11 Infrastructure, not waivers: promoting access to medicines in developing countries

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The COVID-19 pandemic has cast new light on the need to improve access to medicines in the developing countries.[1] A major issue at the moment is whether intellectual property protection of pharmaceuticals, industrial designs, copyrights, and related trade secrets under the Agreement on Trade-Related Aspects of Intellectual Property Rights (1994)[2] should be temporarily suspended so as to facilitate access to vaccines and related medicines in developing countries.[3] This waiver proposal was first put forward by South Africa on October 15–16, 2020,[4] with respect to certain provisions of the TRIPS agreement "for the prevention, containment and treatment of Covid-19," and it has subsequently won the support of numerous developing and least-developed countries.[5]

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[1] *See, e.g.,* Frederick M. Abbott & Jerome H. Reichman, *Facilitating Access to Cross-Border Supplies of Patented Pharmaceuticals: The Case of the Covid-19 Pandemic*, 23 J. Int'l Economic Law 535–566 (2020).

[2] *See* Agreement on Trade Related Aspects of Intellectual Property Rights, April 15, 1994, 1869 U.N.T.S. 299, 33 ILM 1197 (1994) (*hereinafter* TRIPS Agreement), Arts 27–34, 39. For the limited legal powers of the World Health Organization (WHO), *see* Leila Nadya Sadat, *Pandemic Nationalism, Covid-19 and International Law*, Washington Univ. St. Louis School of Law, Legal Studies Research Paper Series No. 0621-0206 (February 2021).

[3] *See* the World Trade Organization (WTO), *TRIPS Council Agrees to Continue Discussions on IP Response to Covid-19*, July 20, 2021. Available at: http://www.wto.org/english/news_e/news2/_e/trp-20ju/21_e.htm (*hereinafter*, WTO News Report (2021)). *See also* Third World Network Information Service on Trade, IP, and Health, August 10, 2021, "TRIPS Waiver Proposal Being Undermined by EU at WTO."

[4] WTO News Report (July 2021), n 3, at 2/3.

[5] *Ibid.*; *see further* Third World Network (TWN), Info Service on WTO and Trade Issues (June 21/12). Available at: http://www.twn.my/title2/wto.info/2021/ti210612/utm.

A legal basis for the proposed waiver can be found in the Agreement Establishing the World Trade Organization (WTO) in 1994.[6] Nevertheless, the very existence of this debate highlights the failure of many developing countries to promote access to medicines by exploiting the flexibilities that the TRIPS Agreement itself otherwise expressly makes available for such purposes, notably in Articles 31 and 31*bis* authorizing the use of compulsory licenses.[7] This, indeed, is the thrust of an alternative proposal put forward by the European Union,[8] which reminds the developing countries that "in urgent situations, such as a pandemic, the usual requirement to negotiate with the rightsholder of the vaccine patent does not apply."[9] Hence, in the view of the EU, the proposed waiver, with its corresponding disruption of international trade law, is both unnecessary and undesirable.[10]

It is, of course, clear that the TRIPS Agreement did generally provide the global pharmaceutical industry with strong protection of both patentable pharmaceuticals and related trade secrets.[11] All WTO member countries—except for about thirty-three of the Least Developed Countries (LDCs)[12]— must

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[6] Marrakesh Agreement Establishing the World Trade Organization, April 15, 1995, Art. IX(3)(a), *entered into force* January 1, 1995. Available at: www.wto.org., *viz*: "in exceptional circumstances, the Ministerial Conference may decide to waive an obligation imposed on a member by this agreement or any of the Multilateral Trade Agreements, provided that any such decision shall be taken by three-fourths of the Members unless otherwise provided for in this paragraph." *See also ibid*., Art. IX(3)(b)–(3)(c) on procedural aspects for seeking such a waiver.

[7] *See* TRIPS Agreement, n 2, Arts 31 and 31*bis*; *see also ibid*., Art 30 (limitations and exceptions to patent protection), 70.8–70.9.

[8] *See* WTO News Report (July 2021), n 3, at 2/3, *citing* Arts 31 and 31*bis* of the TRIPS Agreement, n 2; for support of the EU's contrary proposal, *see* World Trade Organization (WTO), Draft General Counsel Declaration on the TRIPS Agreement and Public Health in the Circumstances of a Pandemic, WTO/IP/C/W681. Available at: https://docs.wto.org/dot2te/Pages/55/directdoc.aspx? (discussed in WTO News Report (2021), n 3 at 2/3).

[9] WTO News Report (2021), n 3, at 2/3.

[10] *Ibid.*; for similar views of major developed countries (U.S., E.U., U.K., Switzerland), *see* TWN (2021), n 5, at 618.

[11] *See* n 2; *see* also Jayashree Watal & Rong Dai, *Product Patents and Access to Innovative Medicines in a Post-TRIPS Era*, WTO Staff Working Paper ERSD-2019-05 (April 4, 2019). *See generally*, Carlos M. Correa, Trade Related Aspects of Intellectual Property Rights; Commentary on the TRIPS Agreement, 2nd edn (2020).

[12] TRIPS Agreement, n 2, Art. 66 (as extended over time, now to 2033); *see* WTO Council for Trade-Related Aspects of Intellectual Property Rights, *Extension of the Transition Period Under Article 66.1 of the TRIPS Agreement for Least-Developed Country Members for Certain Obligations with Respect to Pharmaceutical Products*, Decision of the Council for TRIPS, IP/C/73, Nov. 6, 2015.

provide producers with the mandated levels of intellectual property protection or risk being sued for damages inflicted on relevant producers for failure to comply with the express obligation of the TRIPS Agreement.[13] However, it is equally well established that the TRIPS Agreement itself codified exceptions and limitations to these exclusive rights that were viewed as directly beneficial to the developing countries.[14] Of these so-called "flexibilities" the rights of WTO Members to issue compulsory licenses (including government-use licenses) on pharmaceutical products was of primary importance.[15]

To be sure, Article 31(f) of that Agreement had initially limited the scope of compulsory licenses to countries that possessed local manufacturing capacity. Countries that lacked such capacity could not seek assistance from those that did because exports under complimentary compulsory licenses were expressly blocked by Article 31(f).[16] However, in 2009, that obstacle was alleviated by a waiver to Article 31(f) initially proposed in the Doha Declaration on the TRIPS Agreement and Public Health[17] and subsequently ratified by the General Counsel Decision on the Implementation of Paragraph 6 of the Doha

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[13] *See* TRIPS Agreement, n 2, Arts 41–49, and especially Art. 64.; *see also* World Trade Organization, Understanding on the Rules and Procedures Concerning the Settlement of Disputes, Final Act Embodying the Results of the Uruguay Round of Multi-Lateral Trade Negotiations, April 15, 1994 Annex 2, *entered into force* on Jan. 1, 1995. *See generally*, J. H. Reichman, *Universal Minimum Standards of Intellectual Property Protection Under the TRIPS Component of the WTO Agreement*, *reprinted in* C. M. Correa & A. A. Yusuf (eds), Intellectual Property and International Trade: The TRIPS Agreement 21–88 (1998).

[14] *See* TRIPS Agreement, n 2, Arts 29–31, and Art 31*bis* as later codified. *See further* nn 22 and 24, and accompanying text.

[15] *See generally* Valbona Muzaka, *Dealing with Public Health and Intellectual Property for Pharmaceuticals at the World Trade Organization*, *in* Health for Some: The Political Economy of Global Health Governance, International Political Economy Series, ISBN 978-0-333-711/0-1 (Sandra J. Maclean, Sherri A. Brown & Pietar Fourie, *eds*.) (2009), at 183–195 (stressing the importance of WTO's Doha Declaration on TRIPS and Public Health, n.17).

[16] *See* TRIPS Agreement, n 2, Arts 31 and 31*bis*; *see generally* 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 Provisions*, 10 J. Int'l Economic Law 921 (2007); *see also* Jerome H. Reichman & Catherine Hasenzahl, *Nonvoluntary Licensing of Patented Inventions*, ITCSD/UNCTAD Issue Paper No. 5 (2003).

[17] WTO, Declaration on the TRIPS Agreement and Public Health, WTO Ministerial Conference, Fourth Session, Doha November 9–14, 2001, WT/MIN(01)/DEC/2, November 20, 2001, Paragraph 6 (*hereinafter* Doha Declaration). *See generally* Sigrid Sterckx, *Patterns and Access to Drugs in Developing Countries: An Ethical Analysis*, 4(1) Developing World Bioethics ISSN 1471-8847, Nov. 1, 2004 at 70–75.

Declaration on the TRIPS Agreement and Public Health in 2003.[18] That same decision was finally codified as Article 31*bis* in the Protocol Amending the TRIPS Agreement of 2005.[19] This provision expressly allows a country with production capacity to issue a second compulsory license on pharmaceuticals to be exported to other countries under initial compulsory licenses even though such countries lacked the capacity to produce the goods under those initial licenses.[20]

Under this provision, countries that issue compulsory licenses on pharmaceuticals without having local production capacity can appeal for help to countries that do possess such capacity and that are willing to assist the countries in need of such medicines. Article 31*bis* thus enables any country with production capacity that has not opted out of these provisions to issue a second compulsory license, under which pharmaceuticals required for export can be made available to countries lacking production capacity that have nonetheless issued compulsory licenses for this purpose. In other words, countries needing pharmaceuticals at prices lower than they can obtain from producers may conceivably rely on these "back to back" compulsory licenses, in order to obtain the products at cheaper prices from countries willing and able to produce them for export under compulsory licenses of their own, as authorized by Article 31*bis* of the TRIPS Agreement.[21] Moreover, the Doha Declaration of 2001, in Paragraph 5, expressly emphasized the importance of all the flexibilities embodied in the TRIPS Agreement, including Articles 30, 31, and eventually 31*bis*, as binding on all WTO Members with the same duties of implementation as those afforded the bundle of exclusive rights otherwise embodied in that same Agreement.[22]

In principle, these provisions set the stage for a vigorous expansion of exports of pharmaceuticals from countries with production capacity to countries lacking such capacity but nonetheless able to obtain medicines from other

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[18] General Counsel Decision on the Implementation of Paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health, August 30, 2003, WT/L/540 and CORR. 1, September 1, 2003.

[19] Protocol Amending the TRIPS Agreement, *adopted* December 6, 2005, WT/L/64/ 8 December 2005. However, some countries—including the United States—have opted out, and some Free Trade Agreements may have further limited the use of Article 31*bis* by agreement of the parties. *See, e.g.,* Abbott & Reichman (2007), n 16, at 947–949.

[20] *See* Protocol Amending the TRIPS Agreement, n 19.

[21] For details *see* Abbott & Reichman (2007), n 16, at 936–949.

[22] *See* Doha Declaration, n 17, Art. 5; *see also*, *ibid*. art. 4 ("we agree that the TRIPS Agreement does not and should not prevent Members from taking measures to protect public health… and in particular to promote access to medicines for all… [I]n this connection, we reaffirm the right of WTO Members to use to the full the provisions in the TRIPS Agreement, which provide flexibility for this purpose…").

countries under the compulsory licensing provisions discussed above.[23] In reality, however, these measures have been underutilized in practice and have sometimes even been weakened by provisions of Free Trade Agreements.[24] The usual reasons for this under-utilization of TRIPS flexibilities is that the enabling provisions are "too complicated" for most developing countries to implement.[25] However, Professors Abbott and I have elsewhere explained why this excuse does not hold up in practice.[26]

While those supporting the proposed waiver see it as an easy way out of these alleged complexities of the TRIPS Agreement, that premise rests on a number of false suppositions. First of all, it ignores the fact that "waivers" will not produce much-needed pharmaceuticals. On the contrary, operating under the so-called waiver, states would immediately fall back on national laws regulating access to and use of pharmaceutical products. Under the TRIPS Agreement of 1994, however, most countries were already obliged to harmonize the relevant legal regimes in a manner to implement the international minimum standards required by that agreement, although actual conformity still varies from region to region.[27] A waiver of that regime could thus induce nation states to adopt new legislation that deviates from their existing compliance regimes, and thereby induce them to set off an array of national deviations like those of the past that were finally overcome by the harmonizing effects of the TRIPS Agreement. Reliance on *ad hoc* national laws thus constitutes an unpromising pathway that could set back access to medicines under hard-earned lessons and, at the very least, could disrupt, and possibly compromise, compliant national legislation. The bottom line is that waivers do not produce pharmaceutical products but could instead unleash a new wave

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[23] *See, e.g.,* the cases of Thailand and Brazil (as well as Japan), Abbott & Reichman (2007), n 16, at 950–953.

[24] *See, e.g.,* Watal and Dai, n 11 (finding that patent protection has a positive effect on launch likelihood, especially for innovative pharmaceuticals, but that "this effect is quite limited in low-income countries"). *See also* Fabienne Orsi *et al., TRIPS Post-2005 and Access to New Anti-Retroviral Treatments in Southern Countries: Issues and Challenges*, 21 Aids (2007), (1–7 ISSN 0269-9370). For the adoption of compulsory licenses in some fifteen African countries, see Yousef A. Vawda & Bonginkosi Shozi, *Eighteen Years after Doha: An Analysis of the Use of Public Health TRIPS Flexibilities in Africa*, South Center Research Paper 103 (February 2020) at 27–31; *see also* Abbott & Reichman (2007), n 16, at 962–967 (discussing Free Trade Agreements (FTAs) of the United States and the EU).

[25] *See, e.g.,* Medicines san Frontieres (MSF), Access to Medicine Campaign, *Doha Derailed, A Progress Report on TRIPS and Access to Medicines*, August 27, 2003; MSF, *Neither Expeditious or a Solution: The WTO August 10th Decision is Unworkable*, International Aids Conference, Toronto, Canada, August 2009.

[26] *See* Abbott & Reichman (2007), n 16.

[27] *See generally* Orsi *et al.*, n 24; *see also* Vawda and Shozi, n 24.

of deviant and self-interested national legislation on access to medicines in a manner suggestive of juvenile delinquency.

In an article published in 2007, Professor Fred Abbott and I explained why the existing flexibilities under the TRIPS Agreement are not, in fact, complicated.[28] The false notion that the TRIPS flexibilities are unduly complicated is largely promulgated by special interests taking signals from the pharmaceutical industry itself, or by so-called public interest groups that often seem allergic to international intellectual property law.

The deeper problems arise from the fact that developing countries—with some important exceptions—have often ignored the flexibilities codified in the TRIPS Agreement, with the result that they have acquired relatively little cumulative experience in how to manage these compulsory licensing provisions efficiently.[29] As a result, the international community at large, and the developing countries as a group, often lack the necessary infrastructure to render these flexibilities operational easily and efficiently at the domestic level. Here, accordingly, are a few suggestions based on previous work in this area.

The first problem is that because the issuance of compulsory licenses remains a case-by-case initiative, most states seem reluctant to undertake it on their own. In other words, so long as this approach remains the norm, the provisions of Articles 31 and 31*bis* of the TRIPS Agreement may seem to present a formidable task that has to be learned and relearned with each new emergency. From this perspective, one begins perhaps to understand why diplomats unschooled in international intellectual property law are tempted to opt for so-called "waivers" rather than maximizing the possibilities for coordinated access to medicines inherent in the systematic use of compulsory licensing, which could elicit real-world solutions as problems arise.

To disprove the alleged complexity of the relevant TRIPS provisions, one only has to look at the system of compulsory licensing in the United States itself. As I have explained in an earlier article, the United States probably issues more compulsory licenses on patented inventions in any given year than the rest of the world taken together.[30] That follows because virtually every patented invention in the United State bearing on national security is subject to government use licenses in exchange for reasonable royalties determined by the Federal Court of Claims.[31] Ironically, and despite this ingrained practice, the United State government routinely criticizes developing countries

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[28] *See* Abbott & Reichman (2007), n 16; *see also* Watal and Dai n 11.

[29] As of 2020, Article 31 of TRIPS had been invoked in some fourteen African countries. Vawda and Shozi, n 24 at 30.

[30] Reichman and Hasenzahl, n 16.

[31] *Ibid*.

for embarking on a similar route with regard to pharmaceuticals in order to preserve the profits of national pharmaceutical companies flowing from cross-border supplies of essential medicines.

Disregarding this unsustainable complexity myth, a more likely problem when a compulsory license is under consideration in developing countries is that each case seems to rest on its own merits, while these countries generally lack experience in invoking relevant legal flexibilities.[32] Moreover, this reluctance to embark on relatively new or untested legislative regulatory pathways is reinforced by criticism and more-or-less veiled threats of retaliation from developed countries seeking to defend the interests of their pharmaceutical industries.[33]

On closer analysis, moreover, an even deeper reason for this failure to adequately exploit existing flexibilities could be the lack of legal or technical infrastructure at the regional or global levels to support broader use of compulsory licenses for patented pharmaceuticals as well as access to the necessary manufacturing capacity. While some efforts have been made to form regional policy frameworks, such as the East African Community (EAC) TRIPS Policy Initiative and the South African Developing Community (SADC) Strategy,[34] each case seems to rest on its own merits with little resort to cumulative experience and without the expertise of some established regulatory infrastructure.[35] Issuing a compulsory license and finding a suitable and qualified producer abroad who is willing and able to invoke a second compulsory license and to organize the purchase and actual exportation of specific products on a rational and financially viable basis remains a case-by-case unsolved problem at the national level. What is lacking, in other words, is some transnational infrastructure that could enable states to implement existing TRIPS flexibilities in a manner that would standardize the required responses and enable states to invoke a global procedure for pooled procurement strategies that would

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[32] *See* Vawda and Shozi, n 24, at 11, citing evidence that the African Regional Intellectual Property Organization (ARIPO) has failed to address the vast majority of TRIPS flexibilities available to its Members. *See further* B. K. Baker, *A Full Description of WTO TRIPS Flexibilities Available to ARIPO Member States and a Critique of ARIPO's Comparative Study Analyzing and Making Recommendations Concerning Those Flexibilities*, 39–41 (2019). Available at: http://kelinkyena.org./wp-content/uploads/2019/05/ARIPO-Member-States-Obligations-and-flexibilities-under-the-WTO-TRIPS-Agreement-March-2019pdf.c.

[33] *See ibid*., at 10, citing U.S. embassies' advice to companies seeking to do business abroad, with reference to the compilation of a Section 301 Watch List under the U.S. Trade Act of 1974.

[34] *See* Vawda and Shozi, n 24, at 9.

[35] *See also,* Sadat, n 2, at 6–10.

quickly and readily meet their access to medicines needs without obliging each state to reinvent the relevant legal wheel on its own.[36]

In a more recent article published in September 2020, Professor Abbott and I have stressed the importance of two components of any transnational infrastructure capable of converting the compulsory licensing provisions of the TRIPS Agreement into a workable cross-border modality for accessing much-needed medicines at affordable prices.[37] The first step is to exploit the potential importance of pooled procurement strategies. In other words, if one state badly needs specific medicines at affordable prices to meet a given need, that same need is likely to exist elsewhere in several other developing countries. Pooling the demand for the same medical products in multiple countries, all willing to resort to compulsory licenses when needed would, in and of itself, create a strong bargaining position *vis à vis* the original pharmaceutical companies at issue.[38]

A failure of these same companies to respond adequately to such demand could then illicit a plethora of compulsory licenses from several different countries. By the same token, a bundled demand for any given product by multiple countries under threat of pooled compulsory licenses could, in and of itself, create a marketing opportunity for either the producer companies or their rivals, irrespective of threats to take adverse legal action. In other words, the combined market for lower-priced drugs might itself constitute a desirable economic opportunity for the producer who otherwise faces multiple compulsory licenses, even if the price per product must necessarily drop significantly in order to comply with the threatened pool of compulsory licenses. Moreover, compliance with these licenses, whether voluntary or not, could generate competition from other companies who suddenly find themselves freed from the normal restraints of patented inventions by dint of a determined resort to TRIPS flexibilities. In other words, the very existence of a pooled procurement strategy could generate an alternative market that pharmaceutical companies might be wise to defend lest they be expropriated by an otherwise unwanted

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[36] *See generally* F.M. Abbott, R. B. Abbott, J. Fortunak, P. G. Sampath, D. Walwyn, *Opportunities, Constraints and Critical Supports for Achieving Sustainable Local Pharmaceutical Manufacturing in Africa: With a Focus on the Role of Finance*, Open Society Foundation- Public Health Program, Final Report: Executive Summary (March 18 2021).

[37] *See* Abbott & Reichman (2020), n 1.

[38] *See* Vawda and Shozi, n 24, at 10, *citing* Southern African Development Community (SADC), *Strategy for Pooled Procurement of Essential Medicines and Health Commodities*, 2013–2017. Available at: https://www.sadc.int/files/7614/1895/8441/SADC-strategy-for-pooled-procurement-of-essential-medicines-and-health-commodities.pdf(SADC).

competitor who shelters under the protection of validly issued compulsory licenses.

That said, the question of "validly issued compulsory licenses" may nonetheless remain something of a mystery to governments unaccustomed to this or analogous medical procurement strategies. In other words, a certain lack of experience—coupled with diverse threats from powerful transnational pharmaceutical companies—could nonetheless inspire fear or reluctance on the part of governments that are not used to engaging in these specialized intellectual property ventures.

That is why Professor Abbott and I have strongly recommended the formation of a basic transnational infrastructure to deal with these recurring problems in the form of Regional Pharmaceutical Supply Centers (RPSCs).[39] The task of such centers, once established, would be to master the law and practice of implementing Articles 31 and 31*bis* of the TRIPS Agreement on a broad-based, transnational scale. While every compulsory license might otherwise pose a new set of questions and problems for single governments unused to such undertakings, the RPSCs would become masters of procurement strategies under the legal regimes embodied in Articles 31 and 31*bis* of TRIPS. The centers would thus constitute legal infrastructure for the efficient and timely implementation of compulsory licenses duly issued under these provisions when necessary.

The proposed RPSCs would also have standardized contracts and methodologies for implementing transnational procurements of medicines, whether compulsory licenses were needed or not. They would know where to find the necessary production capacity; they would bargain with relevant states to deliver these supplies when they possessed that capacity in return for issuing compulsory licenses when necessary. Moreover, their cumulative expertise and existing contracts, as licensed purchasers under standardized compulsory licenses, could make these companies worthy competitors of Big Pharma in their own right. That, in turn could persuade the latter to avoid the hassle of unwanted competition by substantially lowering their prices early on, thereby possibly avoiding the need for compulsory licenses over time.

What seems lacking, in other words, is the specialized legal infrastructure required to make pooled procurement strategies more effective from a cross-border perspective. The formation of RPSCs could, in turn, make the process of cross-country supply a matter of legal expertise, coupled with the growing market power of pooled purchasing agents. Over time, these Regional Centers could thus become anti-monopolistic tools in the supply of medicines, which would benefit developing countries. They could thus acquire market

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[39] *See* Abbott & Reichman (2020), n 1.

power as potential exporters of pharmaceuticals that might counterbalance the market power of producers under exclusive patent rights.[40]

The object of the exercise is thus not just to counterbalance the power of big pharmaceutical companies. It is rather to better adjust their inventive capacity and related market power to the global needs for lifesaving medicines. Just as governments that finance medical research may have a legitimate interest in regulating access to the resulting medical products,[41] so too does the world at large have a basic need to access such medicines at affordable prices, especially when confronted with public health emergencies.[42] Needless to say, the incentive for pharmaceutical companies to invest and invent should not be unduly undermined. That said, medicines are not products that people can avoid or do without by looking elsewhere. They are essential to human life, but they will not save lives if they are too expensive for those who need them the most.

The TRIPS Agreement, as it has ultimately evolved, thus represents a compromise in the public interest. There are valid incentives for the pharmaceutical industry to invest in patented products. At the same time, there is now a solid set of compulsory licenses available to governments to better ensure affordable access to these lifesaving products. By combining pooled procurement strategies with the threat of compulsory licenses under the aegis of Regional Pharmaceutical Supply Centers, the TRIPS Agreement—properly implemented—could ensure both the production and dissemination of essential medicines to the benefit of all mankind. It does, therefore, seem to be time to think about how these existing tools could be properly employed., rather than returning to ground zero in every emergency via a ceaseless search for "waivers" within the existing legal regime.

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[40] Notice that LDCs can already export products made under compulsory licenses to each other under the amended TRIPS Art. 31*bis*(3), notwithstanding, *ibid*., Art. 31(f); *see* Vawda and Shozi, n 24, at 15–16.

[41] *See* Patent and Trademark Law Amendments Act (Bahyl-Dole Act), Pub. L. 96-517 (1980).

[42] *See* Abbott, *et al.*, n 36.