

Using TRIPS flexibilities to facilitate access to medicines

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Abstract The problem of how to mitigate the impact of pharmaceutical patents on the delivery of essential medicines to the world's poor is as far from being resolved as it has ever been. Extensive academic commentary and policy debate have achieved little in terms of practical outcomes. Although international instruments are now in place allowing countries to enact legislation that permits the generic manufacture of patented pharmaceuticals, many countries have not yet enacted appropriate legislation and most of those that have yet to make use of it. One major problem is that the requirements of international instruments and implementing legislation are seen as being so stringent as to be unworkable. This paper calls for fresh attempts to enact workable legislation that fits within the prescribed requirements of international law without going beyond them. It argues that high-income nations should refocus on their moral obligation to enact appropriate legislative mechanisms and provide appropriate incentives for their use. Draft legislation currently being considered in Australia is used to illustrate how workable legislative frameworks can be developed.

Abstracts in **عربي**, **中文**, **Français**, **Русский** and **Español** at the end of each article.

TRIPS and access to medicines

When the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) was annexed to the Agreement Establishing the World Trade Organisation (WTO) in 1994, it set minimum standards for intellectual property (IP) protection that must be observed and enforced by all WTO Member States.^{1,2} TRIPS negotiations were long and complex, as documented by many commentators.^{3–5} Many low- and middle income countries (as classified by the World Bank) resisted the inclusion of an IP regime in the WTO system because they feared that it might obstruct development goals and access to important goods such as essential medicines.⁶ Ultimately, however, they were constrained to accept the “TRIPS package” as an indivisible component of the WTO system. Since TRIPS came into force, bilateral and regional trade agreements have tended to set even higher standards for IP protection, in what Peter Drahos refers to as “the global ratchet” for IP rights.⁷

An extensive body of commentary has been generated on the potentially detrimental effects of various aspects of the TRIPS package on public health and development, particularly in low- and lower-middle-income countries.^{8–10} Inadequate provision of basic public health care continues to afflict many of these countries. The United Nations (UN) clearly recognizes this. In 2001, the Committee on Economic, Social and Cultural Rights stated that national and international IP regimes must be consistent with the human rights obligations of states.¹¹ In 2011, the United Nations General Assembly recognized the need to preserve TRIPS flexibilities to facilitate measures for improving access to health care, and United Nations Member States agreed that IP rights provisions in trade agreements should not undermine these flexibilities.¹²

The World Health Organization (WHO) has taken several measures to counteract the potentially adverse health impact of IP protection. In particular, in 2008 the sixty-first World Health Assembly adopted Resolution 61.21, which endorsed the Global Strategy and Plan of Action on Public Health, Innovation and Intellectual Property.¹³ This Global Strategy aims, among other things, to improve the delivery of and access to health products and medical devices by effectively overcoming

barriers to access. Adoption of the Global Strategy followed an 18-month period of deliberations and meetings of the WHO Intergovernmental Working Group on Public Health.¹⁴ More recent measures by the WHO include an intensive study on access to medical technologies and innovation, conducted in collaboration with the World Intellectual Property Organization (WIPO) and the World Trade Organization (WTO),¹⁵ as well as release of its *Zero Draft Global Plan for the Prevention and Control of Non-communicable Diseases 2013–2020*.¹⁶ Various forms of technical assistance have been provided by WIPO to low- and lower-middle-income countries in formulating IP laws and policies using the TRIPS flexibilities.¹⁷

These ongoing activities on the part of international agencies are vital in addressing the growing public health crisis in the world's poorest countries. Relevant domestic activity in the majority of industrialized nations has, however, failed to match this international activity. With this in mind, the specific question that this paper examines is whether it is possible for rich countries to create robust and workable legislative frameworks to facilitate the delivery of essential medicines to their poorer neighbours within TRIPS flexibilities. It is argued that this is necessary because the responsibility of providing health care to those most in need should not be left solely to middle-income countries that have thriving generic pharmaceutical industries, such as Brazil (which is classified as upper-middle-income) and India (lower-middle-income). It is contrary to the tenets and spirit of articles 66 and 67 of TRIPS to leave this task entirely to middle-income countries; those articles enjoin rich countries to facilitate technology transfer to low- and lower-middle-income countries and provide technical support where needed.

TRIPS compulsory licensing flexibility

The key TRIPS flexibility, as highlighted in the Doha Declaration on TRIPS and Public Health (the Doha Declaration),¹⁸ is the right of WTO Member States to include in their patent legislation a provision for use without authorization of the patent holder, as provided in Article 31. “Compulsory licensing” is the term generally adopted in domestic legislation implementing

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Article 31. Although the grounds upon which compulsory licences can be granted are not limited by TRIPS, Article 31 provides a list of minimum standards that must be included in implementing legislation. However, these requirements are relaxed to some extent for public non-commercial use, in national emergencies, and other circumstances of extreme urgency, and in the face of anticompetitive conduct. Article 5 of the Doha Declaration confirms that WTO Member States have the freedom to determine the grounds for compulsory licensing and that public health crises, including those linked to the epidemics human immunodeficiency virus (HIV) infection, tuberculosis, malaria and other diseases, can represent a national emergency or other circumstance of extreme urgency.

Following the Doha Declaration, several compulsory licences were issued for generic manufacture of patented pharmaceuticals.^{19,20} Some countries, most notably Thailand, developed an express strategy of using compulsory licensing to reduce health-care costs.²¹ It is beyond the scope of this paper to debate the legitimacy of such strategies or of the retaliatory response from other countries, which have been discussed in detail elsewhere.^{19,22} Rather, the focus of this paper is on how compulsory licensing might be used by rich countries to assist those countries that lack any drug manufacturing capacity. Article 31(f) of TRIPS has constrained countries that do have manufacturing capacity in their ability to provide assistance because it requires that manufacture under compulsory licensing be predominantly for supply of the domestic market, even when the licence is issued for a national emergency or other circumstance of extreme urgency or for public, non-commercial use. This problem was well recognized in Doha negotiations and resulted in the inclusion of Paragraph 6 in the Doha Declaration, which called on the TRIPS Council to find an “expeditious solution.” After a period of protracted negotiations, the Doha Paragraph 6 Implementation Decision (the Implementation Decision) was adopted in August 2003.²³ One key aspect of the Implementation Decision was an agreement to waive reliance on Article 31(f). Some time later, the Protocol Amending the TRIPS Agreement (the Protocol) was adopted by the WTO General Council on 6 December 2005.²⁴

In essence, the Implementation Decision and the Protocol allow countries with manufacturing capacity to adopt legislation that permits the granting of compulsory licences for the production of pharmaceuticals for export, and countries that lack manufacturing capacity to introduce equivalent legislation to facilitate import. That said, both instruments impose stringent conditions on the terms of the implementing legislation, a fact that has sparked criticism that such legislation is unworkable in practice.²⁵ The crucial question is whether the framework that has been established by the Implementation Decision and the Protocol is so flawed that it should be abandoned.²⁶

To date, there is little to suggest that the Implementation Decision and the Protocol can meaningfully contribute to reversing the failure of the industrialized world to supply essential medicines to the countries that need them the most. Nor does there appear to be widespread enthusiasm for using Implementation Decision and Protocol mechanisms to facilitate the provision of low-cost or no-cost pharmaceuticals to those most in need. Although the waiver remains in place, the Protocol is not yet in force and will only take effect upon acceptance by two thirds of all WTO Member States. So far, only 45 of the 155 Member States of the WTO have accepted the amendment.²⁷ The deadline for accession was originally 1 December 2007 but has been extended three times and now expires on 31 December 2013. Still fewer countries and territories have implemented the Protocol. To date, only Albania, Canada, China, Croatia, European Communities, Hong Kong Special Administrative Region, India, the Republic of Korea, Norway, the Philippines, Singapore and Switzerland have notified that they have implemented compliant domestic legislation.²⁸ Moreover, nine years after the adoption of the Implementation Decision, only Rwanda has used the system to import antiretrovirals (ARVs) from Canada,²⁹ and the period it took to achieve that was anything but expeditious.³⁰ Granted, the Implementation Decision was never intended to deliver medicines at affordable prices, but rather, to ensure that countries lacking manufacturing capacity in the pharmaceutical sector could benefit from the TRIPS compulsory licensing regime. Can it be said to have deliv-

ered on that mandate? Even the TRIPS Council has not been able to give its unequivocal support.³¹

The need to have in place a robust global system to allow for the legitimate manufacture of generic ARVs for HIV infection is as pressing as ever. Malaria, tuberculosis and other diseases also continue to spread on epidemic scales and new health crises continue to emerge.³² Low-income countries have until 2016 to comply fully with TRIPS,¹⁰ but middle-income countries, including some of the key producer countries such as Brazil, India and Thailand, had to accept earlier dates for compliance. Indian generic pharmaceutical companies have been lead suppliers of ARVs and other medicines in the non-industrialized world,³³ but their capacity to continue to supply such drugs is limited now that the country has become fully compliant with TRIPS. India did not provide patent protection for pharmaceutical products before 2005. Thus, generic manufacturing and export of drugs that were under patent in other countries could take place without the risk of patent infringement action.³⁴ The manufacture and export of cheap generic versions of patented drugs can now only continue under licence from the patent holder or through compulsory licensing, which puts India in the same situation as other countries that have allowed pharmaceutical patents for many years.

Strategies for delivering cheaper medicines

New strategies are being considered to ensure that cheaper medicines flow to countries most in need. They include public-private partnerships,³⁵ prize schemes,^{36,37} patent pools,³⁸ tax incentives³⁹ and other measures. Although these schemes hold promise, they tend to focus on the production of new medicines, which is inevitably a long and risky process.⁴⁰ What should be more immediately achievable is the delivery of medicines already in existence but unavailable through conventional channels where pharmaceutical patents allow for monopoly pricing. The flexibilities inherent in the TRIPS Agreement, as confirmed in the Doha Declaration, provide the framework for this to be achieved. By agreeing to the Doha Declaration, governments in some of the wealthiest countries clearly recognized their

obligations in this regard. For example, in 2003 in Australia, the then Minister for Trade, Hon Mark Vaile, stated in reference to the negotiations around the implementation of paragraph 6 of the Doha Declaration that:

“... all WTO member countries had a moral obligation to resolve this issue ... we must move past old battle lines and all work to ensure the solution makes its contribution to dealing with the public health problems poorer countries face.”⁴¹

Agreement on the utilization of compulsory licensing through the Implementation Decision and the Protocol in places lacking manufacturing capacity would appear to be an important further step in the right direction. However, it seems that during the course of negotiations over the implementation of paragraph 6 the desire of rich countries to constructively participate in finding an appropriate resolution dwindled.⁴² Inevitably, as so often happens with international agreements of this nature, TRIPS, the Doha Declaration and their sequelae were political compromises that did not necessarily correspond with the intentions stated at the outset. Despite this, it is argued here that these mechanisms should not yet be abandoned completely, if nothing else because of the lack of other available options to fill the void. All countries with manufacturing capacity should instead be striving to implement legislation in compliance with the Protocol as a matter of urgency.

As a first step towards making the compulsory licensing model more workable, countries should be looking to implementation strategies that impose minimal obligations on potential licensees and importing countries. In this regard, the Canadian experience perhaps provides a useful example of how not to approach the implementation task.³⁰ Hurdles in the Canadian legislation that go beyond the obligations prescribed in the Implementation Decision and the Protocol include: (i) a requirement to list eligible pharmaceutical products, together with complex procedures for additions to the list; (ii) stringent negotiation requirements, including during national emergencies or other circumstances of extreme urgency; (iii) complex notification procedures with some double reporting requirements for export and import countries; and

(iv) lack of provision for amendment of compulsory licences, once issued.^{43,44} Attempts to amend the Canadian legislation to remove some of these hurdles have so far been unsuccessful but continue.⁴⁵

How, then, might countries take a better approach to the implementation process? The situation today is increasing in complexity because of the many bilateral free trade agreements that have been entered into, often with TRIPS-plus obligations.^{10,46} From an Australian perspective, for example, while TRIPS provides no limitations on the grounds for compulsory licensing, Article 17.9.7(b) of the Australia–United States Free Trade Agreement (AUSFTA) limits the grounds to cases of public non-commercial use, national emergency, other circumstances of extreme urgency and anticompetitive conduct. Although this list probably covers most of the circumstances in which Australian companies might be requested to provide medicines to those in need in other countries, the rationale for restricting compulsory licensing to these grounds is unclear.⁴⁷ Although Australian legislation limited the grounds for compulsory licences before entering into the AUSFTA, the difficulty that this agreement presents is that it circumscribes the capacity for the Australian Parliament to amend the legislation in the future.

The Australian draft legislation

The Australian government has recently drafted a bill amending national patent legislation, to provide a legal environment for exporting pharmaceuticals under Protocol and AUSFTA conditions. The Exposure Draft Intellectual Property Laws Amendment Bill 2012 was released for public comment in August 2012.⁴⁸ This draft legislation provides a useful case study of the way in which rich nations can draft legislation in compliance with the Implementation Decision and the Protocol within the additional confines imposed by a bilateral free trade agreement. The Explanatory Memorandum to the Exposure Draft lists an eight-step process created by the legislation for obtaining a licence (referred to in the legislation as a “patented pharmaceutical invention compulsory licence” or PPI compulsory licence).⁴⁹ Table 1 provides

an overview and commentary of the eight-step process.

For the most part, the Amendment Bill appears to have been written in a way that imposes minimal obligations on licensees and importing countries, while taking into account the requirements imposed by the Implementation Decision, the Protocol and the AUSFTA. The restrictions imposed internationally make it difficult to see how the overarching design of the framework could be altered substantially. Admittedly, important obligations remain, each of which may be a disincentive for uptake by generic manufacturers and importing countries.

Médecins Sans Frontières has highlighted several shortcomings of the international regime, among them (i) the requirement for negotiations with the patent holder (which can be waived for situations of national emergency, extreme urgency and public non-commercial use); (ii) separate labelling and marketing requirements; (iii) the requirement of notifying the WTO, which opens importing countries to pressure; and (iv) the lack of flexibility and of the ability to respond to changed circumstances in a timely fashion (e.g. the requirement that a new application be submitted to provide unused drugs to other countries).⁵⁰

The additional requirement in the draft Australian legislation of engaging in prior negotiation in circumstances of public non-commercial use may create a further disincentive, together with the requirement to apply for a licence through a judicial rather than administrative process. On the other hand, it is well recognized that countries must maintain a fine balance in their patent legislation to ensure that the patent grant has some value. If there are too many ways to work around patent rights, the incentive to innovate may be reduced. The risk of re-importation to the manufacturing country or to other markets is perhaps the most serious concern for patent holders and explains why the notification, labelling and marketing requirements were included in the Implementation Decision and the Protocol. It is hard to imagine that these obligations could ever be negotiated out of the international framework and, as such, generic manufacturers and importing countries have to find ways to accommodate them.

Although this Amendment Bill is not the perfect solution, it appears to

Table 1. **Essential steps in applying for a patent pharmaceutical invention compulsory licence under the Australian Exposure Draft Intellectual Property Laws Amendment Bill 2012**

Essential steps	Details	Commentary
Identify the relevant patent(s)	– includes patented pharmaceutical products and processes	– makes good sense for PPI compulsory licences to be available for processes as well as products
Try to obtain authorization	– not necessary for national emergency or other circumstance of extreme urgency but needed for public non-commercial use (which is not defined)	– requirement goes beyond TRIPS for public non-commercial use – less onerous than Canadian legislation, which requires an attempt to obtain authorization in all circumstances
Notify intent to use the system	– if no authorization granted after 30 days, or in a national emergency or other circumstance of extreme urgency, eligible importing country ^a notifies TRIPS Council (if WTO member) or Commissioner of Patents (if not)	– notification of this nature is a mandatory Protocol requirement – 30 days is a reasonable timeframe, mirroring that of other countries – appropriate to have expedited processes for national emergencies or other circumstances of extreme urgency
Apply to Federal Court for compulsory licence	– must include a statement from the eligible importing country that it will take reasonable measures to prevent re-exportation (which are not defined) – <i>Parties</i> : applicant, patentee, others with an interest through patentee, importing country (their option) – <i>Key considerations</i> : good faith; import for national emergency, other circumstances of extreme urgency, or public non-commercial use; compliance with notification requirements (prescribed by regulation)	– fear of re-exportation is sticking point for manufacturing countries. As such, adequate mechanisms for prevention are essential – query whether preferable to have an administrative procedure (e.g. to Commissioner for Patents), as in Canada (TRIPS is silent on this) – AUSFTA limits grounds. Query whether other grounds are needed: may depend on the breadth of the public non-commercial use ground
Notify granting of licence	– notify Commissioner of Patents of licence and web site where shipment information will be provided. Commissioner notifies the TRIPS Council	– not unduly onerous, but there are concerns about importing countries being exposed to pressure by having to disclose
Manufacture and export	– in accordance with terms of the (non-exclusive) licence, including quantities, purpose, labelling, duration	– these conditions could deter entry of generic products
Notify details of shipment	– quantities, destinations, labelling and markings of the product(s) posted on the nominated web site	– could deter entry of generics
Determine remuneration	– negotiated or determined by the Federal Court. Can be determined when the Court first grants the licence, if parties agree	– unclear that the Federal Court is the appropriate body because of lack of expertise on such matters. Would Commissioner of Patents be better?
Other notable inclusions	– can apply for an ancillary licence for dependent patents; can apply for amendments – revocation where substantive circumstances no longer exist or for acts of non-compliance. Consider adverse effect on licensee and eligible importing country	– ancillary licence is useful addition – important to have an opportunity to amend – not provided in Canadian legislation – query which acts of non-compliance justify revocation

AUSFTA, Australia–United States Free Trade Agreement; PPI, patented pharmaceutical invention; TRIPS, Agreement on Trade-Related Aspects of Intellectual Property Rights; WTO, World Trade Organization.

^a Eligible importing country includes: least developed countries; countries self-nominated to the TRIPS Council; countries prescribed by regulation.

have sufficient merit to be introduced and passed by the Australian Parliament. However, implementing this legislation is not enough; it must also be used, as otherwise it risks becoming yet another redundant process in Australian patent law, in light of the fact that generic compulsory licensing provisions have existed for many years but not a single licence has been issued.⁴⁷

Conclusion

Australia's move towards putting into practice the Implementing Decision

and the Protocol is a positive step in redressing the imbalance in the ability to access medicines between lower-income countries and rich countries. Other rich countries that have not yet implemented compliant legislation should follow suit with due haste. Implementation will not solve the problem of lack of access to essential medicines in poor countries, but it is an important step.

If legislation of the nature of Australia's Amendment Bill is ever to be more than a symbolic gesture, governments will need to encourage generic manufacturers to manufacture under

compulsory licence for export to beneficiary countries by providing tax or other incentives. Beyond this, Australia and other rich countries are in an ideal position to help their close neighbours improve their own generic manufacturing capabilities through financial aid, technology transfer, infrastructure and training. ■

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ملخص

استخدام جوانب المرونة في الاتفاق المتعلق بالجوانب التجارية لحقوق الملكية الفكرية "تريس" لتيسير إتاحة الأدوية لا توجد حلول في الأفق لمشكلة كيفية التخفيف من أثر براءات اختراع المستحضرات الصيدلانية على إيتاء الأدوية الأساسية إلى الشعوب الفقيرة في العالم كما كان الحال من قبل. ولم تحقق التعليقات الأكاديمية والنقاشات السياسية الموسعة سوى القليل فيما يخص الحصائل العملية. وعلى الرغم من تطبيق صكوك دولية في الوقت الحالي للسماح للبلدان بسن تشريعات تسمح بالتصنيع العام للمستحضرات الصيدلانية الحاصلة على براءات اختراع، إلا أن العديد من البلدان لم تسن حتى الآن تشريعات ملائمة ومعظم البلدان لم تستفد منها. وتمثل إحدى المشاكل الرئيسية في أنه يتم

النظر إلى متطلبات الصكوك الدولية وتنفيذ التشريعات على أنها صارمة بدرجة غير عملية. وتدعو هذه الورقة إلى محاولات جديدة لسن تشريعات عملية تناسب المتطلبات المحددة للقانون الدولي دون أن تتعدها. وتزعم أنه ينبغي على الدول المرتفعة الدخل إعادة التركيز على التزامهم الأخلاقي لسن آليات تشريعية مناسبة وتوفير حوافز ملائمة لاستخدامها. وتستخدم مسودة التشريع الذي يتم النظر فيها في الوقت الراهن في أستراليا لإيضاح الكيفية التي يمكن من خلالها وضع أطر تشريعية عملية.

摘要

利用 TRIPS 灵活性方便药品的使用

在为世界上的穷人提供基本药物方面，如何缓解药物专利影响的问题一直以来都远未解决。广泛的学术评论和政策争论在实际成果上收效甚微。虽然现在已经制定了可使国家立法允许非商标制造专利药品的国际契约，但是许多国家尚未制定适当的立法并且大多数国家还没有加以利用。其中一个主要的问题在于国际契约和实施立法的要求被视为太过严格而行不通。本

文要求尝试在国际法的范围内制定符合其规定要求的可行的立法。本文认为，高收入国家应该将重点转到自己的道德义务上，制定适当的立法机制，并提供使用这些机制的适当的激励措施。文章使用澳大利亚目前正在考虑的立法草案来说明如何制定可行的立法框架。

Résumé

Utiliser les flexibilités des aspects des droits de propriété intellectuelle liés au commerce (ADPIC) pour faciliter l'accès aux médicaments

La question de savoir comment mitiger l'impact des brevets pharmaceutiques sur la fourniture de médicaments essentiels aux populations pauvres du monde est, plus que jamais, loin d'être résolue. Peu de résultats pratiques sont ressortis des commentaires et débats politiques académiques. Bien que des instruments internationaux soient maintenant mis en place et permettant les pays à promulguer des lois permettant la fabrication de versions génériques de médicaments brevetés, de nombreux pays n'ont pas encore adopté de législation appropriée et la plupart n'en ont même pas encore fait l'usage. Un des principaux problèmes est le fait que les exigences des instruments

internationaux et la législation à mettre en œuvre sont perçues comme rigoureuses et impraticables. Cette publication appelle à de nouvelles tentatives de promulgation d'une législation exécutable, compatible avec les exigences prescrites par la loi internationale, sans pour autant les dépasser. Il est ici suggéré que les nations à hauts revenus se recentrent sur leur obligation morale de promulguer des mécanismes législatifs appropriés et veillent, de manière appropriée, à favoriser leur utilisation. Un projet de loi actuellement à l'étude en Australie est utilisé pour montrer comment des cadres législatifs praticables peuvent être développés.

Резюме

Использование гибкости положений ТРИПС для облегчения доступа к лекарствам

Проблема смягчения последствий влияния фармацевтических патентов на поставки основных лекарственных средств малоимущим людям в мире так же далека от своего разрешения, как и раньше. Множество комментариев ученых и политических дебатов мало к чему привели с точки зрения практических результатов. Хотя в настоящее время действуют международные документы, согласно требованиям которых страны должны принять законодательство, разрешающее производство аналогов запатентованных лекарственных препаратов, многие страны еще не приняли соответствующее законодательство, а большинство стран, которые уже приняли его, пока не воспользовались им. Одной из основных проблем является то, что требования международных документов и законодательства, реализующего

их, считаются настолько строгими, что кажутся неосуществимыми. Эта статья призывает предпринять новые попытки ввести в действие работоспособное законодательство, которое вписывается в установленные требования международного права и не выходит за их границы. В статье утверждается, что странам с высоким уровнем дохода следует переориентироваться на выполнение своего морального обязательства ввести в действие соответствующие законодательные механизмы и обеспечить надлежащие стимулы для их использования. Законопроект, который в настоящее время рассматривается в Австралии, используется для иллюстрации возможности разработки работоспособной законодательной базы.

Resumen

Cómo utilizar los aspectos flexibles de los ADPIC para facilitar el acceso a los medicamentos

El problema de cómo mitigar el impacto de las patentes farmacéuticas en el suministro de medicamentos básicos a los pobres del mundo está aún lejos de resolverse. Los amplios debates políticos y académicos no han conseguido mucho en lo que a resultados prácticos se refiere. Si bien se han puesto en marcha instrumentos internacionales que permiten a los países promulgar leyes que permitan la fabricación genérica de fármacos patentados, muchos países no han promulgado aún leyes adecuadas y la mayoría de ellos aún no las han aplicado. Un problema importante es que los requisitos de los instrumentos internacionales y

la normativa de aplicación son demasiado estrictos para ser factibles. Este artículo lanza un llamamiento para que se realicen nuevas tentativas de promulgación de leyes factibles que se ajusten a los requisitos preceptivos del derecho internacional sin sobrepasarlos. Sostiene que los países de renta alta deben centrar su atención en su obligación moral de promulgar mecanismos legislativos adecuados y facilitar incentivos apropiados para su uso. Se emplean los proyectos de ley que se están considerando actualmente en Australia para demostrar cómo pueden desarrollarse marcos legislativos factibles.

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