compulsory_license_efavirenz.

[8] *Compulsory License for Ritonavir, granted to Eskegroup*, Unofficial English Translation (Public Citizen), 14 April 2010 available at http://www.citizen.org/documents/EcuadorCompulsoryLicenseTranslationUNOFFICIAL.pdf.

combination HIV medicine (in 2012).[9] In 2012, Ecuador also issued a compulsory license for HIV medicine abacavir/lamivudine.[10]

- In 2012, India issued a compulsory license for a cancer medicine.[11]
- In 2004, 2007, and 2012, Indonesia issued compulsory licenses for seven HIV medicines.[12]
- A limited number of compulsory licenses have been issued in response to the COVID-19 pandemic, including a license on lopinavir-ritonavir in Israel. The U.S. government also gave contractual rights to government use licenses in at least 59 contracts for purchase of covid-related medical technologies.[13]

### 1.1 Expanding grounds for and clarifying conditions for compulsory licenses

As clarified by the Doha Declaration, WTO Member States have complete freedom to determine the grounds upon which compulsory licenses may be granted, and Indonesia should expand the grounds for such licenses. Under the TRIPS Agreement and the Doha Declaration, there are no disease restrictions, country-status restrictions, or field of technology restrictions. The Paris Convention[14] does place some limits on the timing of compulsory licenses for non-working.

As a general rule, countries are far better off articulating multiple and broad grounds for compulsory licenses instead of restricted grounds.[15] After all, a patent is a sovereign grant of exclusive, i.e., monopoly, rights and the patentee takes such rights with full notice of possibility that the granting government might issue compulsory and government-use licenses. Countries should retain maximum policy space for the exercise of government discretion about the myriad circumstances where involuntary use should be permitted to safeguard public interests.

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[9] *Ecuador's Compulsory License for Abacavir+Lamivudine – Brief Summary*, Unofficial English Translation (Public Citizen), 12 November 2012, available at http://www.citizen.org/English-summary-ecuador-CL-2012.

[10] Knowledge Ecology International, '*Ecuador issues a compulsory license on abacavir/lamivudine on 12 November 2012'* http://keionline.org/node/1589.

[11] *Bayer Corporation v. Union of India and Ors*, Intellectual Property Appellate Board, M.P.Nos.74 to 76 of 2012 & 108 of 2012 in OA/35/2012/PT/MUM, 14 September 2012, available at http://www.ipab.tn.nic.in/223-2012.htm.

[12] *See, e.g.*, *President Decree of the Republic of Indonesia No. 76 of 2012 About Implementation of the Government of Patent Medicines*, 2012, Unofficial English Translation (Public Citizen), available at http://www.citizen.org/documents/PresidentalDecree20121.pdf

[13] James Love, *KEI Review of 62 COVID-19 Contracts Reveals 59 Authorizations for Non-Voluntary Use of Third Party Patents Under 42 U.S.C. 1498*, KNOWLEDGE ECOLOGY INT'L (July 20, 2022), https://www.keionline.org/37987.

[14] Paris Convention Paris Convention for the Protection of Industrial Property (1883 as amended through 1979), Article 5A(4), "A compulsory license may not be applied for on the ground of failure to work or insufficient working before the expiration of a period of four years from the date of filing of the patent application or three years from the date of the grant of the patent, whichever period expires last; it shall be refused if the patentee justifies his inaction by legitimate reasons. Such a compulsory license shall be non-exclusive and shall not be transferable, even in the form of the grant of a sub-license, except with that part of the enterprise or goodwill which exploits such license." Available at http://www.wipo.int/treaties/en/text.jsp?file_id=288514.

[15] Brook K. Baker, PROCESSES AND ISSUES FOR IMPROVING ACCESS TO MEDICINES: WILLINGNESS AND ABILITY TO UTILIZE TRIPS FLEXIBILITIES IN NON-PRODUCING COUNTRIES, UK DFID, Health Systems Resource Centre (2004); Cecilia Oh, *Compulsory licenses: recent experiences in developing countries*, 1 INT'L J. INTELLECTUAL PROP. 22-36 (2006); Jerome H. Reichman & Catherine Hasenzahl, NON-VOLUNTARY LICENSING OF PATENTED INVENTIONS: HISTORICAL PERSPECTIVE, LEGAL FRAMEWORK UNDER TRIPS, AND AN OVERVIEW OF THE PRACTICE IN CANADA AND THE USA (2003); Reed Beall & Randall Kuhn, *Trends in Compulsory Licensing of Pharmaceuticals Since the Doha Declaration: A Database Analysis*, 9:1 PLOS MED e1001154 (2012).

As stated above, the Doha Declaration reaffirms that countries are free to determine the grounds upon which licenses might be granted.[16] Common grounds include unreasonable pricing, not reasonably supplying market need, and refusals to license. However, it is highly desirable to list addition specific grounds, e.g., to prevent the risk of stock-outs, to promote the development and marketing of rational fixed-dose combinations, and to protect public health and the public interest more broadly[17].

**Recommendations**

**Grounds:**
**Article X**
Compulsory License is a License to work a Patent, issued pursuant to a Decision of the designated government official or office on the basis of application for the following reasons:

a. the patented invention is not worked or not fully worked domestically by the Patent Holder;
   (i) it does not meet the reasonable requirements of the public with respect;
   (ii) it is not available to the public at a reasonably affordable price;
   (iii) it has not been worked locally other than by importation and the patent holder fails to demonstrate that it is not economically or technologically feasible to manufacture in whole or in part domestically;
b. the Patent is worked by the Patent Holder or Licensee in a form and by means harmful or abusive to the public interest;
c. the Patent is an enhancement of a previously issued Patent, and as such cannot be worked without working the Patent of another party that remains under protection.;
d. there is an emergency or other urgent matter of national interest.;
e. the patent holder has refused to grant a license on reasonable terms within a reasonable period of time of no more than three months, despite a request to do so, for the purpose of access to an essential facility, including to be able to produce and market rational fixed-dose combination medicines, or to be able to commercialize a promising dependent technology;
f. there is a risk of supply interruptions of essential products such as medicines;
g. there is a need to promote local production and technology transfer;
h. there is any other public interest or public health need;
i. the patent holder has been found to have engaged in an anti-competitive practice.[18]

**Conditions:**
**Article XX**
The decision on the granting of the Compulsory License as referred to in paragraph (1) shall contain a requirement that the exploitation of the invention under a compulsory license shall be predominantly for the supply of the domestic market except when the compulsory license has been granted to remedy an anti-competitive practice.

**Transfer of Compulsory License:**
**Article XXX**
(1) A Compulsory License may not be transferred, except with that part of the enterprise or goodwill which enjoys such use, including by inheritance.
(2) In case a Compulsory License is transferred by inheritance or otherwise, the Ministerial Regulation on the granting of the Compulsory License shall remain applicable to the transferee or heir.
(3) A Compulsory License that is transferred by inheritance or otherwise as referred to in paragraph (1) shall be reported to the Minister to be registered in the general register of patents and published in:
   a. electronic media; and/or
   b. other media.
(4) A Compulsory License that is transferred by inheritance or otherwise as referred to in paragraph (1) shall remain bound by the terms of its granting and other conditions, particularly regarding the period

[16] Doha Declaration, *supra* note 3, para. 5(b), "Each member has the right to grant compulsory licenses and the freedom to determine the grounds upon which such licenses are granted."
[17] UNDP, USING LAW TO ACCELERATE TREATMENT ACCESS IN SOUTH AFRICA: AN ANALYSIS OF PATENT, COMPETITION AND MEDICINES LAW, 71 (2013).
[18] Competition-based licenses are described further in section 1.8, *infra*.

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| | of time as set forth in the decision on the granting of the Compulsory License as referred to in Article 90 paragraph (2). |
| (5) | In the event that the transferee or heir fails to report the transfer of a Compulsory License as referred to in paragraph (3) to the Minister, the Ministerial Decision on the granting of the Compulsory License shall be void. |

### 1.2 Provisional compulsory licenses on pending patents

It has become increasingly apparent that governments should retain power to issue compulsory licenses on unpublished, published, and pending patent applications, including those submitted under the Patent Cooperation Treaty or pursuant to a regional patent procedure, as well as on granted patents. The European Commission has proposed to do so in its recent proposal to establish a regional compulsory license mechanisms during emergencies.[19] Some important medicines, including SARS-CoV-2 vaccines, monoclonal antibodies, and antivirals and curative hepatitis C direct acting antivirals, have received regulatory approval and entered the market before patent applications have been granted, and in some instances even before they were published. Governments have the right under TRIPS to grant guaranteed generic access to medicines and other products covered by pending patents – they should have no less right with respect to access to pending patents than to granted ones.

| Recommendation |
|---|
| **Article XXXX**<br>A provisional compulsory license can be granted on a pending product or process patent application when it is in the public interest to do so. This includes both published and unpublished patent applications including those filed pursuant to the Patent Cooperation Treaty or any relevant regional patent system. A provisional license applicant need not satisfy any additional requirements until the patent is granted. If and when a patent is granted, the provisional licensee shall be required to apply for a compulsory license, but shall have leave to continue to exploit the patent until such license is granted upon payment of adequate remuneration to the patent holder pursuant to Royalty Guidelines hereafter established. |

### 1.3 Compulsory licenses for import

Countries' patent laws should explicitly clarify that compulsory licenses can be issued to foreign licensees as needed.

| Recommendation |
|---|
| **Article XXXXX**<br>In the event it is not possible for a pharmaceutical product patented domestically for treatment of endemic disease to be produced in Indonesia, the Minister may issue a compulsory License for the import of that pharmaceutical product; however, the Minister may also grant compulsory licenses for importation where it is advantageous to do so. |

### 1.4 Local working requirement and failure of local working as grounds for compulsory licenses

The Paris Convention in Article 5A(2) authorizes countries of the Union to provide for compulsory licenses in case of failure by the patentee to work the patent locally (e.g. to produce locally, rather than merely import). Likewise, although this proposition is not without some

[19] Olga Gargula, *On the European Commission's proposal to create a new EU-wide compulsory licensing regime* (2023) https://papers.ssrn.com/sol3/papers.cfm?abstract_id=4552851.

controversy,[20] local working requirements are fully permissible under TRIPS and not just with respect to the issuance of compulsory licenses.[21] To ensure certainty, the definition of local working should also be clarified. There is UN agency support for such provisions. UNCTAD wisely recommended the retention of Indonesia's local working requirement:

> ***UNCTAD Recommendation 18:*** *The local working requirement in the Patent Law can likely be maintained on the grounds that the TRIPS negotiators have left this issue ambiguous. Where the Patent Law does not already specify a time limit, such as in the case of the right to prevent imports of products that are made using patented processes, consideration should be given to introducing a time element whereby a patent holder would be given a sufficient amount of time to begin working the underlying patent or expose him/herself to the loss of rights. While there is no reason why different time periods in which a patent holder needs to work his or her patent could be adopted before s/he risks a compulsory license or a right to import a product that is made using a process-patent, such time periods should generally be uniform across patent categories.*

This Review agrees that the local working requirement is lawful and that countries should retain the right to issue compulsory licenses on the grounds that the patent is not work locally even though it is economically feasible to do so, but that a reasonable time period must be established. This Review also concludes that there should be an opportunity for the right holder to prove that local production within the specified time period is not economically feasible. However, this Review also believes that a general failure to work the patent, even by import, need not be satisfied only via license to local company. There may well be circumstances where local capacity is absent or insufficient or where the government can arrange a license to a foreign entity that allows for some domestic inputs, including packaging and labeling.

| **Recommendations** |
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| **Article XXXXXX**<br>The Patent Holder shall manufacture the product or use the process that issued a Patent within the country unless it has had insufficient time or it is commercially unreasonable to do so, in which event the Patent Holder shall still seek partial manufacturing with local inputs when it is economically and technologically feasible to do so.<br><br>**Article XXXXXXX**<br>The Compulsory License as referred to in Article XXXXXX may only be granted by the Minister if the Minister is of the opinion that the said Patent may be implemented, in whole or in part, in Indonesia in a feasible economic scale and give benefits to society; |

### 1.5 Broaden and clarify government use licenses

Countries should enact broad grounds for government-use licenses beyond defense, security, and urgent need. Article 31(b) of the TRIPS Agreement clearly allows for government-use or

[20] Those who argue against the legality of local working requirements often point to Article 27.1 of the TRIPS Agreement which prohibits discrimination against imports in the granting patents available or enjoyment of patent rights.

[21] Michael Halewood, *Regulating Patent Holders: Local Working Requirement and Compulsory Licenses at International Law*, 35 OSGOODE HALL L.J. 243-287 (1997); Bryan Mercuriio & Mitali Tyagi, *Treaty Interpretation in WTO Dispute Settlement: The Outstanding Question of the Legality of Local Working Requirements*, 19 MINN. J. INT'L L. 275-326 (2010); Chia-Ling Lee, *The Legality of Local Patent Working Requirements under the TRIPS Agreement*, 2 N.T.U.T. J. INTELL. PROP. L. & MGMT. 39-48 (2013); Paul Champ and Amir Attaran, *Patent Rights and Local Working Under the WTO TRIPS Agreement: An Analysis of the Brazil Patent Dispute*, 27 YALE J. INT'L L. 365-293 (2002).

"public non-commercial use" licenses, requiring only notice[22] and remuneration[23] - there are no restrictions on allowable grounds. The United States has the simplest and easiest to use government use provision in the world. Pursuant to 28 U.S.C. section 1498(a), any U.S. official or government contractor receiving the authorization or consent of the government[24] can make use and manufacture the invention of a patent subject only to the patent holders right to seek reasonable and entire compensation for the same. There are no special grounds required except use by or for the Federal government. Government use of section 1498 has been quite extensive, with the primarily user being the U.S. Department of Defense, but affected products include "medicines, Blackberry smartphone services, software used by the Federal Reserve Bank to curb fraud, technology used by NASA to explore space and weapons of all types."[25] More recently, the U.S. broadly used its section 1498 authority in procurement contracts for covid-related medical products. In addition, it is permissible to issue government-use licenses for importation.

One special advantage of government use CLs (and likewise for emergency use CLs) is that there is no duty to negotiate with patent holders, which has the added advantage of allowing CLs on products and their patented components in a single CL application rather than having to identify all relevant pending and granted patents in advance of the CL application. Although there may be a subsequent duty to identify relevant patents or to acknowledge the legitimate patent claims of product and product component rightsholders, the government will fulfill its CL-related duties primarily by paying ad hoc adequate remuneration.

| **Recommendation** |
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| **Article Y**<br>(1) The Government may work a Patent on its own behalf in the public interest, including on the following premises:<br>a. pertains to the defence and security of the State; or<br>b. represents an extremely urgent need in the public interest.<br>(2) The implementation of a Patent by the Government as referred to in paragraph (1) shall be on a limited basis, primarily to meet domestic demand, and [be] noncommercial in nature.<br><br>**Article YY**<br>(1) If the Government intends to authorize public, non-commercial use of a Patent, the Government shall promptly notify the Patent Holder of this matter in writing, if and when the Government knows of the Patent without being required to make a patent search; however in no event is the Government or its authorized contractor required to engage in any prior negotiations with the Patent Holder.<br><br>**Article YYY**<br>(1) The implementation of a Patent by the Government as referred to in Article 104 paragraph (1) shall be conducted by giving adequate remuneration to the Patent Holder, pursuant to remuneration guidelines established by a Government Regulation.<br><br>**Article YYYY** |

[22] "[W]here the government or contractor, without making a patent search, knows or has demonstrable grounds to know that a valid patent is or will be used by or for the government, the right holder shall be informed promptly."

[23] TRIPS, Article 31(h).

[24] "For the purposes of this section, the use or manufacture of an invention described in and covered by a patent of the United States by a contractor, a subcontractor, or any person, firm, or corporation for the Government and with the authorization or consent of the Government, shall be construed as use or manufacture for the United States."

[25] *Written Statement of James Love*, Knowledge Ecology International, at the United States International Trade Commission Investigation into Trade, Investment and Industrial Policies in India, Investigation No. 332-543, p. 15 (4 Feb. 2014), available at http://keionline.org/sites/default/files/KEI_USITC_IVN_332-543_14Feb2014.pdf.

(1) In case the Government cannot implement a Patent by itself, the Government may appoint another party to implement the said Patent, including by importation.

### 1.6 Fully incorporate Article 31*bis* and an Article 30 exception to Article 31(f)

A fundamental flaw in the Article 31(f) of the TRIPS Agreement is that it limits exportation of goods produced pursuant to a compulsory license to non-predominate quantities. This provision creates a serious disadvantage for countries that have insufficient capacity to manufacturer medicines locally or where it is inefficient to do so, and who must therefore rely on imports. In such instances, governments could issue an "ordinary" compulsory license to a foreign company, but, if there were also an applicable patent in the country of production/export, then a compulsory license would have to be issued in that country as well. The Article 31(f) paradox is that the licensed exporting company might not be able to export sufficient quantities to fulfill foreign needs because of the "predominately for domestic use" rule.

The drafters of the Doha Declaration recognized this dilemma and instructed the WTO to devise an expeditious decision in paragraph 6 of the Declaration. Unfortunately, the decision-making was not expeditious, but finally on 30 August 2003 the WTO General Council issued a decision declaring a waiver from Article 31(f), the so-called 30 August 2003 Decision.[26] In addition to being delayed, the 30 August 2003 Decision imposed considerable procedural requirements on both importing and exporting countries issuing compulsory licenses and further restricts the quantity of pharmaceutical products that might be exported. The Decision has been called "labyrinth"[27] and as being "neither expeditious, nor a solution."[28] As evidence of its impracticality, the Decision has only been used once by a Canada company, Apotex, to export antiretrovirals to one country, Rwanda, and then only after a multi-year delay.[29] The August 30 Decision has been subsequently adopted as an Article 31*bis* amendment to the TRIPS Agreement.[30]

Despite the flaws inherent in TRIPS Article 31*bis*, countries should adopt its procedures both for the purpose of exportation if there is domestical manufacturing capacity, and for importation if there isn't. Just because a country has significant domestic pharmaceutical

[26] Decision of the General Council of 30 August 2003, Implementation of Paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health, WT/L/540 and Corr.1, available at http://www.wto.org/english/tratop_e/trips_e/implem_para6_e.htm. The "temporary waiver" of the Decision was made into a permanent proposed amendment to TRIPS in December 2005, under a new Article 31bis, available at http://www.wto.org/english/tratop_e/trips_e/wtl641_e.htm. The amendment will become part of TRIPS only upon ratification by at least two-thirds of the WTO members. May 2014, less than half of all WTO members had ratified the amendment. See Members accepting amendments of the TRIPS Agreement, available at http://www.wto.org/english/tratop_e/trips_e/amendment_e.htm.

[27] Brook K. Baker, *Arthritic Flexibilities for Accessing Medicines, Analysis of WTO Action Regarding Paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health*, 14 IND. INT'L & COMP. L. REV. 613-715 (2004); Frederick M. Abbott & Jerome H. Reichman, *The Doha Round's Public Health Legacy: Strategies for the Production and Diffusion of Patented Medicines under the Amended TRIPS Provision,* 10 J. INT'L ECON. L. 921-987 (2007); Frederick M. Abbott, *The WTO Medicines Decision: World Pharmaceutical Trade and the Protection of Public Health*, 99 AM. J. INT'L L 317 (2005).

[28] Medecins Sans Frontieres *Canada, "Neither Expeditious, Nor a Solution: the WTO August 30 Decision is Unworkable"*, (2006) at p. 2.

[29] For a discussion of the timeline for the Apotex license and a summary of debate at the WTO on the effectiveness of the 30 August 2003 Decision, see ICTSD, Canada Medicines Bill Under Threat, 15:10 BRIDGES (23 March 2011), available at http://www.ictsd.org/bridges-news/bridges/news/canadian-access-to-medicines-bill-under-threat.

[30] https://www.wto.org/english/res_e/publications_e/ai17_e/trips_art31_bis_oth.pdf.

capacity in some areas, that does not mean that it has sufficient capacity – in terms of technology know-how and market size – with respect to each and every medicine it might need in the future – particularly biologic medicines and vaccines.

There have been several proposals to simplify domestic implementation of the 30 August 2003 Decision/Article 31*bis*, including a so-called one-license solution that was proposed in Canada but allowed to lapse in Parliament.[31] Countries can and should adopt all lawful flexibilities to make use of Article 31*bis* as simple and expeditious as possible. Not only could it adopt the one-license solution, but it could provide for strict time limits on the obligation to engage in negotiations for a voluntary license on commercially reasonable terms, it could waive prior negotiations in response to compulsory licenses issued on the grounds of emergency or for public, non-commercial use, and it could, like Canada, adopt remuneration guidelines with tiered royalties,[32] or it could adopt fixed percentage royalties as discussed further in section 1.10, *infra*. In addition, like India, countries could make granting of humanitarian licenses for export mandatory.

However, countries also have additional freedom under Article 30 of the TRIPS Agreement to adopt an even more expeditious system – essentially a limited exception to allow the importation of or exportation of unlimited quantities of pharmaceutical products when needed to address an insufficiency of efficient pharmaceutical manufacturing capacity for the medicine in question in the importing country.[33] Although several other countries, including Canada, China, India, the Netherlands, the European Commission, Korea, and Switzerland have adopted laws implementing Article 31*bis*,[34] only Uganda seems to have adopted both Article 31*bis* and an Article 30 limited exception system.

| **Recommendations** |
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| **Article Z**<br>(1) In the event it is not possible for a pharmaceutical product patented in Indonesia to be produced in Indonesia, the Minister may issue a compulsory License for the import of that pharmaceutical product.<br>(2) In the event that any country requires a pharmaceutical product patented in Indonesia for treatment of an endemic disease and it is ~~possible~~ economically feasible for the pharmaceutical product to be produced in Indonesia, the Minister ~~may~~ shall issue a compulsory License at the request of that country for production of the patented pharmaceutical product for export to the country requesting it, if the importing country or countries have insufficient capacity to manufacture the pharmaceutical product domestically. |

[31] Richard Elliott, *Fixing Canada's Access to Medicines Regime – Bill C-398*, IP-WATCH (18 Nov. 2012), available at http://www.ip-watch.org/2012/11/18/fixing-canadas-access-to-medicines-regime-bill-c-398/; Bill C-398 available at http://www.parl.gc.ca/HousePublications/Publication.aspx?Language=E&Mode=1&DocId=5391829&File=4.

[32] *See* Canadian Access to Medicine Regime CAMR), sections 21.01 to 21.19 of the Patent Act. "Under CAMR, the remuneration, or royalty fee, to be paid by the license holder to the patent holder is calculated according to a formula which multiplies the monetary value of the supply contract by an amount that fluctuates on the basis of the importing country's rank on the UN Human Development Index. Under this formula, the lowest country on the index would pay a royalty of approximately 0.02 percent, and the highest 3.5 percent. Where a patent holder is of the view that the royalty resulting from the application of the formula is inadequate, it may apply to the Federal Court for an order setting a higher amount. In considering the merits of such an application, the Court must take into account the economic value of the use of the licensed product by the importing country and the humanitarian and non-commercial reasons underlying the issuance of the license." REPORT ON THE STATUTORY REVIEW OF SECTION 21.01 TO 21.19 OF THE PATENT ACT (2007), available at http://www.camr-rcam.gc.ca/doc/camr_rcam_report_rapport-eng.php#fnb74-ref.

[33] Baker, *supra* note 27.

[34] *See*, *Members' laws implementing the 'Paragraph 6' system*, World Trade Organization, available at http://www.wto.org/english/tratop_e/trips_e/par6laws_e.htm.

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| (3) As an alternative to the mechanism described in paragraphs (1) and (2), Indonesia hereby adopts procedures in accordance with the WTO 30 August 2003 Decision or Article 31*bis* of the TRIPS Agreement, if adopted and as amended, and the Annex thereto.<br>(4) The procedures and requirements of the WTO 30 August 2003 Decision shall be further specified by a Government Regulation. |
| **Recommended Regulatory Approach** |
| Pursuant to authority granted in Article Z, implementing regulations concerning the 30 August 2003 Decision mechanism should be carefully drawn with respect to required conditions, notifications and procedures set forth in the Decision. It is important to adopt the single-license approach and thus to allow licensees "to export to one or more eligible importing countries" as defined in the 30 August 2003 Decision, which includes least developed countries automatically and other countries that have provided required notifications to the WTO. There should be no limits on the pharmaceutical products that can be exported and pharmaceutical products should be defined expansively: "pharmaceutical product" means any patented product or product manufactured through a patented process, of the pharmaceutical sector needed to address public health problems, especially those resulting from HIV/AIDS, tuberculosis, malaria and other epidemics, and includes active ingredients necessary for its manufacture and diagnostic kits needed for its use." If the license is being issued to satisfy a public, non-commercial use in the importing country, there shall be no obligation for the prospective licensee to have engaged in prior negotiations with the Patent Holder. Finally, the time period for prior negotiations should be reduced to one month (30 days) or less. |

### 1.7 Authorize competition-based licenses

The Article 31(k) of the TRIPS Agreement specifically authorizes the issuance of competition-based compulsory licenses and waives requirements of prior negotiation and limitations on exports with respect to such licenses.[35] The East Africa Community has specifically recommended that its Partner States adopt compulsory license remedies for abuse of patent right[36] and the UNDP has done so as well in its analysis of the intersection between IP and competition policy.[37] Because competition-based licenses have several other advantages – the possibility of lower royalties and an obligation to protect the acquired interests of the licensee, such licenses have advantages for domestic licensees, most especially with respect to access to external markets. Such licenses should be easy to obtain and should not require recourse to specialized investigations and adjudications at the Commission for the Supervision of Business Competition, if clear standards are provided as to what might constitute an anti-competitive practice. As a basic principle, there should be clear and easy-to-use procedures.[38]

The UNCTAD IP Review specifically recommended that competition-based licenses be allowed in Indonesia's amendment of its Patents Act:

> ***UNCTAD Recommendation 16:*** *Provided that the DGIPR can secure a revision of Article 50 of the Competition Law, a subparagraph (4) should be introduced in Article 75 of the Patent Law that tracks the language of Article 31(k) of the TRIPS Agreement. A subparagraph should be introduced in Article 99 along similar lines, which would allow the possibility of issuing a government-use license upon a finding of anti-competitive behaviour.*[39]

This Review agrees with that recommendation, which is already reflected in recommendations

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[35] *See* TRIPS, Article 31(k), (b) and (f).

[36] East Africa Community, EAC REGIONAL INTELLECTUAL PROPERTY POLICY ON THE UTILISATION OF PUBLIC HEALTH-RELATED WTO-TRIPS FLEXIBILITIES AND THE APPROXIMATION OF NATIONAL INTELLECTUAL PROPERTY LEGISLATION (2013), Policy Statement No. 11(b), at 21.

[37] UNDP, USING COMPETITION LAW TO PROMOTE ACCESS TO HEALTH TECHNOLOGIES: A GUIDEBOOK FOR LOW- AND MIDDLE-INCOME COUNTRIES (2014).

[38] Baker, *supra* note 15.

[39] UNCTAD, DEVELOPMENT DIMENSIONS OF INTELLECTUAL PROPERTY IN INDONESIA: ACCESS TO MEDICINES, TRANSFER OF TECHNOLOGY AND COMPETITION (2011) [UNCTAD IP IN INDONESIA].

contained in subsection 1.1, *supra*, but recommends specifically that other government entities issuing compulsory licenses, be authorized to find anti-competitive activity. Procedures for making anti-competitive findings should be set forth in implementing regulations and could reference anti-competitive practices and licensing terms discussed further in section 1.12, *infra*.

| **Recommended Regulatory Approach** |
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| Pursuant to authority granted by Article 92 of the Draft Amended Patents Act, standards for determining anti-competitive behavior, including but not limited to anti-competitive licensing terms should be specified. |

### 1.8 Authorize judicial licenses

Rightsholders often seek provisional measures (temporary injunctions or interdicts) even before the alleged infringing party has had an opportunity to be heard in court. These provisional measures not only allow orders against continuing (alleged) infringement, they also allow seizures and detainment of suspected infringing goods. Moreover, at least in some jurisdictions, they cannot be appealed because they are considered interlocutory. Broad forms of provisional relief pose a significant disincentive for generic producers, including local producers, to enter the market. Even where the generic producer believes the putative patent right to be weak or that its conduct is not infringing, the patent holder has an immediate upper-hand that stops the business in its tracks, even after it has invested considerable resources to enter the market.[40] If and when the case proceeds to trial, patent holders typically seek the entry of a permanent injunction against infringement, which completely halts the infringing competition no matter what its social value.

Article 50.1[41] and Article 44.1[42] of the TRIPS Agreement require Member Countries to provide provisional measures and permanent injunctions to prevent infringement, including the entry of infringing, imported products into the market. Although these provisions require that provisional measures and injunctions should be *available* in at least some circumstances, these circumstances can be *strictly limited* by equitable principles, including the interest of the public in access to medicines. Thus, in the absence of exceptional grounds for provisional or injunction relief, remuneration in the form of on-going royalties can be ordered instead of an injunction. The legality of such a limitation on injunctive and provisional relief under TRIPS is clarified by Article 44.2 of the TRIPS Agreement, which allows for the judicial award of compensation as an alternative to injunctive relief:

> Notwithstanding the other provisions of this Part and provided that the provisions of Part II specifically addressing use by governments, or by third parties authorized by a government, without the authorization of the right holder are complied with, Members may limit the remedies available against such use to payment of remuneration in accordance with subparagraph (h) of Article 31. In other cases, the remedies under this Part shall apply *or, where these remedies are inconsistent with a Member's law, declaratory*

[40] *See*, UNDP, supra note 17, at 74.

[41] "The judicial authorities shall have the authority to order prompt and effective provisional measures:
(a) to prevent an infringement of any intellectual property right from occurring, and in particular to prevent the entry into the channels of commerce in their jurisdiction of goods, including imported goods immediately after customs clearance;
(b) to preserve relevant evidence in regard to the alleged infringement."

[42] "The judicial authorities shall have the authority to order a party to desist from an infringement, *inter alia* to prevent the entry into the channels of commerce in their jurisdiction of imported goods that involve the infringement of an intellectual property right, immediately after customs clearance of such goods. Members are not obliged to accord such authority in respect of protected subject matter acquired or ordered by a person prior to knowing or having reasonable grounds to know that dealing in such subject matter would entail the infringement of an intellectual property right."

*judgments and adequate compensation shall be available* (emphasis added).

There is now strong precedent for the granting of judicial, royalty-bearing licenses both in the United States and in India. In the United States, the leading case, *eBay Inc. v. MercExchange, L.L.C.*,[43] the U.S. Supreme Court upturned decades of practice whereby parties claiming patent infringements were routinely granted temporary and permanent injunctions. *eBay* reversed that consistent granting of injunctions and ruled that courts should award injunctions only after evaluating traditional equitable principles, in the U.S. the standard four-factor balancing test. Since the *eBay* decision it has now become almost routine that U.S. courts order ongoing royalty-arrangements in lieu of issuing permanent injunctions, especially, but not only, when the patent holder is a non-practicing entity.[44] Similarly, in India, courts have become willing to deny injunctions and instead grant royalty-bearing licenses in infringement cases, especially where public health interests are at stake.[45] In *Roche v. Cipla* the court weighted harm to third parties and noted that court cannot "be unmindful of the right of the general public to access lifesaving drugs which are available and for which such access would be denied if the injunction were granted."[46]

Based on these precedents, countries can enact provisions to ensure that temporary court injunctions and permanent injunctions issued pursuant to their Patents Acts are not mandatory and that instead courts have specific discretion to award compensatory damages in the form of on-going royalties that provide adequate remuneration, especially with respect to medicines required to meet public health needs.

| **Recommendations** |
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| **Article ZZ**<br>Upon a request from the party that might have suffered due to the implementation of a Patent, a court may issue an interim decision to:<br>a. prevent the entry of goods suspected to infringe the Patent and/or rights pertaining to the Patent;<br>b. seize and prevent the loss of evidence by the infringing party; and/or<br>c. halt infringement to prevent greater losses, but<br>d. such temporary injunction shall not be issued when there is another satisfactory remedy in the form of adequate on-going remuneration in the form of a percentage royalty payment;<br>e. the discretion of the court to order a percentage royalty payments shall be particularly appropriate with respect to pharmaceutical product required to meet a public health need;<br>f. the amount of adequate remuneration in the form of an ongoing percentage royalty payment shall be guided by the Remuneration Guideline. |

## 1.9 Allow compulsory licenses on know-how

Because patent applicants do not always disclose sufficient information to allow efficient production, even by persons skilled in the art, in some case compulsory licenses on patents alone might be insufficient to achieve the desired purpose of allowing competing production

[43] 547 U.S. 388 (2006).

[44] *See*, Jaideep Venkatesan, *Compulsory Licensing of Nonpracticing Patentees after eBay v. MercExchange*, 14 VA. J. LAW & TECH. 26-47 (2009).

[45] *See Hoffman La Roche v. Cipla & Anr*, IA No. 642/2008 in CS (OS) No.89/2008. The refusal to grant a preliminary injunction was vindicated by an eventual trial on the merits in 2012 where it was found that Cipla had not in fact violated the patent at issue. Elsewhere, the Supreme Court of Appeal in South Africa has recently ruled that the impact on a temporary injunction on the public interest should be weighed before entering such an order, but on the merits of the case rejected awarding a royalty and instead awarded the temporary order. *Cipla Medpro v. Aventis Pharma*; *Aventis Pharma SA v. Cipla Life Sciences* [2012] ZASCA 108 (26 July 2012).

[46] Ibid at para 85.

and sale of patented goods, especially vaccines, biologics, and other complex medicines. In some instances, it might actually be necessary to gain access to a right holder's "know how," even though such know how might be subject to trade secret protection.[47] One approach would be to create an trade secret exception with respect information submitted to medicines regulatory authorities allowing them to disclose relevant manufacturing information/know-how to potential generic producers in the public interest of expanded, expedited, and/or more affordable supply.[48] In addition, it would be desirable to adopt patent law that clarifies that if access to know how is needed to fully effectuate the purpose of a compulsory or government-use license then a compulsory license on such know-how shall be issued on reasonable terms and conditions.[49] One of the terms could be separate compensation to the right holder beyond the royalty due on the patent right alone. Secondly, however, in order to protect the know-how owner's interest in preventing further dissemination of its trade secrets, there could be a confidentiality term prohibiting the know-how licensee disclosing the know-how to third parties without the consent of the right holder.

| **Recommendations** |
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| **Article A**<br>In addition to the compulsory license permissible under paragraph (1), an additional involuntary license may be issued on otherwise confidential manufacturing know-how when it is not commercially practicable to implement the patent pursuant to a paragraph (1) license based on the patent disclosures alone, on the following terms and conditions:<br>a. In order to obtain such a license on know-how, the prospective licensee must have first asked the know-how owner for a license thereto on commercially reasonable terms for a period of not less than three months and have been unsuccessful in obtaining such a voluntary license;<br>b. A license on know-how shall be conditioned on the payment of adequate remuneration, taking into account the economic value of the use, pursuant to Remuneration Guidelines promulgated by the Secretary, said remuneration being in addition to any remuneration paid with respect to any patent related compulsory license;<br>c. Said license on know-how shall be non-exclusive and non-assignable;<br>d. The know-how disclosed shall be considered confidential and the licensee shall be required to enter into a written agreement not to disclose the information to third parties and that if such disclosure is made the license is terminable and the licensee may be sued for damages. |
| **Recommended Regulatory Approach** |
| This provision should have implementing regulations addressing the circumstances for establishing when the patent disclosures are insufficient to allow commercially practical implementation of the patent. The proposed Remuneration Guidelines should address compensation for know-how, which might ordinarily be a lump-sum payment. The regulations should also address the form and substance of the required confidentiality term. |

### 1.10 Adequate remuneration – promulgate and reference Royalty Guidelines

Article 31(f) of the TRIPS Agreement requires adequate remuneration to the right holder based on the economic value of the license in the country that issues it. James Love has described multiple models for determining adequate remuneration.[50] For example, legislation in Canada

[47] Max Planck Institute, DECLARATION ON PATENT PROTECTION, *supra* note 1, at 11.

[48] K. M. Gopakumar, Chetali Rao & Sangeeta Shashikant, TRADE SECRETS PROTECTION AND VACCINES: THE ROLE OF MEDICINE REGULATORY AGENCIES, Third World Network (2021) https://twn.my/title2/briefing_papers/twn/Trade%20secrets%20TWNBP%20Jun%202020%20Gopakumar%20et%20al.pdf.

[49] David Levine & Joshua Sarnoff, *Compelling Trade Secret Sharing*, 74 HASTINGS L.J. 987 (2023), https://hastingslawjournal.org/wp-content/uploads/1-Levine-final.pdf; Olga Gurgula & John Hull, *Compulsory Licensing of Trade Secrets: Ensuring Access to COVID-19 Vaccines Via Involuntary Technology Transfer*, 16 J. INTELL. PROP.L. & PRACT. 1242 (2021).

[50] *See* James Love, REMUNERATION GUIDELINES FOR NON-VOLUNTARY USE OF A PATENT ON MEDICAL TECHNOLOGIES, 67-77 (2005) for a comprehensive review of proposed remuneration guidelines.

provides tiered royalty rates set at 4 percent of the generic price and adjusts the rate downwards according to the importing country's rank on the UNDP Human Development Index. Similarly, the East Africa Community has recommended that Partner States shall "include in their patent laws a provision statement stating that the remuneration shall not exceed the UNDP recommended figure of 4%, and take anti-competitive behaviour into account when determining the amount of remuneration." There is additional precedent for remuneration guidelines in the Philippines.[51]

Article 78 of the Indonesian Patent Law stipulates that the "implementation of a Compulsory License shall be accompanied by the payment of royalties by the compulsory licensee to the Patent Holder." Article 101(2) provides that the "exploitation of a Patent by the Government shall be carried out with the provision of reasonable compensation to the Patent Holder." It would be desirable if both provisions were amended to use the TRIPS-compliant term "adequate remuneration, taking into account the economic value of the authorization." At present, the DGIPR sets the royalty rate in the case of a compulsory license (Article 78(2)), whereas the remuneration rate for government-use licenses can be set elsewhere. The royalty rate can be challenged at the Commercial Court if the patent owner feels that the offered compensation is insufficient (Article 102). As previously mentioned, on the three occasions previously when Indonesia has issued compulsory licenses, it set royalties at .5% of net sales.

This Review recommends the promulgation of clear Remuneration Guidelines, with a cap of no more than 4% of wholesale cost, which would greatly simplify the process of issuing compulsory and government-use licenses. Although royalties of .5% might be considered sufficient and is supported by similar royalty amounts ordered in Thailand in 2006-2007, this Review recommends that the presumptive rate be set higher to offer a more reasonable level of compensation to the patent holder. For example, Zanzibar has adopted a 4% ceiling in Article 14(1)(b) of its Industrial Property Act. The Patent Act and proposed Remuneration Guidelines should also address that remuneration rates can be adjusted downward for compulsory licenses issued to remedy anti-competitive behavior and that royalties on exports to countries with insufficient manufacturing capacity should be based on the economic value of the authorization in the country of importation and use.

| **Recommendations** |
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| **Article B**<br>(1) A compulsory Licensee must pay adequate remuneration to the Patent Holder, taking into account the economic value of the authorization.<br>(2) The amount of remuneration to be paid and method of payment shall be determined by the Minister.<br>(3) The Minister in determining the amount of remuneration and method of payment as referred to in (1) and (2) shall consider the economic value of the authorization and pursuant to Remuneration Guidelines he or she promulgates, in no event greater than 4% of the net selling price, and methods of payment customarily used in Licensing agreements.<br>(4) If the authorization is issued to remedy anti-competitive conduct, the Remuneration Guidelines shall stipulate that the percentage payment can be reduced accordingly including to zero.<br>(5) If the authorization is issued to export to countries with insufficient pharmaceutical manufacturing capacity pursuant to Article 86, the economic value shall be based on the value in the country or importation and use, but if there are no patent rights on the imported pharmaceutical product in the country of importation and use, then the percentage payment should be zero.<br><br>**Article BB** |

[51] Section 35-B(3), the Philippine Republic Act no. 165 of 1947, as amended by Presidential Decree 1263 in 1977.

| (2) The implementation of a Patent by the Government shall be conducted by giving adequate remuneration to the Patent Holder pursuant to the Remuneration Guidelines described in Article B. |
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| **Recommended Regulatory Approach** |
| The proposed Royalty Guidelines should be published, and any level of discretion that applies should be described along with factors that affect the exercise of that discretion. It is clear that it is preferable to set a presumptive royalty rate and to limit upward or downward adjustment to limited special circumstances. |

### 1.11 Further clarify and streamline compulsory licensing procedures and option for presumptive compulsory licenses

As discussed previously, compulsory-licensing procedures should be expeditious and easy-to-use. Some of the procedures concerning compulsory and government-use licenses have been discussed above, including timelines for prior negotiations for voluntary licenses and remuneration guidelines. Although 90 days might ordinarily be a reasonable period of time to conduct negotiations, there are certainly circumstances where such licenses should be issued on an even more expedited basis. Both the compulsory license application and the patent holder is given the right to be heard. The burden of proof or any presumptions in such hearings should at least be that the compulsory license will be granted unless the patent holder carries the burden of production and persuasion that it is not justified. Some countries may wish to go further and state that there is a presumption that compulsory licenses will be granted. [A later section, 1.13 discusses the option of going even further to authorize mandatory compulsory licenses.]

Expedited administrative procedures, rather than judicial procedures, which cost substantially more, should be used. Moreover, independent administrative review by a distinct higher authority is permissible in lieu of judicial review with respect to the legal validity of a license and the amount of remuneration.[52] (At present, Indonesia does not appear to allow even judicial review of the legal validity of a compulsory or government-use license as required by TRIPS Article 31(i).) Once a license decision has been made, even though the patent holder might have a right of appeal to a higher administrative body, there should be no possibility of obtaining a stay or provisional order to prevent the operationalization of the license.

| **Recommendations** |
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| **Article C**<br>(1) Examination of an application for compulsory License shall be conducted by the Minister.<br>(2) In conducting examination as referred to in paragraph (1), the Minister shall summon the Patent Holder and the applicant(s) to hear their evidence and opinions.<br>(3) The Patent Holder may put forward evidence and opinions in accordance with the stipulated period, and the Patent Holder holds the burden of disproving that the compulsory license should not be granted. [**Alternate (3)** The Patent Holder may put forward evidence and opinions in accordance with the stipulated period, but there is a presumption that the patent should be granted.]<br>(4) If the Patent Holder does not put forward his or her opinions within two months of notice of the application, the Patent Holder is presumed to consent to issuance of the compulsory License.<br><br>**Article CC**<br>…<br>(1) The decision by the Minister on the granting of a compulsory License may be contested to the Patent Appeal Commission or such other distinct higher authority designated by the Minister for hearing such appeals against a only in regard to material pertaining to the legality of the license and the amount of remuneration and method of payment.<br>(2) The process to contest to the Patent Appeal Commission or such other distinct higher authority designated by the Minister for hearing such appeals as referred to in paragraph (~~2~~1) shall not halt the implementation of the compulsory License. |

[52] Article 31(i) & (j) of the TRIPS Agreement.

**Article 112**

(1) In case the Patent Holder does not agree ~~to~~ with the legality of the government use or the amount of the reward given by the Government may file a complaint to the-Patent Appeal Commission or such other distinct higher authority designated by the government for hearing such appeals.

(2) The complaint as referred to in paragraph (1) may be filed within a period no later than 90 (ninety) days from the date on which the copy of the Presidential Regulation was sent.

(3) In case the Patent Holder does not file a complaint as referred to in paragraph (1), the Patent Holder shall be deemed to have received the amount of the Reward.

(4) The process of examination of the complaint as referred to in paragraph (1) shall not stop the implementation of the Patent by the Government.

**Recommended Regulatory Approach**

Implementing regulations should further specify requirement for applications for compulsory licenses and the forms of evidence and presumptions in hearings on applications for compulsory licenses. The regulations should seek to ensure speedy and easy to use procedures.

## 1.12 Authorize licenses of right

Patent holders sometimes wish to make their invention readily available to third parties without requiring the formality of negotiations of voluntary licenses. In such circumstances, there should be easy-to-use mechanisms for the patent holder to register a license of right to the public notice of the relevant patent(s).

**Recommendations**

**Article D**

(1) In addition, at any time after the date of the sealing of a patent, the patentee may apply to the Secretary for the patent to be endorsed with the words "licenses of right" and where such an application is made, the Secretary shall, if satisfied that no agreement exists to the contrary, cause the patent to be endorsed accordingly.

(2) Where a patent has been endorsed under (1), any person shall at any time thereafter be entitled as of right to a license under the patent upon such conditions as may be specified in the application for licenses of right, so long as such terms are not prohibited, and in default of such specification by the patentee, be decided by the Secretary on the application of the person requiring the license.

**Recommended Regulatory Approach**

Further requirements with respect to licenses of right should be specified by regulation.

## 1.13 Mandatory compulsory licenses

Countries may wish to allow mandatory compulsory licenses. This approach has precedents with respect to Article 31bis licenses and may be further justified at least with respect to government use and emergency compulsory licenses, but perhaps more broadly.

### A. Mandatory compulsory license for patents whose term was extended by GATT implementation

In 1995, as mandated by the Uruguay Round Agreements Act, patent terms in the United States were changed from 17 years from the date the patent was granted to 20 years from the date the patent application was filed. This extended patent terms for many products, including pharmaceuticals. In 1995-96, Senate Bill 1277 (104th Congress)[53] proposed a statutory mandatory compulsory license for products brought to market prior to patent expiration, provided that a generic manufacturer had previously made "substantial investment" toward

[53] S. 1277 (104th): Pharmaceutical Industry Special Equity Act of 1996, https://www.govtrack.us/congress/bills/104/s1277/text.

bringing a product to market in anticipation of the pre-1995 patent expiration. The mandatory compulsory license would have applied to over 100 brand name pharmaceutical products, but it was never enacted.

B. The Regulation (EC) No 816/2006 of the European Parliament and of the Council of 17 May 2006 on Compulsory Licensing of Patents Relating to the Manufacture of Pharmaceutical Products for Export to Countries with Public Health Problems.[54]

This regulation set out requirements and conditions for implementing the WHO's 30 August 2003 decision on the export of medicines to countries that lack sufficient manufacturing capacity. The compulsory licenses are mandatory: "Member States *shall* grant a compulsory license to any person making an application in accordance with Article 6 and subject to the conditions set out in Articles 6 to 10 (emphasis added)."[55]

Article 12 of Directive 98/44/EC of the European Parliament and of the Council of 6 July 1998 on the Legal Protection Of Biotechnological Inventions requires mandatory cross licenses to patent holders who must grant a compulsory license to a secondary patent holder who cannot exploit the patent without such a license.[56] This is in accordance with TRIPS Article 31(l)(ii).

C. INDIA, Art. 31*bis* licenses for export

In February 2005, India amended its patent law, to provide for patent protection for pharmaceutical inventions. The legislation created a mandatory compulsory license for products that were already manufactured and marketed in India under Section 11 A:

> "(7) On and from the date of publication of the application for patent and until the date of grant of a patent in respect of such application, the applicant shall have the like privileges and rights as if a patent for the invention had been granted on the date of publication of the application:
>
> Provided that the applicant shall not be entitled to institute any proceedings for infringement until the patent has been granted:
>
> Provided further that the rights of a patentee in respect of applications made under sub-section (2) of section 5 before the 1st day of January, 2005 shall accrue from the date of grant of the patent:
>
> Provided also that after a patent is granted in respect of applications made under subsection (2) of section 5, *the patent-holder shall only be entitled to receive reasonable royalty from such enterprises which have made significant investment and were producing and marketing the concerned product prior to the 1st day of January, 2005 and which continue to manufacture the product covered by the patent on the date of grant of the patent and no infringement proceedings shall be instituted against such enterprises*." [Emphasis added].[57]

India had previously amended its Patents Law in 2002 to add a mandatory compulsory license for export for countries that lack capacity to manufacture medicines domestically:

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[54] https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32006R0816&from=EN.
[55] *Id*. Article 1.
[56] https://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CELEX:31998L0044:EN:HTML#d1e740-13-1.
[57] https://www.wipo.int/edocs/lexdocs/laws/en/in/in065en.pdf.

92A. Compulsory license for export of patented pharmaceutical products in certain exceptional circumstances.—

(1) Compulsory license *shall be available* for manufacture and export of patented pharmaceutical products to any country having insufficient or no manufacturing capacity in the pharmaceutical sector for the concerned product to address public health problems, provided compulsory license has been granted by such country or such country has, by notification or otherwise, allowed importation of the patented pharmaceutical products from India. [Emphasis added]

(2) The Controller *shall, on receipt of an application in the prescribed manner, grant a compulsory license* solely for manufacture and export of the concerned pharmaceutical
product to such country under such terms and conditions as may be specified and published by him. [Emphasis added]

(3) The provisions of sub-section (1) and (2) shall be without prejudice to the extent to which pharmaceutical products produced under a compulsory license can be exported under any other provision of this Act.

Explanation.—For the purposes of this section, 'pharmaceutical products' means any patented product, or product manufactured through a patented process, of the pharmaceutical sector needed to address public health problems and shall be inclusive of ingredients necessary for their manufacture and diagnostic kits required for their use.[58]

| **Recommendation** |
|---|
| **Article F**<br>Compulsory licenses shall be granted in the case of production for export pursuant to licenses authorized by Art. 31bis of the TRIPS Agreement, government use licenses, and emergency or matters of extreme urgency licenses. |

## 2. Proposed checklist for analyzing country adoption of TRIPS-compliant compulsory licensing provisions

| **1. Broad grounds for issuing compulsory and government use licenses** | |
|---|---|
| a. the patented invention is not worked or not fully worked domestically by the Patent Holder;<br>(i) it does not meet the reasonable requirements of the public with respect;<br>(ii) it is not available to the public at a reasonably affordable price;<br>(iii) it has not been worked locally other than by importation and the patent holder fails to demonstrate that it is not economically or technologically feasible to manufacture in whole or in part domestically;<br>b. the Patent is worked by the Patent Holder or Licensee in a form and by means harmful or abusive to the public interest;<br>c. the Patent is an enhancement of a previously issued Patent, and as such cannot be worked without working the Patent of another party that remains under protection~~.~~;<br>d. there is an emergency or other urgent matter of national interest~~.~~;<br>e. the patent holder has refused to grant a license on reasonable terms within a reasonable period of time of no more than three months, despite a request to do so, for the purpose of access to an essential facility, including to be able to produce and market rational fixed-dose combination medicines, or to be able to commercialize a promising dependent technology;<br>f. there is a risk of supply interruptions of essential products such as medicines;<br>g. there is a need to promote local production and technology transfer; | |

[58] Ibid.

| | |
|---|---|
| h. there is any other public interest or public health need;<br>i. the patent holder has been found to have engaged in an anti-competitive practice | |
| **2. CLs available on granted, pending, and filed patent applications (national, 3. PCT, relevant regional body)** | |
| **4. CLs available for importation** | |
| **5. CLs available for absence or insufficiency of local working 1(a) above.** | |
| **6. CLs for emergencies and urgent matters,**<br>a. no negotiations required<br>b. can be granted for all patents relating to a product | |
| **7. CLs on broad grounds available for government use (non-commercial public use)**<br>a. no negotiations required<br>b. can be granted for all patents relating to a product | |
| **8. CLs for anti-competitive actions**<br>a. Refusals to license, excessive pricing, and other grounds<br>b. no negotiations required<br>c. reduction of royalties<br>d. Unlimited quantities for export | |
| **9. Non-predominant quantities can be exported** | |
| **10. Article 31bis licenses**<br>a. for import<br>b. for export | |
| **11. Article 30 exception to export restrictions in Article 31(f)** | |
| **12. Allowance for judicial CLs** | |
| **13. Short timeline within which to conduct negotiations, where required, on commercially reasonable terms** | |
| **14. Remuneration guidelines adopts** | |
| **15. Easy-to-use administrative procedures and non-judicial review procedures** | |
| **16. Burden of persuasion**<br>a. Burden to disprove need for CL rests on the patent holder<br>b. Presumption that CL will be granted<br>c. Option for mandatory CLs | |
| **17. Provide for CLs of right** | |
| **18. Provide for access to trade secrets/confidential information**<br>a. Exceptions to trade secret/confidential information protections essential to manufacture of equivalent products, especially if compulsory licenses on relevant patents are granted<br>b. CLs on trade secrets/confidential information<br>c. Allow disclosure of manufacturing know-how and other relevant confidential information from medicines regulatory authorities to authorized manufacturers, including compulsory licensees | |

## Appendix C. Reference Documents and Python Code for Webscraping

| Country | Full Text Name | English Translation (if needed) |
|---|---|---|
| Algeria | Ordonnance n. 03-07 du 19 Joumada El Oula 1424 correspondant au 19 juillet 2003 relative aux brevets d'invention | Order No. 03-07 of 19 Daily Journal 1424 corresponding to July 19, 2003 relating to patents |
| Argentina | Ley de Patentes de Invención y Modelos de Utilidad, Decreto 260/96, Apruébase el texto ordenado de ley Ley No. 24.481, modificada por su similar No. 24.572 (T.O. 1996) y su Reglamentación | Patent and Utility Model Law, Decree 260/96, Approves the ordered text of Law No. 24,481, modified by its similar No. 24,572 (T.O. 1996) and its Regulations |
| Argentina | Patent Regulation of Sections of Law No. 24.481 as amended by Law No. 24.572 of 1995 | |
| China | Order of the President of the People's Republic of China No. 8, The Decision of the Standing Committee of the National People's Congress on Amending the Patent Law of the People's Republic of China, adopted at the 6th Meeting of the Standing Committee of the Eleventh National People's Congress on December 27, 2008, is hereby promulgated and shall go into effect as of October 1, 2009. | |
| China | Implementing Regulations of the Patent Law of the People's Republic of China | |
| China | Order of the Director of the State Intellectual Property Office No. 64, The Measures for Compulsory Licensing of Patent Implementation has passed the review of the directorate meeting, which are hereby promulgated and will come into force on as of May 1, 2012. | |
| China | Order of the President of the People's Republic of China No. 55, Decision of the Standing Committee of the National People's Congress on Amending the Patent Law of the People's Republic of China adopted at the 22th Meeting of the Standing Committee of the Thirteenth National | |

| | | |
|---|---|---|
| | People's Congress on October 17, 2020, is hereby promulgated and shall go into effect on June 1, 2021. | |
| Colombia | Diario Oficial No. 47172 de 2008, Ministerial de Comercia, Industria y Turismo Decreto 4302 (Nov. 13 2008) | Official Journal No. 47172 of 2008, Ministry of Trade, Industry and Tourism, Decree 4302 |
| Colombia | Decreto 410 de 1971, Por el cual se expide el Código de Comercio el Presidente de ley República de Colombia | Decree 410 of 1971, By which the President of Colombia issues the Commercial Code |
| Colombia | Subregional Integration Agreement (Cartagena Agreement), Decision 486 - Common Provisions on Industrial Property of September 14, 2000 | |
| Ecuador | Función Ejecutiva Decreto No. 118, Declárase de interés público el acceso a las medicinas utilizadas para el tratamiento de enfermedades que afectan a la población ecuatoriana y que sean prioritarias para la salud pública, para lo cual se podrá conceder licencias obligatorias sobre las patentes de los medicamentos de uso humano que sean necesarios para sus tratamientos. | Executive Function Decree No. 118, Access to medicines used for the treatment of diseases that affect the Ecuadorian population and that are a priority for public health is declared to be in the public interest, for which compulsory licenses may be granted on the patents of medicines for human use that are necessary for their treatment. |
| Ecuador | Resolución No. 10-04 P-IEPI, Instructivo para la concesión de licencias obligatorias sobre patentes de fármacos | Resolution No. 10-04 P-IEPI, Instructions for the granting of compulsory licenses on drug patents |
| Ecuador | Código Orgánico de la Economía Social de los Conocimientos, Creatividad e Innovación (Registro Oficial No. 899 Suplemento) | Organic Code of the Social Economy of Knowledge, Creativity and Innovation (Official Registry No. 899 Supplement) |
| Ecuador | Secretaria Nacional de Educación Superior, Ciencia, Tecnología e Innovación SENESCYT Acuerdo No. SENESCYT-2020-077, EXPÍDESE EL REGLAMENTO DE GESTIÓN DE LOS CONOCIMIENTOS | National Secretariat of Higher Education, Science, Technology and Innovation SENESCYT Agreement No. SENESCYT-2020-077, THE REGULATIONS OF KNOWLEDGE MANAGEMENT ARE ISSUED |

| | | |
|---|---|---|
| Jordan | Patent Regulations Official Gazette No. 4522 dated 13.12.2000 We Abd Allah the Second Ibn El Hussien, King of the Hashemite, Kingdom of Jordan Pursuant to Article 31 of the Constitution and what was Decided by the Council of Ministers on November 6, 2001 Order that the following regulation be **applied: Regulation number 97 for the year 2001- Patentof invention regulations issued pursuant to Article 38 of the patent law number 32 for the year.** | |
| Jordan | Patents of Invention Law, Law No. 32 for the Year 1999 (and its amendment by: Temporary Law No. 71 for the Year 2001) | |
| Jordan | Barqawi, Laila (2023). Promoting Jordan's use of compulsory licensing during the pandemic, South Centre Research Paper No. 184 | |
| Malaysia | Patent Regulations 1986 | |
| Malaysia | Laws of Malaysia Act 291 Patent Acts 1983 (incorporating all amendments up to 16 August 2006) | |
| Mexico | Reglamento de la Ley de la Propiedad Industrial, Nuevo Reglamento publicado en el Diario Oficial de la Federación el 23 de noviembre de 1994, TEXTO VIGENTE, Última reforma publicada DOF 16-12-2016 | Regulation of the Industrial Property Law, New Regulation published in the Official Gazette of the Federation on November 23, 1994, CURRENT TEXT, Last reform published DOF 16-12-2016 |
| Mexico | Secretaria de Economia: DECRETO por el que se reforman, adicionan y derogan diversas disposiciones del Reglamento de la Ley de la Propiedad Industrial. | Economy Secretariat: DECREE amending, adding to and repealing various provisions of the Industrial Property Law Regulations. |
| Mexico | Ley Federal de Proteccion de la Propiedad Industrial, TEXTO VIGENTE a partir del 05-11-2020, Nueva Ley publicada en el Diario Oficial de la Federación el 1 de julio de 2020 | Federal Law on the Protection of Industrial Property, TEXT IN FORCE as of 11-05-2020, New Law published in the Official Gazette of the Federation on July 1, 2020 |
| Panama | Ley No. 61 de 2012, QUE REFORMA LA LEY 35 DE 1996, POR LA CUAL SE DICTAN DISPOSICIONES SOBRE LAPROPIEDAD INDUSTRIAL | Law No. 61 of 2012, Which Reforms the Law 35 of 1996, whereby provisions are dictated on Industrial Property |

| | | |
|---|---|---|
| Peru | Ley que modifica, incorpora y regula diversas disposiciones a fin de implementar el Acuerdo de Promoción Comercial suscrito entre el Perú y los Estados Unidos de América, LEY Nº 29316 | Law that modifies, incorporates and regulates various provisions in order to implement the Trade Promotion Agreement signed between Peru and the United States of America, LAW No. 29316 |
| Peru | Subregional Integration Agreement (Cartagena Agreement), Decision 486 - Common Provisions on Industrial Property of September 14, 2000 | |
| Philippines | Regulations on Interpartes Proceedings (Petitions for Cancellations of a Mark Patent, Utility Model, Industry Design, Opposition to Registration of a Mark & Compulsory Licensing) | |
| Philippines | Republic Act No. 9502, An Act Providing for Cheaper and Quality Medicines, Amending for the Purpose Republic Act No. 8293 or the Intellectual Property Code, Republic Act No. 6675 or the Generics Act of 1988, and Republic Act No. 5921 or the Pharmacy Law and for other Purposes. | |
| Philippines | JOINT DOH-DTI-IPO-BFAD ADMINISTRATIVE ORDER NO. 2008-01, THE IMPLEMENTING RULES AND REGULATIONS OF REPUBLIC ACT 9502 OTHERWISE KNOWN AS THE "UNIVERSALLY ACCESSIBLE CHEAPER AND QUALITY MEDICINES ACT OF 2008" | |
| Philippines | Republic Act No. 8293 AN ACT PRESCRIBING THE INTELLECTUAL PROPERTY CODE AND ESTABLISHING THE INTELLECTUAL PROPERTY OFFICE, PROVIDING FOR ITS POWERS AND FUNCTIONS, AND FOR OTHER PURPOSES | |
| Romania | Regulations on the Implementation of The Patent Law No. 64/1991 as republished, Official Gazette of Romania, Part I, No. 456/18.VI.2008 | |
| Romania | Patent Law No. 64/1991, Official Gazette of Romania, Part I, No. 613/19 August 2014 (Republication) | |

| | | |
|---|---|---|
| Thailand | Patent Act B.E. 2522 (1979) As Amended by the Patent Act (No. 2) B.E. 2535 (1992) and the Patent Act (No. 3) B.E. 2542 (1999) | |
| Thailand | Ministerial Regulations No. 26 (B.E. 2542) Issued under the Patent Act B.E. 2522 | |
| Turkey | Law No. 6769 of December 22, 2016 on Industrial Property, Industrial Property Code | |
| Ukraine | Law of Ukraine On Protection of Rights to Inventions and Utility Models (WTO doc IP/N/1/UKR/1) | |
| Ukraine | Cabinet Minsters of Ukraine Resolution No. 877 of 4 December 2013, Kyiv, On Approval of the Procedural for Granting Permission by the Cabinet of Ministers of Ukraine to Use the Patented Invention (Utility Model) Concerning Medicines | |

**Python Code for Webscraping Documents from wipolex.com**

```
from urllib.request import urlopen

from urllib.request import urlretrieve

import re


# https://realpython.com/python-web-scraping-practical-introduction/


# Base URL and the rest of the search URL

url_base = "https://www.wipo.int"

url_search =
"/wipolex/en/legislation/results?countryOrgs=DZ&subjectMatter=12&subjectMatter=21&subjectMa
tter=19&subjectMatter=1&subjectMatter=17&subjectMatter=9&typeOfText=207&typeOfText=210&t
ypeOfText=205&last=true"


# Load the source of the search page and get the URLs of all the linked results

page = urlopen(url_base + url_search)

html_bytes = page.read()

html = html_bytes.decode("utf-8")

urls = re.findall("<a href=\"(/wipolex/en/legislation/details/[0-9]*)\">", html)


pdf_str = "https://wipolex-resources-eu-central-1-[0-9]*.s3.amazonaws.com/edocs/lexdocs/laws/[a-
z]*/[a-z]*/.*.pdf"



# Loop through each linked page, find the pdf file location(s), and download them

for u in urls:

        page_sub = urlopen(url_base + u)

        html_sub_bytes = page_sub.read()

        html_sub = html_sub_bytes.decode("utf-8")


        pdf_url = re.findall("<a href=\"(/wipolex/en/text/[0-9]*)\">PDF</a>",html_sub)

        for pu in pdf_url:
```

```
            page_pdf = urlopen(url_base + pu)
            html_pdf_sub_bytes = page_pdf.read()
            html_pdf_sub = html_pdf_sub_bytes.decode("utf-8")

# https://realpython.com/python-download-file-from-url/
            pdf_url = re.findall("src=\"("+ pdf_str + ")\"",html_pdf_sub)
            filename = re.findall("[a-zA-Z0-9_-]*.pdf",pdf_url[0])
            urlretrieve(pdf_url[0],filename[0])
            print("Saved " + filename[0] + " from " + pdf_url[0])
```

## Appendix D. Mini Narratives for Study Countries

### Algeria

Algeria's patent law includes a fairly limited set of grounds on which the government may issue a compulsory or government use license. Specifically, it has a very narrow set of possible grounds for anti-competitive remedy licenses, and emergency licenses, the latter which is limited to circumstances that threaten "national security". It does, however, include a fairly broad set of grounds that fall under the "public interest" category, including public health, economic development and excessive pricing. For public interest and national security grounds, it allows for both government use and private use of the patented product or process.

The presence of procedural flexibilities allowed by the TRIPS Agreement are likewise quite minimal. One area that stands out, however, is the lack of prior negotiation requirements for some licenses. For national security, anti-competitive remedy and public interest grounds (including both government and non-government use), prior negotiation is not required. This is particularly important since this arguably exceeds the flexibilities allowed under the TRIPS Agreement – under which public interest licenses would still maintain a prior negotiation requirement. The law also states that "if the beneficiary of the license is industrially exploiting the patented invention or has made serious preparations" to do so, then that will provide a justification for not withdrawing the license even if the original circumstances that gave rise to the license cease to exist. Substantively, the main provision that stands out is that licenses can be issued on filed as well as granted patents in the context of public interest and anti-competitive remedy licenses.

Beyond these, Algeria's compulsory license law is quite minimal. Algeria has not adopted key procedural provisions that would make it easier to grant a compulsory license, such as placing the burden of proof on the patent holder to disprove the need for a license, a presumption that the license will be granted (in absence of clear evidence to the contrary) or even mandatory compulsory licenses in certain cases. Algeria also has no guidelines for either remuneration or commercially reasonable terms which would simplify prior negotiations and eventual remuneration agreements with patent holders. Moreover, Algeria has no clear provisions that would facilitate the granting of export-based licenses or particularly allow import of licensed products (such as pharmaceuticals). Overall, Algeria has many avenues for legislative reform that could expand the grounds on which compulsory licenses can be granted, as well as procedural hurdles that petitioners need to overcome and the various possible uses for those licenses (including import and export).

### Argentina

Argentina's patent law includes a fairly limited set of grounds on which the government may issue a compulsory or government use license. Although it does allow these licenses in the context of non-use or suspension of use of a patent, and dependent patents, as well as a detailed list of anti-competitive remedy grounds, it does not have any provision for compulsory licenses issued in the public interest. Nevertheless, it does include a broad ground for health emergencies and national security that incorporates additional flexibilities. Government use licenses seem to be mostly limited to the same categories (health emergency and national security) and for some general non-commercial use.

For licenses in the case of non-exploitation, suspension of exploitation or secondary patents ("general exploitation licenses"), petitioners must show that they have made an effort of prior negotiation, but the time for that negotiation is limited to 150 days. Additionally, the decision of whether to grant a CL is supposed to be taken within 90 days (though appealable before the Federal Civil Commercial court). No prior negotiation is required in the context of anti-competitive remedy, emergency or government use licenses, and in at least the emergency and government use licenses, there is a presumption that the licenses will be granted. Finally, challenges to the grant of a CL cannot result in injunctive relief against the license holder – and even after the CL circumstances have discontinued, withdrawal of the license is not automatic, but must take into consideration the "legitimate interests of the license holder".

Argentina's law includes a few additional flexibilities governing the use of the licensed product or process. For non-commercial public use, for example, there is also an implied flexibility to grant licenses over multiple patents at once, so long as the government or contractor "without conducting a patent search" does not know or have a demonstrable reason that they should know, that such patents are being used). Moreover, and this is a unique provision found in national laws, the authorization granted under a compulsory license of *any* sort "may extend to patents related to components and processes of manufacturing that allow the exploitation of the product". As for import and export licenses, the baseline standards apply – that import is generally considered a legitimate way to exploit the patent, and that export of non-predominant quantities is permitted. In addition to this, export may exceed those non-predominant quantities in the case of anti-competitive remedy and health emergency licenses.

Although there are several important provisions in the Argentine law, the procedures lack several of the characteristics that would make it easier to grant compulsory licenses. In the first place, it does not have a fully fleshed out procedure for issuing government use or non-commercial use licenses. Since the guidance is vague or unclear, that will be harder for the various ministries involved to carry out procedure. Second, it continues to put the bulk of the burden of proof on the petitioner for the license – there is no mandatory license, no presumption in favor of the petitioner and no way to avoid going to court if the patent holder does not like the result. Finally, no legal provision allows access to trade secrets or confidential information by way of compulsory licenses. This would be a significant bottleneck in the context of a situation like COVID, where the patent itself did not provide enough information on its own to create generic versions of COVID-vaccines. Overall, Argentina includes a high number of TRIPS flexibilities in terms of the process for granting and the use of those licenses, at least relative to the other countries in the study. However, it lacks the sufficient breadth in including public interest and other emergency grounds for issuing them.

**China**

China's patent law includes a fairly limited set of grounds on which the government may issue a compulsory or government use license. While the Chinese law does include a diversity of grounds for general exploitation licenses (including non-use, insufficient use, suspension of use and dependent patents), it contains very limited grounds for issuing anti-competitive remedy, public interest, emergency and government use licenses. For the purposes of access to medicines, however, China has managed to include public health as a relevant ground for issuing public interest licenses.

China's law includes almost no procedural flexibilities that would be permitted under the TRIPS Agreement. The one exception to this is that, for anti-competitive remedy, emergency and public interest licenses, there is no requirement that the petitioner first attempt to negotiate a voluntary license. This is particularly important since this arguably exceeds the flexibilities allowed under the TRIPS Agreement – under which public interest licenses would still maintain a prior negotiation requirement. When it comes to the license use for import and export, the baseline standards apply – that import is generally considered a legitimate way to exploit the patent, and that export of non-predominant quantities are permitted. In addition to this, export may exceed those non-predominant quantities in the case of anti-competitive remedy and public health licenses.

China's compulsory licenses law has plenty of room to expand its adoption of TRIPS flexibilities. In the first place, China could expand the grounds on which emergency and government use licenses. It could provide limited timelines for prior negotiations and guidelines for commercially reasonable terms as well as remuneration. All of these would make requesting the CL much easier and clearer for the petitioner. The Chinese law also continues to put the bulk of the burden of proof on the petitioner for the license – there is no mandatory license, no presumption in favor of the petitioner and no way to avoid going to court if the patent holder does not like the result. Moreover, CL holders do not have adequate protection for their interests by shielding them from injunctions requested by patent holders and providing them a right of continued use (even if the circumstances that gave rise to the CL no longer exist) to protect their legitimate interests. Finally, China could introduce substantive flexibilities that allow licenses to be granted on filed as well as granted patents and on all patents related to a final product, especially for government use and emergency licenses.

**Colombia**

Colombia's patent law includes a fairly broad set of grounds on which the government may issue a compulsory or government use license. In fact, Colombia's law represents the broadest set of public interest and general exploitation license grounds of the whole study sample. In addition to the usual non-use and insufficient use grounds, Colombia allows petitioners to request a CL in circumstances of suspension of use of the patent for at least one year, the patented product or process not being used locally, where exploitation has not satisfied the national market demand in reasonable quantity, quality or price, or that the patent holder has refused to license on reasonable terms. Public interest licenses can be issued when (1) the patents are of interest for public health, (2) when they are necessary for economic development (3) when the product has not been put on the market in quantities and qualities sufficient for normal consumption or (4) when prices are excessive.

The TRIPS flexibilities that Colombia has adopted are (1) no prior negotiation for anti-competitive remedy, emergency use, government use and public interest licenses, (2) several options for mandatory compulsory licenses – in which the patent is made "subject to license" and thus any petitioners who request the license (and show that they can exploit it or are a public entity) will be granted that license. There are also protections for CL holders – such that (3) challenges do not result in injunctive relief and (4) they may continue to use the patent even when the original circumstances that gave rise to the CL have ceased, subject to their legitimate expectations. By contrast with this expansiveness, Colombia includes very few flexibilities that related to the use of the patent. For import and export, only the baseline standards apply – that

import is generally considered a legitimate way to exploit the patent, and that export of non-predominant quantities is permitted. Even further, Colombia does not allow import at all for CL holders of general exploitation licenses – they must manufacture the product within Colombia's territory.

Colombia has various ways it can expand its adoption of TRIPS flexibilities. For general exploitation licenses, for example, it could introduce limited timelines for prior negotiations and guidelines for what constitutes commercially reasonable terms in those negotiations. It could also introduce guidelines for remuneration and limit review of these decisions to administrative bodies (rather than judicial ones). More importantly, Colombia should introduce provisions that allow export beyond non-predominant quantities for medicines and for products under anti-competitive remedy licenses, as well as specifying import as an option for general exploitation CLs and especially for medicines.

**Ecuador**

Ecuador, like Colombia, has a fairly broad set of grounds on which the government may issue a compulsory or government use license. Ecuador's law represents the broadest set of government use license grounds and is among the most expansive in including both general exploitation and public interest license grounds. Government use licenses may be granted for almost any reason, including emergencies, public interest, public health concerns and national security as well as general non-commercial use. The law also allows for general exploitation licenses in the context of non-use, under-use, suspension of use, failure to manufacture locally, and failure to satisfy national market demand. The public interest grounds are a short list, but substantially broad and focused on public health ("public interest" and "public health").

When it comes to adopting the procedural and use-based TRIPS Flexibilities, Ecuador is among the most ambitious countries in the study. It allows for no prior negotiation for anti-competitive remedy, emergency use, government use and public interest licenses. Once more, this is particularly important since this arguably exceeds the flexibilities allowed under the TRIPS Agreement – under which public interest licenses would still maintain a prior negotiation requirement. Ecuador also limits the timeline for prior negotiations in general exploitation licenses to 4 months. This timeline is shortened in the case of pharmaceutical products to 45 days. Moreover, the burden of proof remains with the patent holder in the case of general exploitation licenses and all other licenses are granted on an almost mandatory basis. That is to say, the patent is made "subject to license" and thus any petitioners who request the license (and show that they can exploit it or are a public entity) will be granted that license. Finally, CL holders are protected from injunctive relief in the case where a patent holder challenges the license.

Ecuador also embodies the maximum amount of flexibility around export of the licensed product, allowing export beyond non-predominant quantities under anti-competitive remedy as well as pharmaceutical products. Even more importantly, it allows exportation of pharmaceutical products as long as it conforms to the rules in Article 31bis ("The Decision of the WTO of 30 August 2003, or the rule that replaces it", art. 319.3).

Despite its ambitious compulsory licensing law, Ecuador could still expand its adoption of TRIPS flexibilities. In addition to limiting the timeline for prior negotiations, the law could also provide guidelines for what constitutes commercially reasonable terms during those

negotiations. It could also limit the review mechanism to an administrative procedure so that CL petitioners are not held up in the courts for extended periods of time. In terms of the use under the license, Ecuador could allow licenses to be granted for all patents related to a final produce and for filed/pending as well as granted patents. Finally, it could include a provision that allows for the specific import of pharmaceutical products under these licenses in accordance with TRIPS Article 31*bis*.

**Jordan**

In general, Jordan's law is quite skeletal and has quite a few options for expanding the law to improve the effectiveness and useability of compulsory licenses. Jordan has a relatively broad set of grounds on which the government can issue emergency and government use licenses, while maintaining quite narrow policy space for other types of compulsory licenses, and no option for a public interest license. For emergencies and government use, the language is relatively broad ("emergency or matters of extreme urgency", "national security", and "public non-commercial use") but also includes explicitly granting of CLs for export the context of pandemics or epidemic diseases.

Procedurally, given the limitations of Jordan's short set of provisions on this, there are very few TRIPS flexibilities built into the law. Jordan does allow compulsory and government use licenses to be granted without prior negotiation with the patent holder in the usual contexts – emergency, government use, and anti-competitive remedies. The also does make a reference to the preservation of the rights of a CL holder in the case where the license might otherwise be terminated (as when the circumstances which gave rise to it have ceased). The law also includes the basic provisions allowing for export of non-predominant quantities and import as a generally acceptable way to exercise the license. As noted above it also has a brief mention of export licenses ("in compliance with the Kingdom's obligations with the World Trade Organization agreements") and allows additional export for anti-competitive remedy licenses.

Beyond these, however, Jordan has plenty of room to revise its law in accordance with those WTO commitments. It could introduce a general public interest license option and include any grounds that it deems in the interest of the country, such as economic development, environmental protection, innovation, and much more. It could also introduce a provision allowing for compulsory licenses on dependent patents, as have most other study countries. Other provisions that could be added include:

- Limited timelines and guidelines for commercially reasonable terms in prior negotiations
- Remuneration guidelines for granted compulsory and government use licenses.
- Provisions that place the burden of proof squarely on the shoulders of the patent holder or create a presumption in favor of the CL petitioner.
- Options for mandatory licenses (where the government subjects certain patents to license and any petitioner with capacity to exploit can be granted such a license.
- Protection of CL holders from injunctive relief in the context where the granted CL is being challenged by the patent holder.

- Review mechanism that is limited to administrative procedures (rather than being stuck in court)
- Allowing CLs to be granted on all patents related to a final product and to filed/pending as well as granted patents.
- Specifically including provisions for import of pharmaceuticals (alongside the existing export provision) under TRIPS Article 31*bis*.

**Malaysia**

Malaysia's patent law includes a fairly broad set of grounds on which the government may issue a compulsory or government use license. In addition to the usual non-use, insufficient use grounds and dependent patent context, Malaysia allows petitioners to request a CL in circumstances of excessive pricing and failure to work the patent locally. Public interest licenses can be issued when (1) in the general public interest, (2) the patents are of interest for public health, and (3) when they are necessary for economic development. Emergency licenses may be granted generally for emergencies, as well as national security and for the purposes of nutrition. Government use licenses are permitted in general for all the same grounds as public interest and emergency licenses – including public health, economic development and nutrition. Malaysia also includes the basic anti-competitive remedy license.

In terms of other flexibilities, however, Malaysia's law does not seem to be overly ambitious. It does allow for no prior negotiation for anti-competitive remedy, emergency use, government use and public interest licenses. Once more, this is particularly important since this arguably exceeds the flexibilities allowed under the TRIPS Agreement – under which public interest licenses would still maintain a prior negotiation requirement. It also places the burden of proof to disprove the need for a CL on the patent holder in most cases and provides for administrative review only of these decisions. Finally, it makes any license revocation subject to the legitimate interests of the licensee, even if the original circumstances for the license have disappeared. In terms of use of the patent under the license, Malaysia does not go beyond the usual allowance for export of non-predominant quantities and import as an implied right of use under a license.

In order to adopt a more ambitious compulsory and government use licensing law, Malaysia has a lot of room to expand their procedural and use provisions. New provisions could include:

- Limited timelines and guidelines for commercially reasonable terms in prior negotiations
- Remuneration guidelines for granted compulsory and government use licenses.
- Options for mandatory licenses (where the government subjects certain patents to license and any petitioner with capacity to exploit can be granted such a license.
- Protection of CL holders from injunctive relief in the context where the granted CL is being challenged by the patent holder.
- Allowing CLs to be granted on all patents related to a final product and to filed/pending as well as granted patents.

- Specifically allowing for export beyond non-predominant quantities under anti-competitive remedy licenses.
- Specifically including provisions for both export and import of pharmaceuticals (alongside the existing export provision) under TRIPS Article 31*bis*.

**Mexico**

Mexico's patent law includes a very limited set of grounds on which the government may issue a compulsory or government use license. Indeed, it is the most limited in terms of the policy space for granting compulsory and government use licenses of all our study countries. It does not allow for any anti-competitive remedy or public interest licenses, it limits general exploitation licenses to non-use (and even allows the patent holder a whole year upon the petitioner's CL request to begin exploiting), and its government use licenses are limited to the same grounds as the emergency use licenses. The latter limits even the grounds on which a government might otherwise decide that it wants to exercise its right of "public non-commercial use".

Procedurally, Mexico's law does not require prior negotiation for emergency and government use licenses. It also seems to have a mandatory CL option in the case of health emergencies (declared as such by the General Health Council), whether for commercial or government use, and it does seem also to limit review of a granted CL to administrative procedures. Beyond that, no other procedural flexibilities have been adopted. In terms of use of the patent under the license, Mexico does not go beyond the usual allowance for export of non-predominant quantities and import as an implied right of use under a license.

Mexico's law is so limited that there are numerous ways it could revise the law and quickly improve its effectiveness and useability. Mexico could start by adding in nationally strategic public interest licenses for any grounds the government identifies – including environmental, new essential technologies, economic and industrial development and others. It could also include a provision for general "public non-commercial use" by the government so that a government use license may be granted for any purpose considered important at the time. And it definitely could introduce a license that acts as a remedy for anti-competitive behavior. Beyond that, it could introduce the following new provisions to expand use and improve useability.

- Limited timelines and guidelines for commercially reasonable terms in prior negotiations
- Remuneration guidelines for granted compulsory and government use licenses.
- Provisions that place the burden of proof squarely on the shoulders of the patent holder or create a presumption in favor of the CL petitioner.
- More options for mandatory licenses beyond the public health context (where the government subjects certain patents to license and any petitioner with capacity to exploit can be granted such a license).
- Protection of CL holders from injunctive relief in the context where the granted CL is being challenged by the patent holder.

- Conditioning revocation of a license on the legitimate interests of the licensee (even when the original circumstances have ceased.
- Allowing CLs to be granted on all patents related to a final product and to filed/pending as well as granted patents.
- Specifically allowing for export beyond non-predominant quantities under anti-competitive remedy licenses.
- Specifically including provisions for both export and import of pharmaceuticals (alongside the existing export provision) under TRIPS Article 31*bis*.

**Panama**

Panama's patent law includes a very limited set of grounds on which the government may issue a compulsory or government use license. Indeed, it is the second most limited in terms of the policy space for granting compulsory and government use licenses of all our study countries. It does not allow for any general exploitation (for non-use or insufficient use) or public interest licenses, and its government use licenses are largely limited to the same grounds as the emergency use licenses. It does, however, allow for GULs in the general context of "public non-commercial use".

Panama's law is also among the most limited when it comes to adopting the procedural and use-based flexibilities. However, it does not require prior negotiation for anti-competitive remedy, emergency and government use licenses. It also seems to create a kind of presumptive license in the context of public health by including language that states that "nothing shall impede the Republic of Panama from taking measures to protect public health". Moreover, Panama's law makes any license revocation subject to the legitimate interests of the licensee, even if the original circumstances for the license have disappeared. Beyond that, no other procedural flexibilities have been adopted. In terms of use of the patent under the license, Panama does not go beyond the usual allowance for export of non-predominant quantities and import as an implied right of use under a license.

Panama's law is so limited that there are numerous ways it could revise the law and quickly improve its effectiveness and useability. Panama could start by adding in nationally strategic public interest licenses for any grounds the government identifies – including environmental, new essential technologies, economic and industrial development and others. It could also add a general exploitation license, present in all of the other study countries, for non-use and insufficient use of a patented product or process. Beyond that, it could introduce the following new provisions to expand use and improve useability.

- Limited timelines and guidelines for commercially reasonable terms in prior negotiations
- Remuneration guidelines for granted compulsory and government use licenses.
- Options for mandatory licenses such that the government directly subjects a patent to licensing and any petitioner with capacity to exploit can be granted such a license.
- A review mechanism that is limited to administrative procedures (rather than being stuck in court)

- Protection of CL holders from injunctive relief in the context where the granted CL is being challenged by the patent holder.
- Allowing CLs to be granted on all patents related to a final product and to filed/pending as well as granted patents.
- Specifically allowing for export beyond non-predominant quantities under anti-competitive remedy licenses.
- Specifically including provisions for both export and import of pharmaceuticals (alongside the existing export provision) under TRIPS Article 31*bis*.

**Peru**

Peru's compulsory and government use licensing law can best be described as average. It includes many of the most common provisions and has very little specifically aimed at improving access to medicines. It has a mid-range level of flexibility when it comes to the grounds for granting licenses. The law includes provisions for the five broad types of licenses (general exploitation, anti-competitive remedy, public interest, emergency and government use), but the text is limited to only a brief mention of each. In that sense, the broad categories are there, but specific types of grounds which might facilitate the granting of certain licenses on specific grounds (like medicines, ecology, or economic development) are omitted. In fact, there is no specific reference at all to health, public health, medicines, or illnesses.

One area where Peru's law stands out, however, is in its adoption of procedural flexibilities. It allows for no prior negotiation for anti-competitive remedy, emergency use, government use and public interest licenses. Once more, this is particularly important since this arguably exceeds the flexibilities allowed under the TRIPS Agreement – under which public interest licenses would still maintain a prior negotiation requirement. The law places the burden of proof on the patent holder in the case of dependent patent and anti-competitive remedy licenses. It protects CL holders from injunctive relief in the context where the granted CL is being challenged by the patent holder, and it makes any license revocation subject to the legitimate interests of the licensee, even if the original circumstances for the license have disappeared. Flexibilities in the use of the patent under a license are extremely constrained however, and even import seems to be prohibited in most cases, allowing only export of non-predominant quantities.

Given Peru's average level of flexibility, there is plenty of room for Peru to expand the useability and effectiveness of its compulsory and government use licensing law. In the first place, reform of the law could include various specific grounds under each of the general exploitation, public interest, emergency, and government use licenses. Specific grounds could include insufficient use, excessive pricing, environmental protection, access to new essential technologies, economic and industrial development and others. Even in the area of procedural flexibilities, Peru could introduce limited timelines and guidelines for commercially reasonable terms in prior negotiations, as well as remuneration guidelines for granted compulsory and government use licenses. It could likewise limit review of granted CLs to an administrative procedure so that CL holders are not held up in court for long periods. More importantly, Peru's law should be reformed to expand the possible uses available under these licenses, such as:

- Allowing CLs to be granted on all patents related to a final product and to filed/pending as well as granted patents.
- Specifically allowing for export beyond non-predominant quantities under anti-competitive remedy licenses.
- Allowing import as a general rule for all CLs and GULs.
- Specifically including provisions for both export and import of pharmaceuticals (alongside the existing export provision) under TRIPS Article 31*bis*.

**Philippines**

The Philippines' patent law includes a fairly broad set of grounds on which the government may issue a compulsory or government use license, especially for public interest, emergency and government use licenses. Public interest licenses can be issued when (1) in the general public interest, (2) the patents are of interest for health, nutrition or "the development of any other sector" and (3) in the pharmaceutical context, if demand is not adequately met "on reasonable terms". The latter of these specifically refers to affordable access to medicines. Emergency licenses are more limited – to the case of drugs or medicines and government use licenses are permitted in general for all the same grounds as public interest and emergency licenses – including public health, economic development, and nutrition. The Philippines also includes the basic anti-competitive remedy license.

The Philippines also has a rare provision that allows for a CL when the existence of public non-commercial use of a patented drug or medicine by the patent holder ("without satisfactory reason") is established. This suggests that perhaps if the patent holder is making non-commercial use of the patented medicine, then it should be available for others to do the same.

The Philippines have adopted moderately ambitious procedural flexibilities to protect the interests of CL holders. For example, as most of the study countries, it does not require prior negotiation for emergency, government use and anti-competitive remedy licenses. It also protects CL holders from injunctive relief in the context where the granted CL is being challenged by the patent holder (unless issued by the Supreme Court) and makes any license revocation subject to the legitimate interests of the licensee, even if the original circumstances for the license have disappeared. The government may also directly expropriate certain patents in situations of emergency of public interest.

The Philippines has one of the most ambitious laws, however, when it comes to expanding use under compulsory and government use licenses. It implicitly allows government use licenses to be granted on all patents related to a final product (so long as the government has no reason to know that these other patents exist – a no patent search requirement standard). It allows export of non-predominant quantities of licensed products, as well as additional export under anti-competitive remedy licenses and in the case of medicines consistent with TRIPS Article 31*bis*. Moreover, though import is not generally permitted under these licenses, it is specifically allowed when it comes to pharmaceutical products under license.

In order to more completely adopt TRIPS flexibilities, the Philippines could expand its general exploitation license grounds to include insufficient use, suspension of use, excessive pricing and more. It could also adopt a general "emergency or maters of extreme urgency" license,

which it does not currently have. It could also adopt the following to expand effectiveness and useability of these licenses:

- Limited timelines and guidelines for commercially reasonable terms in prior negotiations
- Remuneration guidelines for granted compulsory and government use licenses.
- Provisions that place the burden of proof squarely on the shoulders of the patent holder or create a presumption in favor of the CL petitioner.
- Options for mandatory licenses (where the government subjects certain patents to license and any petitioner with capacity to exploit can be granted such a license.
- A review mechanism that is limited to administrative procedures (rather than being stuck in court)
- Allowing CLs to be granted on filed/pending, as well as granted, patents.
- Allowing import as a general rule for all CLs and GULs.

**Romania**

Romania's patent law includes a very limited set of grounds on which the government may issue a compulsory or government use license. Indeed, it is the third most limited in terms of the policy space for granting compulsory and government use licenses of all our study countries. While its general exploitation and anti-competitive remedy licenses are relatively average in terms of scope, Romania's emergency and government use licenses are extremely limited to "emergencies" "matters of extreme urgency" and "public non-commercial use". Romania also does not grant any public interest licenses.

Procedurally, there are very few TRIPS flexibilities built into the law. Romania does allow compulsory and government use licenses to be granted without prior negotiation with the patent holder in the usual contexts – emergency, government use, and anti-competitive remedies. The law also does make a reference to the preservation of the rights of a CL holder in the case where the license might otherwise be terminated (as when the circumstances which gave rise to it have ceased). Like the Philippines, Romania's law implicitly allows government use licenses to be granted on all patents related to a final product (so long as the government has no reason to know that these other patents exist – a no patent search requirement standard). It allows export of non-predominant quantities of licensed products, as well as additional export under anti-competitive remedy licenses. The law also generally includes import as an acceptable way to exploit the patent under the license.

Due to the narrow grounds for granting licenses and the lack of built-in procedural and use flexibilities, Romania's law has a wide range of possible reforms. Romania could start by adding in nationally strategic public interest licenses for any grounds the government identifies – including environmental, new essential technologies, economic and industrial development and others. It could expand the grounds for general exploitation licenses to include contexts where the patent holder refuses to license the patent at all and where the product is offered only at excessive prices. It could also expand the grounds on which emergency and government use licenses are granted to, at the very least, pharmaceutical products or public health emergencies.

Romania is one of very few countries that has no reference to either health or medicines in its CL law. Other TRIPS flexibilities that could be adopted include:

- Limited timelines and guidelines for commercially reasonable terms in prior negotiations
- Remuneration guidelines for granted compulsory and government use licenses.
- Provisions that place the burden of proof squarely on the shoulders of the patent holder or create a presumption in favor of the CL petitioner.
- Options for mandatory licenses (where the government subjects certain patents to license and any petitioner with capacity to exploit can be granted such a license.
- Protection of CL holders from injunctive relief in the context where the granted CL is being challenged by the patent holder.
- Review mechanism that is limited to administrative procedures (rather than being stuck in court)
- Allowing CLs to be granted on filed/pending, as well as granted, patents.
- Specifically including provisions for import and export of licensed products under TRIPS Article 31*bis*.

**Thailand**

Thailand's patent law includes a fairly broad set of grounds on which the government may issue a compulsory or government use license. In fact, it has the broadest scope for public interest and government use licenses of any of the study countries. Thailand has general exploitation CLs that includes a ground for failure to work the patent locally. Grounds on which a public interest or government use license may be issued include (1) "any service for public consumption, (2) any service which is of vital importance to the defense of the country, (3) any service for the preservation or realization of natural resources or the environment, (4) to prevent or relieve a severe shortage of food, medicines or other consumption items, or (5) for any other public service. This language is as broad as it can be to allow the Thai government to increase domestic access to almost any patented product or process that is in the interests of the public. The only think really lacking in the Thai law is that it does not allow for anti-competitive remedy licenses.

In terms of TRIPS flexibilities that encourage broad and easy execution of CLs, Thailand (like most countries) does not require prior negotiation with patent holders for public interest, emergency, and government use licenses. Once more, this is particularly important since this arguably exceeds the flexibilities allowed under the TRIPS Agreement – under which public interest licenses would still maintain a prior negotiation requirement. For all compulsory and government use licenses, it places the burden of proof on patent holders to disprove the need for a license and allows only administrative review of CLs once they are granted. Moreover, for general exploitation licenses, the law makes a reference to the preservation of the rights of a CL holder in the case where the license might otherwise be terminated (as when the circumstances which gave rise to it have ceased). In stark contrast with the huge breadth of grounds by which the Thai government can issue CLs, the scope for use-based flexibilities is

very narrow – Thailand's law does not go beyond the usual allowance for export of non-predominant quantities and import as an implied right of use under a license.

The main ways for Thailand to reform its compulsory and government use licensing law towards improving access to medicines is in the area of flexibilities related to the granting and use of the patented product under the license. Specifically, it could expand the applicability of the law to all patents related to a final product (multi-patent licenses) issuing granting CLs on filed and pending as well as granted patents. It should also make sure to adopt language that makes explicit the right of Thailand to import medicines under the license and to export to eligible countries according to TRIPS Article 31*bis*. IF it adds an anti-competitive remedy license, it should make sure to allow additional export under that license as well. Procedurally, Thailand could also:

- Limited timelines and guidelines for commercially reasonable terms in prior negotiations
- Remuneration guidelines for granted compulsory and government use licenses.
- Options for mandatory licenses (where the government subjects certain patents to license and any petitioner with capacity to exploit can be granted such a license.
- Protection of CL holders from injunctive relief in the context where the granted CL is being challenged by the patent holder.

**Turkey**

Turkey's patent law includes a very limited set of grounds on which the government may issue a compulsory or government use license. Although it does include the usual non-use and insufficient use grounds for issuing licenses, the scope for emergency and government use licenses are quite narrow. Moreover, government bodies are not specifically identified as potential recipients of emergency or public interest licenses.

The Turkish law is likewise quite limited in terms of ease- and scope-of-use. It allows no prior negotiation with patent holders in the usual contexts (emergency, government use and anti-competitive remedies). It does include one option for a mandatory compulsory license (for circumstances related to the public interest). However, the scope for use-based flexibilities is very narrow – Turkey's law does not go beyond the usual allowance for export of non-predominant quantities and import as an implied right of use under a license.

Given the limitations of the Turkish law there is plenty of room for improvement to create a law that contributes toward improved access to medicines. It could expand the grounds for granting these licenses to situations of excessive pricing, refusal to license and ecological or environmental needs. It could also make explicit the fact that government entities as well as private firms, can be licensees – further expanding the power of the government to use those patented products for the public good. To improve scope- and ease-of-use for the licenses, Turkey could also adopt the following provisions:

- Limited timelines and guidelines for commercially reasonable terms in prior negotiations
- Remuneration guidelines for granted compulsory and government use licenses.

- Additional options for mandatory licenses.
- Protection of CL holders from injunctive relief in the context where the granted CL is being challenged by the patent holder.
- Review mechanism that is limited to administrative procedures (rather than being stuck in court)
- Conditioning revocation of a licenses on the legitimate interests of the licensee (even when the original circumstances have ceased).
- Allowing CLs to be granted on all patents related to a final product and to filed/pending as well as granted patents.
- Specifically allowing for export beyond non-predominant quantities under anti-competitive remedy licenses.
- Specifically including provisions for import of licensed products under TRIPS Article 31*bis*.

**Ukraine**

Ukraine's patent law includes an uneven set of grounds on which the government may issue a compulsory or government use license. While it includes very little in the way of government use licensing and has no provision for anti-competitive remedy licenses, Ukraine's general exploitation license options are better than average (includes both insufficient use and suspension of use as grounds) and both public interest and emergency licenses include a reference to health and epidemics respectively. It should be noted that although there is no reference to government use when it comes to emergencies, national security and epidemics (all part of the emergency use license), the use of a patent during those situations is identified simply as "not an infringement of patent rights". Presumably, then the government, like the private person would be able to engage in patent use under those circumstances.

Ukraine's law has very few of the possible procedural flexibilities allowed by the TRIPS Agreement. It does not require prior negotiation for public interest and, presumably, emergency licenses (since the latter is not considered infringement at all). It also places the burden of proof in a CL petition on the patent holder in general exploitation and public interest licenses. Moreover, unlike most laws in our study countries, Ukraine does include some remuneration guidelines for licenses involving medicines. In the area of use-related flexibilities, Ukraine's law does not go beyond the usual allowance for export of non-predominant quantities and import as an implied right of use under a license. The one exception to this is that there is a special export license option in accordance with TRIPS Article 31*bis*.

To improve the effectiveness and ease-of-use of the country's compulsory and government use licensing provisions, Ukraine could first adopt an anti-competition remedy license and explicitly expand the possible grounds for a government use license. Other provisions that Ukraine could adopt include:

- Limited timelines and guidelines for commercially reasonable terms in prior negotiations

- Remuneration guidelines for granted compulsory and government use licenses beyond those related to medicines.
- Options for mandatory licenses (where the government subjects certain patents to license and any petitioner with capacity to exploit can be granted such a license.
- Protection of CL holders from injunctive relief in the context where the granted CL is being challenged by the patent holder.
- Review mechanism that is limited to administrative procedures (rather than being stuck in court)
- Conditioning revocation of a licenses on the legitimate interests of the licensee (even when the original circumstances have ceased).
- Allowing CLs to be granted on all patents related to a final product and to filed/pending as well as granted patents.
- Specifically allowing for export beyond non-predominant quantities under anti-competitive remedy licenses (assuming that licensing option is adopted)
- Specifically including provisions for import of licensed products under TRIPS Article 31*bis*.

## Appendix E. Full Scoring Tables

### Appendix E. Box 1. Gilead's HCV license excluded the following middle-income countries (Gilead Sciences 2014)

| | | |
|---|---|---|
| Albania | Georgia | Montenegro |
| Algeria | Grenada | Morocco |
| Argentina | Hungary | Panama |
| Armenia | Iran | Paraguay |
| Azerbaijan | Iraq | Peru |
| Belarus | Jamaica | Philippines |
| Belize | Jordan | Romania |
| Bosnia Herzegovina | Kazakhstan | Serbia |
| Brazil | Kosovo | St. Lucia |
| Bulgaria | Lebanon | Syria |
| China | Libya | Thailand |
| Colombia | Macedonia | Tunisia |
| Costa Rica | Malaysia | Turkey |
| Dominican Republic | Marshall Islands | Ukraine |
| Ecuador | Mexico | Venezuela |
| El Salvador | Micronesia | West Bank and Gaza |
| | Moldova | Yemen |

### Appendix E. Table 1. Breadth of grounds of compulsory and government use licenses

| | AL | AR | CH | CO | EC | JO | MA | ME | PA | PE | PH | RO | TH | TU | UK |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| General exploitation license grounds | | | | | | | | | | | | | | | |
| non-use | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 0 | 1 | 1 | 1 | 1 | 1 | 1 |
| insufficient use/not meeting domestic demand | 1 | 0 | 1 | 1 | 1 | 1 | 1 | 0 | 0 | 0 | 0 | 1 | 1 | 1 | 1 |
| suspension of use | 0 | 1 | 1 | 1 | 1 | 0 | 0 | 0 | 0 | 1 | 0 | 0 | 0 | 0 | 1 |
| excessive pricing | 0 | 0 | 0 | 0 | 0 | 0 | 1 | 0 | 0 | 0 | 0 | 0 | 1 | 0 | 0 |
| refusal to license | 0 | 0 | 0 | 1 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| failure to work locally | 0 | 0 | 0 | 1 | 1 | 0 | 1 | 0 | 0 | 0 | 0 | 0 | 1 | 0 | 0 |
| dependent patents | 1 | 1 | 1 | 1 | 1 | 0 | 1 | 0 | 1 | 1 | 1 | 1 | 1 | 1 | 1 |
| ***Percent of possible grounds*** | 42.9 | 42.9 | 57.1 | 85.7 | 71.4 | 28.6 | 71.4 | 14.3 | 14.3 | 42.9 | 28.6 | 42.9 | 71.4 | 42.9 | 57.1 |
| Anti-Competitive remedy grounds | | | | | | | | | | | | | | | |
| anti-competitive practices | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 0 | 1 | 1 | 1 | 1 | 0 | 1 | 0 |

| | | | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| abuse of dominant position of the market | 0 | 0 | 0 | 1 | 1 | 0 | 0 | 0 | 0 | 1 | 0 | 0 | 0 | 0 | 0 |
| patent worked in a manner harmful to public | 0 | 1 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| refusal to license | 0 | 1 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| excessive pricing | 0 | 1 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| ***Percent of possible grounds*** | 20 | 80 | 20 | 40 | 40 | 20 | 20 | 0 | 20 | 40 | 20 | 20 | 0 | 20 | 0 |
| Public interest license grounds | | | | | | | | | | | | | | | |
| General public interest (+3) | 3 | 0 | 3 | 3 | 3 | 0 | 3 | 0 | 0 | 3 | 3 | 0 | 3 | 3 | 3 |
| public health (+3) | 3 | 0 | 3 | 3 | 3 | 0 | 3 | 0 | 0 | 0 | 3 | 0 | 3 | 3 | 3 |
| economic or industrial development | 1 | 0 | 0 | 1 | 0 | 0 | 1 | 0 | 0 | 0 | 1 | 0 | 1 | 1 | 0 |
| product not put on the market in quantities/quality sufficient for normal consumption | 0 | 0 | 0 | 1 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 1 | 0 | 0 |
| excessive pricing | 1 | 0 | 0 | 1 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| ecology or environmental grounds | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 1 | 0 | 1 |
| ***Percent of possible grounds*** | 80 | 0 | 60 | 90 | 60 | 0 | 70 | 0 | 0 | 30 | 70 | 0 | 90 | 70 | 70 |
| Emergency license grounds | | | | | | | | | | | | | | | |
| General emergency, extreme urgency (+3) | 0 | 0 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 0 | 3 | 3 | 1 | 3 |
| national security | 1 | 1 | 0 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 1 | 0 | 1 | 1 | 1 |
| epidemics or serious illnesses (+3) | 0 | 3 | 0 | 0 | 0 | 3 | 0 | 3 | 3 | 0 | 3 | 0 | 0 | 0 | 3 |
| other | 0 | 0 | 0 | 0 | 0 | 0 | 1 | 0 | 0 | 0 | 1 | 0 | 0 | 0 | 1 |
| ***Percent of possible grounds*** | 12.5 | 50 | 37.5 | 50 | 50 | 87.5 | 62.5 | 87.5 | 87.5 | 50 | 62.5 | 37.5 | 50 | 25 | 100 |
| Government use license grounds | | | | | | | | | | | | | | | |
| general emergency, extreme urgency (+3) | 0 | 0 | 0 | 3 | 3 | 3 | 3 | 3 | 0 | 0 | 3 | 3 | 3 | 0 | 0 |
| general public interest (+3) | 3 | 0 | 3 | 3 | 3 | 0 | 3 | 0 | 0 | 0 | 3 | 0 | 3 | 3 | 0 |

| | | | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| general non-commercial use (+3) | 0 | 3 | 0 | 0 | 3 | 3 | 0 | 0 | 3 | 3 | 3 | 3 | 3 | 0 | 3 |
| public health, pharmaceuticals, serious illnesses (+3) | 3 | 3 | 0 | 3 | 3 | 3 | 3 | 3 | 0 | 0 | 3 | 0 | 3 | 3 | 0 |
| national security | 1 | 1 | 0 | 0 | 1 | 1 | 1 | 1 | 0 | 0 | 1 | 0 | 1 | 1 | 0 |
| economic or industrial development | 1 | 0 | 0 | 1 | 0 | 0 | 1 | 0 | 0 | 0 | 1 | 0 | 1 | 1 | 0 |
| ecological or environmental grounds | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 1 | 0 | 0 |
| ***Percent of possible grounds*** | 53.3 | 46.7 | 20 | 66.7 | 86.7 | 66.7 | 73.3 | 46.7 | 20 | 20 | 93.3 | 40 | 100 | 53.3 | 20 |

## Appendix E. Table 2. Procedural flexibility results

| **Type of procedural flexibility** | **Maximum points available** | **Countries** | | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | | **AL** | **AR** | **CH** | **CO** | **EC** | **JO** | **MA** | **ME** | **PA** | **PE** | **PH** | **RO** | **TH** | **TU** | **UK** |
| No prior negotiation with patent holder required | 6 | 6 | 6 | 6 | 6 | 6 | 6 | 6 | 4 | 6 | 6 | 6 | 6 | 6 | 6 | 4 |
| Limited timeline for prior negotiation | 2 | 0 | 1 | 0 | 0 | 2 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| Guidelines for commercially reasonable terms for prior negotiations | 2 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| Remuneration guidelines | 5 | 0 | 4 | 0 | 0 | 3 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 1 |
| Burden of proof to prevent the CL on the patent holder/Presumptive licenses | 5 | 0 | 2 | 0 | 0 | 1 | 0 | 4 | 0 | 1 | 2 | 0 | 0 | 3 | 5 | 3 |
| Option for mandatory CLs | 5 | 0 | 0 | 0 | 5 | 4 | 0 | 0 | 2 | 0 | 3 | 0 | 0 | 0 | 1 | 0 |
| Administrative review available in lieu of judicial review | 10 | 0 | 0 | 0 | 0 | 0 | 0 | 5 | 6 | 0 | 0 | 0 | 0 | 8 | 0 | 0 |
| Challenges to the grant of a CL do not allow injunctive relief (or have "no suspensive effect") | 10 | 0 | 8 | 0 | 10 | 10 | 0 | 0 | 0 | 0 | 10 | 10 | 0 | 0 | 0 | 0 |
| Right of continued use based on interest of licensee | 5 | 5 | 4 | 0 | 5 | 5 | 4 | 4 | 0 | 4 | 5 | 5 | 5 | 1 | 0 | 0 |
| Total points | 50 | 11 | 25 | 6 | 26 | 31 | 10 | 19 | 12 | 11 | 26 | 21 | 11 | 18 | 12 | 8 |
| **% of total possible points (n=50)** | **100%** | **22%** | **50%** | **12%** | **52%** | **62%** | **20%** | **38%** | **24%** | **22%** | **52%** | **42%** | **22%** | **36%** | **24%** | **16%** |

Legend: AL = Algeria; AR = Argentia; CH = China; CO = Colombia; EC = Ecuador; JO = Jordan; MA = Malaysia; ME = Mexico; PA = Panama; PE = Peru; PH = Philippines; RO = Romania; TH = Thailand; TU = Turkey; UK = Ukraine.

## Appendix E. Table 3. Scope of use flexibilities

| | Maximum points | AL | AR | CH | CO | EC | JO | MA | ME | PA | PE | PH | RO | TH | TU | UK |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| License can be granted for all patents related to a final product | 4 | 0 | 2 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 2 | 2 | 0 | 0 | 0 |
| Licenses can be granted on filed patent applications, pending and granted patents | 5 | 2 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 4 | 0 | 0 | 0 |
| License allows export of non-predominant quantities | 10 | 10 | 8 | 10 | 10 | 10 | 8 | 10 | 6 | 8 | 10 | 10 | 10 | 8 | 10 | 8 |
| License allows export beyond non-predominant quantities for anti-competitive remedy licenses | 2 | 0 | 2 | 2 | 0 | 2 | 2 | 0 | 0 | 0 | 0 | 2 | 2 | 0 | 0 | 0 |
| License allows export beyond non-predominant quantities consistent with Art. 31bis | 3 | 0 | 3 | 3 | 0 | 3 | 3 | 0 | 0 | 0 | 0 | 3 | 0 | 0 | 3 | 0 |
| License has general inclusion of importation as a right granted with the license | 5 | 5 | 4 | 5 | 4 | 5 | 4 | 5 | 3 | 4 | 0 | 0 | 5 | 4 | 5 | 4 |
| License specifically mentions importation | 5 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| License specifically mentions importation with respect to medicines consistent with Art. 31bis | 3 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 3 | 0 | 0 | 0 | 3 |
| Total points | 37 | 17 | 19 | 20 | 14 | 20 | 17 | 15 | 9 | 12 | 10 | 20 | 23 | 12 | 18 | 15 |
| **% of total possible points (n=37)** | **100%** | **46%** | **51%** | **54%** | **38%** | **54%** | **46%** | **41%** | **24%** | **32%** | **27%** | **54%** | **62%** | **32%** | **49%** | **41%** |

Legend: AL = Algeria; AR = Argentia; CH = China; CO = Colombia; EC = Ecuador; JO = Jordan; MA = Malaysia; ME = Mexico; PA = Panama; PE = Peru; PH = Philippines; RO = Romania; TH = Thailand; TU = Turkey; UK = Ukraine.

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