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**PROCURING ESSENTIAL MEDICINES UNDER THE AMENDED TRIPS
PROVISIONS: THE PROSPECTS FOR REGIONAL PHARMACEUTICAL
SUPPLY CENTERS**

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PROCURING ESSENTIAL MEDICINES UNDER THE AMENDED TRIPS PROVISIONS: THE PROSPECTS FOR REGIONAL PHARMACEUTICAL SUPPLY CENTERS

By Jerome H. Reichman*

Introduction

The procurement of essential medicines at prices people in poor countries can afford is a complex process in which legal rules are only one component. It entails market intelligence, especially knowledge about the pricing and supply of medicines and about how to forecast demand; it requires global coordination among governmental and nongovernmental agencies pertaining to supply, quality, and the reduction of costs; it depends on opportunities for local production of medicines in low and middle-income developing countries and on regionally aligned or pooled modalities of procurement; and it presupposes certain regulatory capabilities at national, regional and global levels to ensure supplies of quality products.¹

Compared with all of these other important factors, the potential use of TRIPS flexibilities and other tools related to intellectual property law² to facilitate global and regional procurement of essential medicines may, at first glance, appear to be of secondary importance. On closer analysis, however, it becomes clear that the intellectual property component cuts across all these other issues and could become a pivotal, if not dominant factor in organizing and coordinating them into an operationally successful strategy, especially for the Least Developed Countries (LDCs).

Indeed, a primary thesis of this paper is that novel strategies to overcome the intellectual property impediments to the procurement of essential medicines based on regionally coordinated efforts could in themselves produce an organizational infrastructure able to deal effectively with many other operational variables. At the very least, it is worth thinking about how to leverage solutions to the legal problems in ways that simplify these related problems.

I. The Evolving Legal Landscape

Legal obstacles to the procurement of essential medicines only became prominent with the signing of the Agreement Establishing the World Trade Organization in 1994³

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¹ OSI Draft Conference Report, "Enabling Effective Pharmaceutical Procurement," prepared by Anthony So, 13 September 2006, at 2.

² Cite Musungu, TRIPS Flexibilities; Abbott, TRIPS flexibilities pertaining to access to medicines.

³ Marrakesh Agreement Establishing the World Trade Organization (WTO), Annex 1C, Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS Agreement), 1994, arts. 27-34 [hereinafter TRIPS Agreement].

and the coming into force, in 1995, of its Annex C, the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS Agreement).⁴ The TRIPS Agreement imposed harmonized and relatively high international minimum standards of patent protection on all developing countries, starting in 1995, and culminating in 2005.⁵ From 2006 on, countries such as India, Brazil, Argentina, Thailand, and China, which had varying degrees of capacity to produce low-cost generic copies of drugs sold at high prices in the United States, the European Union and Japan, would have to respect foreign patents.⁶

A. The Situation Before the Doha Round

Prices of patented medicines available on the world market were likely to rise as a result, particularly with regard to newer drugs that generic manufacturers would progressively become unable to reverse-engineer without permission in developing countries.⁷ In this connection, we are not talking about so-called “neglected drugs,” which by definition do not attract private investments in research and development. Here we are talking about “*global diseases* ... which affect patients in both rich and poor countries but disproportionately affect the poor.”⁸ Statistics show, indeed, that “many of the major chronic conditions associated with wealthy countries—including cardiovascular disease, stroke, mental illnesses, diabetes and arthritis...are the leading causes of adult disease burdens throughout the world.”⁹ however, patented pharmaceuticals dealing with these and other illnesses that afflict developed and developing countries alike “may be priced at more than 30 times the marginal cost of production” during the period of exclusivity conferred by patents and other exclusive marketing arrangements.¹⁰ The resulting prices exceed the capacity of most people in poor countries to afford them, which gives the economic term “deadweight loss” a particularly grim connotation.¹¹ As Professor Kevin Outterson recently observed, “it is the poor themselves who are neglected rather than just their diseases.”¹²

⁴ See TRIPS Agreement, *supra* note 3, art. 65.4 (allowing developing countries an initial transitional period of five years plus an additional five-year delay on extending product patent protection to areas of technology not previously patentable on their territories); see also *id.* art. 70.8 (requiring mailbox for pharmaceutical patents pending during the transitional period) and 70.9 (requiring a period of exclusive marketing rights for specified patents in the mailbox under specified conditions).

⁵ See TRIPS Agreement, *supra* note 3, arts. 27-34.

⁶ See TRIPS Agreement, *supra* note 3, art. 65.4

⁷ See generally Frederick M. Abbott, *Managing the Hydra: The Herculean Task of Ensuring Access to Essential Medicines*, in INTERNATIONAL PUBLIC GOODS AND TRANSFER OF TECHNOLOGY UNDER A GLOBALIZED INTELLECTUAL PROPERTY REGIME 393-424 (K. E. Maskus and J. H. Reichman eds, Cambridge U. Press, 2005).

⁸ Kevin Outterson, *Patent Buy-Outs for Global Disease Innovations for Low- and Middle-Income Countries*, 32 AMERICAN J. LAW & MEDICINE 159, 161 (2006).

⁹ *Id.*, at 161-63 (citing authorities). See also James P. Love, paper presented to the Chicago-Kent Conference, October 9-10, 2006.

¹⁰ K. Outterson, *supra* note 8, at 159-60.

¹¹ James Love has often noted that, where medicines are concerned, “deadweight loss soon translates into dead bodies.”

¹² K. Outterson, *supra* note 8, at 160, 159-64 (documenting the fact that 80% to 90% of the global sales of patented pharmaceuticals occur in the 30 wealthiest members of the Organization for Economic Cooperation and Development (OECD). However, the pharmaceutical companies have showed remarkable

In principle, of course, the resulting deadweight loss could be greatly reduced if patent owners price discriminated their products to bring them within the reach of average citizens in poor countries.¹³ However, this solution has not been widely practiced outside of the developed countries in the past,¹⁴ and there is little expectation for its adoption in the future for at least two suggested reasons.

One theory is that big pharmaceutical companies fear “reference pricing,” that is, the likelihood that price regulators in developed countries, for example, Canada and the European Union, would weigh lower prices in developing countries against the producers in developed countries, as an excuse to impose further price reductions.¹⁵ The second theory is that the big pharmaceutical companies expect to earn more by selling their products at high prices to affluent circles in developing countries than might be gained from mass marketing at prices nearer the marginal costs of production.¹⁶

While other factors may also apply,¹⁷ my own view is that the two primary reasons identified above reinforce each other, in the sense that the big pharmaceutical companies earn enough from affluent circles in developing countries to deter them from running the risk of a reference pricing boomerang under a different policy. Whatever the reason, the fact remains that pharmaceutical products still on patent are being sold at prices the general public in developing countries cannot afford¹⁸ (unless decisions are made to donate the patents or the end products, as has sometimes occurred with AIDS antiretrovirals, or to subsidize their distribution, as occurs with some AIDS, tuberculosis and malaria drugs¹⁹).

To be sure, one group of countries, the poorest of the poor – technically

skill in segmenting markets with tiered differential pricing in these same OECD countries. *See id.*, at 172; Keven Outterson, *Pharmaceutical Arbitrage: Balancing Access and Innovation in International Drug Markets*, 5 YALE J. HEALTH POL’Y & ETHICS 193 (2005).

¹³ *See e.g.*, Allan O Sykes, *The TRIPS Agreement, Pharmaceuticals, Developing countries, and the Doha “Solution,”* Univ. of Chicago, John M. Olin Law & Economics Working Paper No. 140 (2d series) (2003?) (advocating price discrimination and fearing adverse influence of compulsory licenses).

¹⁴ K. Outterson, *supra* note 8, at 160.

¹⁵ *See, e.g.*, Patricia M. Danzon & Adrian Towse, *Theory and Implementation of Differential Pricing for Pharmaceuticals*, in INTERNATIONAL PUBLIC GOODS AND TRANSFER OF TECHNOLOGY UNDER A GLOBALIZED INTELLECTUAL PROPERTY REGIME (K.E. Maskus & J.H. Reichman, eds., Cambridge U. Press, 2005), 425-56.

¹⁶ This view is often attributed to James Love, CPtech.

¹⁷ *See, e.g.*, Sykes, *supra* note 13, (stressing fears of parallel imports and compulsory licenses as deterrents to more price discrimination).

¹⁸ *See, e.g.*, K. Outterson, *supra* note 8; F. M. Abbott, *supra* note 7, at 393-424; Joan Rovira, *Creating and Promoting Domestic Drug Manufacturing Capacities: A Solution for Developing Countries*, in NEGOTIATING HEALTH: INTELLECTUAL PROPERTY AND ACCESS TO MEDICINES (P. Roffe *et al* eds., Earthscan, 2006), at 227-40 [hereinafter NEGOTIATING HEALTH]. *See also* F. M. Scherer & J. Watal, *Post-TRIPS Options for Access to Patented Medicines in Developing Nations*, 2002 JIEL 913.

¹⁹ *See, e.g.*, Roy Widdus, *Product Development Partnerships on ‘Neglected Diseases:’ Intellectual Property and Improving Access to Pharmaceuticals for HIV/AIDS, Tuberculosis and Malaria*, in NEGOTIATING HEALTH, *supra* note 18, at 205-226. For a critical view, see K. Outterson, *supra* note 8 at 170 (“The Weakness of Voluntary Pricing Programs”).

designated Least-Developed Countries (LDCs) – remained immune from all the TRIPS patent norms until 2006, as the Agreement initially provided, and this built-in waiver was recently extended another seven to ten years.²⁰ But these Least-Developed Countries, like many or most other developing countries, lack production capacity of their own and depend to varying degrees on cheap imports from countries, such as India, where low-cost generics were available.²¹ This general shortage of pharmaceutical manufacturing capacity in poor countries means that once the generic supplier countries became subject to the TRIPS patent norms on pharmaceuticals in 2006, then both developing countries and Least-Developed Countries will be faced with the prospects of higher, and increasingly unaffordable drug prices.²² If suppliers in developing countries failed to comply with these international minimum standards of intellectual property protection and continued to manufacture unauthorized patented drugs, their governments could be hauled before WTO Dispute Settlement Tribunals and subjected to coercive, retaliatory trade sanctions.²³

Nevertheless, developing and Least-Developed Countries retained numerous countervailing weapons to deal with these problems even under the TRIPS Agreement as originally adopted, and without reference to posterior Ministerial action in connection with the Doha Round of Multilateral Trade Negotiations. In particular, the power of Members to impose compulsory licenses for virtually any reason survived the TRIPS negotiations at the end of the Uruguay Round, largely because United States law and practice continues to rely heavily on compulsory licensing of patented inventions for government use.²⁴

However, powerful governments were pressing the developing countries not to invoke compulsory licenses in this period, while even the World Health Organization (WHO) had been advising these same countries not to regulate pharmaceutical prices in the interest of overall free-market policies,²⁵ despite the widespread use of price controls in many OECD countries. At the same time, Big Pharma was challenging the very sovereign powers of developing nations to formulate and implement autonomous public health initiatives that conflicted with its own tough interpretations of post-TRIPS international minimum intellectual property standards.²⁶

²⁰ See TRIPS Agreement, *supra* note 3, art. 66.1. This initial exemption has since been rolled back to 2013, with a further exemption for patents on pharmaceutical products in LDCs until 2016. See *infra* note ____.

²¹ See, e.g., Rovira, *supra* note 18.

²² See *supra* note 5; J. Watal, *Pharmaceutical Patents, Prices and Welfare Losses: Policy Options for India Under the WTO Agreement*, 2003 J. WORLD ECON. 733.

²³ See TRIPS Agreement, *supra* note 3, art. 64; [*Canadian Pharmaceutical case*; *India Mail Box case*].

²⁴ See TRIPS Agreement, *supra* note 3 art. 31; Reichman with Hasenzahl (2003). For the negotiating history, see JAYASHREE WATAL

²⁵ See, e.g., Rovira, *supra* note 18, at 228.

²⁶ For example, the pharmaceutical industry claimed that:

- 1) TRIPS had eliminated a state's power to import parallel products – even genuine goods – from countries where they were sold at lower prices than those in the would-be importing states; i.e., Pharma claimed that, under TRIPS, states could only invoke a doctrine of national exhaustion, not international exhaustion.
- 2) Pharma also claimed that TRIPS had greatly narrowed every state's rights to impose compulsory licenses on patented inventions except in national emergencies; and,

Seasoned international intellectual property lawyers viewed most of these claims as bogus (I cannot take the time to walk you through the TRIPS Agreement to see why), and some important litigation occurred in South Africa and elsewhere, including the WTO itself, that was not favorable to Pharma's position.²⁷ Nevertheless, both the pharmaceutical companies and powerful governments were pressing developing countries to tow the Pharma line, and – with the exception of Argentina and Brazil (who settled with the United States)²⁸ – no governments were willing to run the political risks of bringing legal action to vindicate their rights before WTO tribunals.

What happened, instead, was that the OECD countries decided to launch another round of multilateral trade negotiations, known as the Doha Round, and to do this, they needed the consensus vote of the developing countries. The latter replied that there could be no consensus without resolving questions about their sovereign rights to address public health problems as they deemed necessary, notwithstanding TRIPS.²⁹

B. The Doha Solution

The upshot was a remarkable document, known as the Doha Declaration on the TRIPS Agreement and Public Health, of 14 November 2001 (slightly revised in 2002),³⁰ which vindicated the legal scholars' position and went much farther.³¹ Let us briefly review what the Ministerial Conference said about a state's residual powers to regulate public health.

First, in paragraph 1, the Ministers recognized the gravity of “public health problems afflicting poor countries, especially HIV/AIDS, tuberculosis, malaria, and other

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- 3) That states lacked the power to impose compulsory licenses for the purpose of exporting pharmaceutical products to poor countries that could not manufacture them under local compulsory licenses;
 - 4) Pharma also claimed that TRIPS had generally limited states' powers to implement the new international intellectual property standards in a flexible manner that differed from the high-protectionist patent norms in developed countries.

For the background, see Abbott, above note 5; *see also* Carlos M. Correa, *Health and Intellectual Property Rights*, 79 BULLETIN OF THE WORLD HEALTH ORGANIZATION 381 (2001); Carlos M. Correa, *Implications of the Doha Declaration on the TRIPS Agreement and Public Health*, WHO, Geneva (2002).

²⁷ *See, e.g.*, Abbott, *supra* note 5[7?]. In this period, Professors Correa, Reichman and others defended the WHO's interpretation of the TRIPS standards against attacks from the WTO Secretariat, USPTO, and Big Pharma. The positions espoused by the WHO were vindicated by subsequent Ministerial Decisions. *See* WHO publication. *See also* J. H. Reichman, *Securing Compliance with the TRIPS Agreement after U.S. versus India*, 1 JIEL 585 (1998) (noting Appellate Body's emphasis on legitimacy of flexible local implementation and need for deference to good faith efforts to comply with agreed standards).

²⁸ [cite Brazil and Argentina settlements].

²⁹ This position was always consistent with at least one reading of article * of the TRIPS Agreement. *See, e.g.*, Howse; Reichman (1996); Maskus & Reichman (2005).

³⁰ Doha Declaration on the TRIPS Agreement and Public Health, WTO doc. WT/MIN(01)/DEC/2, available at www.wto.org/english/thewto_e/minist_trips_e.pdf [hereinafter Doha Declaration on Public Health].

³¹ *See, e.g.*, Pedro Roffe et al, *From Paris to Doha: The WTO Doha Declaration on the TRIPS Agreement and Public Health*, in NEGOTIATING HEALTH, *supra* note 18, at 9-26; Correa (2007) *supra* note 26.

epidemics.”³² Notice that they did not require these health problems needing attention to rise to the level of national emergencies, and they did not limit the diseases for which remedial action may be taken to those identified in the text.. Here the Ministers categorically declared as follows:

4. We agree that the TRIPS Agreement does not and should not prevent Members from taking measures to protect public health. Accordingly, while reiterating our commitment to the TRIPS Agreement, we affirm that the Agreement can and should be interpreted and implemented in a manner supportive of WTO Members’ right to protect public health and, in particular, *to promote access to medicines for all*.

In this connection, we affirm the right of WTO Members to use, to the full, the provisions in the TRIPS Agreement, which provide flexibility for this purpose.³³

Then, in paragraph 5, the Ministers underscored some of the key flexibilities set out in the TRIPS Agreement, *viz.*:

- As regards parallel imports, the TRIPS Agreement leaves each member free to establish its own regime for...exhaustion without challenge, subject to the MFN and national treatment provisions of Articles 3 and 4.³⁴
- As regards compulsory licenses, Each member has the right to grant compulsory licenses and the freedom to determine the grounds upon which such licenses are granted.³⁵

Of course, these compulsory licenses remained subject to the conditions set out in article 31 of the TRIPS Agreement. This provision requires, *inter alia*, prior notification of rights holders, and good-faith negotiations with them, except in cases of extreme emergency,³⁶ and the payment of adequate remuneration,³⁷ unless the license results from proceedings sounding in competition law of abuse of patent rights.³⁸ It further requires the bulk of all drugs manufactured under a compulsory license to be sold only on the domestic market.³⁹

This last condition in article 31(f) of the TRIPS Agreement might have posed a

³² Doha Declaration on Public Health, *supra* note 30, ¶1.

³³ *Id.*, ¶4 (emphasis supplied).

³⁴ *Id.*, ¶5(d).

³⁵ *Id.*, ¶5(b)).

³⁶ TRIPS Agreement, *supra* note 3, art. 31(b).

³⁷ *Id.*, art. 31(h).

³⁸ *See id.*, art 31(k), 40.

³⁹ *Id.*, art. 31(f).

serious obstacle to resolving the patents impasse. Consider that, as both domestic and export prices rise under worldwide patent standards after 2005, when all developing countries (but not LDCs) must patent eligible new pharmaceuticals, low-cost imports from, say, India to Kenya, could shrink if drugs cost about the same in the relevant markets.⁴⁰ Meanwhile, if India attempted to impose a compulsory license there, say, on a patented AIDS drug, in order to aid Kenya, which lacked manufacturing capacity, it could not ship more than 49.9% of the resulting products abroad, under this provision in the TRIPS Agreement, unless safeguard provisions in articles 7 and 8 could be read to override this limitation.⁴¹

But here the Doha Declaration on TRIPS and Public Health took the remarkable step of overriding the TRIPS Agreement in this respect. In paragraph 6, the Ministers instructed the Council for TRIPS to remove this obstacle by political means:

We recognize that WTO Members with insufficient or no manufacturing capacities in the pharmaceutical sector could face difficulties in making effective use of compulsory licensing under the TRIPS Agreement. We instruct the Council for TRIPS to find an expeditious solution to this problem and to report to the General Council before the end of 2002.⁴²

The Declaration then went on to address the lack of manufacturing capacity even more directly in paragraph 7. First, it reminded OECD countries that they had a duty “to provide incentives to their enterprises and institutions to promote and encourage technology transfer to least-developed Members pursuant to Article 66.2”⁴³ Second, the Ministers extended the least-developed countries’ immunity from the obligation to protect pharmaceutical patents another ten years, i.e., from 1 January 2006 to 1 January 2016.⁴⁴

However, one stumbling block remained in place as of 2002, namely, that the Council for TRIPS had yet to implement the Ministerial decree to find some agreed way to allow countries with manufacturing capacity to export patented medicines to countries

⁴⁰ Whether patentees in India will display a greater willingness to price discriminate there and elsewhere, than in the past remains to be seen. For the advantages of such a policy for consumers, *see* Sykes, *supra* note .

⁴¹ For the view that articles 7 and 8, plus article XX(d) of the GATT (1994), should be read this way, *see* Keith Maskus & Jerome H. Reichman, *The Globalization of Private Knowledge Goods and the Privatization of Global Public Goods*, in INTERNATIONAL PUBLIC GOODS AND TRANSFER OF TECHNOLOGY UNDER A GLOBALIZED IP REGIME, *supra* note, at . *See also* Suzy Frankel, *WTO Application of “the Customary Rules of Interpretation of Public International Law” to Intellectual Property*, 46 VIRGINIA J. INT’L L. 365, 390-402 (2006). For a critical view that WTO Panels have not read articles 7 and 8 this way, *see* Robert Howse, . *See also* ICSD/UNCTAD, RESOURCE BOOK .

⁴² Doha Declaration on Public Health, *supra* note 30, ¶6.

⁴³ *Id.*, ¶7; TRIPS Agreement, *supra* note 3, art. 66.2.

⁴⁴ Doha Declaration on Public Health, *supra* note 30, ¶7. *See also* [other cites]. The Doha Declaration also allowed LDCs “to seek other extensions of the transition,” in conformity with art. 66.1 of the TRIPS Agreement itself. *See* Doha Declaration on TRIPS and Public Health, *supra* note , ¶8.

that lacked it, against the will of local patentees.⁴⁵ In a word, would-be assisting countries that did not want to invest directly in enabling least-developed countries to manufacture needed medicines locally would have to impose compulsory licenses for export purposes, a practice that TRIPS article 31(f) as written continued to impede.

C. Amending the TRIPS Agreement

It took the TRIPS Council more than two years to address this problem, but it finally reached a compromise agreement on 30 August 2003, known as Implementation of Paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health.⁴⁶ This Decision took the form of a temporary consensual waiver of article 31(f) for specified purposes, adopted by the General Council of the WTO.⁴⁷ After protracted negotiations, that waiver was finally converted to a permanent amendment of the TRIPS Agreement on 6 December 2005,⁴⁸ to be ratified by 2007, with the waiver still in effect until that time.⁴⁹

The Amendment of 6 December 2005 differs little from the Decision of 30 August 2003,⁵⁰ and Madam Jayashree Watal, of the WTO Secretariat, has provided more details.⁵¹ For present purposes, we can summarize the positive aspects of this Amendment, to be known as Article 31*bis* of TRIPS, as follows.

If a WTO Member amends its domestic patent law to allow exports under a compulsory license in order to assist a country that lacks manufacturing capacity, new article 31*bis* will suspend application of old article 31(f). Hence the total production may be exported up to the needs of the importing country.⁵² Notice that all would-be importing countries may benefit from this exception, not just least-developed countries, provided that they can demonstrate “insufficient or no manufacturing capacities in the pharmaceutical sector for the product(s) in question.”⁵³ However, some more advanced

⁴⁵ Doha Declaration on Public Health, *supra* note 30, ¶6.

⁴⁶ Implementation of Paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health, Decision of 30 August 2003, Annex to the Protocol Amending the TRIPS Agreement, art. 31*bis* [hereinafter art. 31*bis*], WTO Doc. WT/L/50, 2 September 2003; see also The Statement of the Chairman, reproduced in the Annex and in the Minutes of the [General Council].

⁴⁷ See generally Frederick M. Abbott, *The WTO Medicines Decision: World Pharmaceutical Trade and the Protection of Public Health*, 99 AJIL 317-58 (2005). For criticism, see Sykes, *supra* note 13; Thomas Cottier, *The Doha Waiver Compromise and Its Effects on the Nature of the TRIPS System of International Intellectual Property Protection*, paper presented to the Workshop on Issues of Public Policy and Trade in Intellectual Property Law, College of Europe, Bruges, Belgium, 5 October 2005.

⁴⁸ Amendment of the TRIPS Agreement, Decision of 6 December 2005, WTO doc. WT/L/64/, 8 December 2005; see also WTO 2005 Press Releases, Press/426, 6 Dec. 2005, “Intellectual Property.”

⁴⁹ See Sisule F. Musungu, *The 6 December 2005 TRIPS Amendment and Public Health at the WTO*, INTELLECTUAL PROPERTY QUARTERLY UPDATE, FOURTH QUARTER 2005, South Center and CIEL, Geneva, 2005, at 1-6.

⁵⁰ See S. Musungu, *supra* note ____.

⁵¹ See Jayashree Watal, paper presented to the Conference on Saving Profits, Saving Lives, North Carolina Journal of International Law and Commercial Regulation, University of North Carolina School of Law, Chapel Hill, North Carolina, February 24, 2006.

⁵² See art. 31*bis*, *supra* note 30, ¶1, plus Annex, ¶1(a), (b).

⁵³ *Id.*, plus Annex ¶2(a)(ii).

countries have opted out of this possibility, and non-LDCs opting in must expressly notify the Council for TRIPS of their intentions to use the system.⁵⁴

If one country asks another for help, two compulsory licenses would likely have to be issued, one in the importing country needing assistance and the other in the exporting country seeking to provide it, where the products would be made, specially packaged to prevent re-exports, and shipped.⁵⁵ In that case, compensation would be paid to the company in the exporting country only, but rates would presumably be based on the value of the product in the poorer importing country.⁵⁶

Of particular interest is the possibility of achieving economies of scale under special rules applicable if developing countries and least-developed countries decided to band together in regional trade agreements (minimum 50% LDCs). These rules would then enable an importing poor country A (say Kenya) to re-export the products made under the compulsory license from assisting country B (say, India) to all the other member countries of the regional trade agreement “that share the health problem in question.”⁵⁷ Note that this power to re-export to a predetermined group of countries derogates from the general rule under article 31*bis*, which normally forbids all re-exports and imposes serious obligations on Members to take measures to prevent them.⁵⁸

For example, the Common Market for Eastern and Southern Africa (COMESA), an African trade block consisting of some twenty countries, reportedly “applied to the WTO in 2002 [under the waiver] for the right to manufacture cheap antiretroviral drugs and to treat COMESA as one region so that drugs manufactured [under compulsory licenses] in one country can be sold to all Member States without problems.”⁵⁹ As a result, economies of scale become possible and producers in India could more confidently invest in large-scale production, because they could potentially supply the entire regional area under amended TRIPS 31*bis*, if the other conditions were met.⁶⁰

Now, there are one or two other good things in this Amendment that I lack time to mention, plus plenty of bad things, especially cumbersome procedural duties and obligations, which others have described. Nevertheless, these provisions taken together create a solid foundation for exploring the possibilities of a pooled regional procurement strategy that I first proposed in 2002,⁶¹ when the legal landscape was much less promising.

⁵⁴ *Id.* ¶1, plus Annex 1(b); Chairman’s Statement, *supra* note ; Musungu, *supra* note --. *See also* FTAs.

⁵⁵ *Id.* ¶2. *See* art. 31*bis*, *supra* note 39.

⁵⁶ *Id.* (requiring “adequate remuneration pursuant to article 31(h)...taking into account the economic value to the importing Member of the use that has been authorized in the exporting Member.”). *See generally* James Love [WHO Guidelines on Compensation for Compulsory Licensing].

⁵⁷ *See* art. 31*bis*, *supra* note 30, ¶3.

⁵⁸ *See id.*, Annex, ¶¶3-4 (measures to prevent re-exportation and to prevent importation of relevant product).

⁵⁹ Rovira, *supra* note 18, at 229.

⁶⁰ *Id.*

⁶¹ *See* J. H. Reichman, *Patents and Public Health in Developing Countries: Bargaining Around the TRIPS Impasse*, paper presented to the Conference on Access to Essential Medicines, University of Wisconsin School of Law, March 8-10, 200?.

II. Towards Regional Pharmaceutical Supply Centers

My proposal to establish collective purchasing organizations in poor countries – Regional Pharmaceutical Supply Centers (RPSC) – was intended to address both problems identified above, namely, high-priced imports and the lack of local manufacturing capacity.⁶² Some experiments with regionally pooled procurement suggest that “these institutions may be able to access and exchange regional expertise more efficiently than global agencies, particularly with regard to new medicine suppliers in the region and local product availability and quality.”⁶³ As a practical matter, regional procurement institutions “may also have the advantage of being able to work more efficiently with national and local governments to harmonize regulatory standards, monitor financial accountability, and monitor the supply chain, all the way to the point of access.”⁶⁴

Besides these practical advantages, it seemed to me that Least-Developed Countries in particular possessed unique possibilities to exploit their preferential status under TRIPS,⁶⁵ not to become havens of piracy, but rather to become models of smart regulatory tactics. However, my proposal faced daunting obstacles between 1995 and 2000 because of the limits on compulsory licensing for export under article 31(f), discussed above,⁶⁶ and also because of the narrow space for exceptions to the TRIPS patent standards under article 30.⁶⁷ Any large-scale pooled procurement initiative undertaken in this period would necessarily have rested on the untested powers of the safeguard clauses in TRIPS – articles 7 and 8 – and on the residual powers of states with regard to public health under article XX(d) of the GATT (1994).⁶⁸ Whatever rights these provisions may ultimately be held to confer on WTO Members, they did not provide an adequate legal foundation for establishing medium and long-term procurement arrangements with risk-averse potential suppliers in other developing countries⁶⁹ or with potential generic producers in developed countries.

In contrast, the recent amendment to the TRIPS Agreement in article 31*bis*,

⁶² *See id.*

⁶³ Anthony So, (Draft) *OSI Report*, *supra* note 1, at 11 (citing examples of African Association of Central Medical Stores (ALAMTE); Gust Cooperation Council; Organization of Eastern Caribbean States (OECS); Pacific Island Countries; PAHO Strategic Fund).

⁶⁴ Anthony So, (Draft) *OSI Report*, *supra* note 1, at 11.

⁶⁵ See TRIPS Agreement, *supra* note 3, arts. 66-67.

⁶⁶ See *supra* text accompanying notes .

⁶⁷ See TRIPS Agreement, *supra* note 3, art. 30; *Canadian Pharmaceutical Products* case; Howse, *supra* note 41.

⁶⁸ See Maskus and Reichman, *supra* note 32, at 41. *See also* RESOURCE BOOK, *supra* note 41; S. Frankel, *supra* note 41.

⁶⁹ “Some level of industrial production of medicines and health supplies already occurs in most countries of the world. For example, large middle-income industrialized countries, such as Argentina, Brazil, China, Cuba, Egypt, India, Indonesia and South Korea have long produced vaccines for domestic use. Even in Africa, manufacturing of health products occurs in 38 countries.” Anthony So, Draft *OSI Report*, *supra* note 1, at 12 (noting that in many of these countries, local manufacturing capacity may be externally funded and staffed).

together with both the spirit and technical provisions of the Doha Ministerial Declaration on the TRIPS Agreement and Public Health, and its progeny,⁷⁰ have provided a solid legal foundation for establishing Regional Pharmaceutical Supply Centers along the lines outlined below. This conclusion follows, in part, from the fact that developing countries lacking production capacity may now freely import needed medicines from willing suppliers abroad under the double compulsory licensing scheme envisioned in article 31*bis*.⁷¹ It also follows from the fact that the LDCs were formally entitled to establish manufacturing zones in their territories to produce generic versions of expensive drugs with impunity from international patent standards, at least until 2016, if not longer.⁷²

Of course, I am downplaying the technical difficulties that Least-Developed Countries might encounter in meeting international quality standards,⁷³ although case studies show that, for example, Bangladesh and Columbia have succeeded in doing so.⁷⁴ I have also chosen to ignore the World Bank's warnings about inefficiency and the lack of comparative advantage in establishing local pharmaceutical production facilities,⁷⁵ in part because the notion that Africa should remain almost totally dependent on foreign suppliers of essential medicines seems repugnant and unacceptable, and in part because it would deprive researchers in developed countries of promising inputs from traditional knowledge that might otherwise become available.⁷⁶ But I do stress that OECD countries labor under an as yet unfulfilled duty to provide incentives to their firms to transfer technology to Least-Developed Countries;⁷⁷ while developing country producers, such as those in India, China and perhaps Brazil, might be induced to invest in supplying medicines even to least-developed countries if it became feasible for production facilities – wherever located -- to attain economies of scale.

In what follows, I will first outline some of the reasons for undertaking a pooled regional procurement approach. I will then sketch the basic proposal and discuss various legal tools and techniques for implementing it.

A. The Social Costs of a Non-cooperative Approach

The Doha Declaration on the TRIPS Agreement and Public Health reflects the common interest of all WTO members in avoiding irreconcilable conflicts between public health policies and the norms of TRIPS. This conclusion follows because all WTO members have a stake in the results of the Uruguay Round and in the integrated

⁷⁰ See *supra* notes and accompanying text.

⁷¹ See *supra* notes and accompanying text.

⁷² See *id.*, ¶8 (allowing LDCs “to seek other extension of the transition periods” as allowed by art. 66.1 of the TRIPS Agreement).

⁷³ See, e.g., Anthony So, (Draft) *OSI Report*, *supra* note 1, at 12.

⁷⁴ See, e.g., Rovira, *supra* note , at 234-38. The WHO has programs to assist both private and public suppliers in this regard. See _____.

⁷⁵ See Rovira, *supra* note 18, at 232 (citing World Bank paper by Kaplan and Lang (2005) which stresses high costs of local production due to imports of equipment and raw materials).

⁷⁶ See TRIPS Agreement, *supra* note 3, art. 66.

⁷⁷ See, e.g., Cottier & _____ (2005); Dutfield (2005); Lewis & Reichman (2005).

global marketplace that it helped to establish.⁷⁸ The Doha Declaration on TRIPS and Public Health thus seeks to reconcile the systemic goals of TRIPS with the needs of states – particularly the developing and least-developed countries – to address serious public health concerns in a manner that inflicts as little damage as possible on the calculus of costs and benefits built into the agreed standards of intellectual property protection.

Everyone understands that translating the principles expressed in the Doha Declaration into laws and practices will not be easy. Along the way, we need to devise a strategy that would maximize the incentives of the private sector to cooperate in the enterprise⁷⁹ while preserving and enhancing the developing countries' capacities for economic growth and autonomy at the local level.⁸⁰

Autonomy requires that developing countries possess both the capacity and the determination to defend their rights and interests under TRIPS and other WTO Agreements, without sacrificing the flexibility inherent in that agreement to unilateral threats and pressures that are often illegal under those same Agreements.⁸¹ In this regard, there are serious concerns, not about the lack of legal tools, but rather about the transaction costs and inefficiencies inherent in the prospects that developing countries will address these problems of access to essential medicines as the need arises and on a state by state basis.

As Professor Fred Abbott's articles show, the status of every medicine in question *vis a vis* different states will vary with the status of patents in each state; their duration; the availability of exclusive marketing rights; the status of the state as developing or Least-Developed Country; the availability of extended transition periods; the availability of parallel imports; the state's specific policy on compulsory licenses and the modalities for implementing it; the availability of supplies from friendly countries; and, with the willingness of state's having stocks to make them available to other states, possibly under complementary compulsory licenses for export.⁸² This list of legal variables poses a potential obstacle to addressing the post-TRIPS problem of access to essential medicines in a sound and systematic manner, especially if single governments attempt to deal with it on a case by case approach.

More generally, haphazard legal action by single states is limited by the territoriality principle of international patent law and by the independence of patents doctrine,⁸³ which support the kind of market segmentation in which each new problem

⁷⁸ See, e.g., Doha Declaration, *supra* note 30, ¶3 (recognizing that “intellectual property protection is important for the development of new medicines.”); Maskus & Reichman, *supra* note 41, at 18-20 (finding that the TRIPS Agreement gave birth to an incipient transnational system of innovation).

⁷⁹ See, e.g., Sykes, *supra* note 13.

⁸⁰ See, e.g., Margaret Chon, *Intellectual Property and the Development Divide*, 27 CARDOZO L. REV. 2821 (2006).

⁸¹ See WTO Panel Report on Section 301 (2000).

⁸² See generally, Abbott I (pre-Doha); Abbott II (post-Doha).

⁸³ See Paris Convention for the Protection of Industrial Property (1967), arts 1-2, 4bis; TRIPS Agreement, *supra* note 3, arts 2.1 (incorporating arts 1-12, 19 of the Paris Convention); 3-4 (national treatment and Most-Favored Nation principle).

entails a new cat-and-mouse game between patentees and the local government. In this game, the patentees are the repeat performers, and their powers are augmented by the limited sources of supply—especially of key active ingredients—outside the control of big pharmaceutical companies based in developed countries. As a result, these companies seem likely to influence the choice of rules under which specific legal contests will occur and the pace at which ultimate decisions will be made.⁸⁴ To the extent that a global strategy facilitates such transactions, then that strategy will likely be theirs, with developing countries forced to stretch their resources to address these shifting tactics as they play out in many different forums.

Strategies premised on national action alone could thus entail high transaction costs in overcoming an endless array of technical legal obstacles, and they could require levels of organizational and administrative skills and drive that are seldom found in developing countries. Given a predictable lack of coordination among developing country governments, moreover, action by single states on a case-by-case approach will remain vulnerable to strong legal and economic pressures by rights holders, in the form of defensive actions to choke off critical sources of supply in addition to efforts to deter other states from seeking alternative sources of supply in the first place. Even when single battles are won over a specific medicine needed in any given country, the whole process must then be wound up and started over again for the next drug in the next country, with all the legal, economic, and political costs to be repeated without end.

Disjointed regulatory action at the national level thus reinforces the tendency to exploit temporary legal loopholes and strategic opportunities that occur almost at random, and usually as a response to strategies dictated by patentees. It also antagonizes these same patentees (and their governments) and further encourages them to exploit temporary legal, technical, and political advantages to maximize short-term gains. At the end of the day, this patchwork quilt of territorial measures and countermeasures adds to the transaction costs of all the stakeholders without appreciably stabilizing the chain of supply or ensuring access to essential medicines for citizens in poor countries as a whole. Above all, this strategy does little to increase local capacity to produce essential medicines or to reduce the dependence of poor countries on distant foreign suppliers whose research agendas are overwhelmingly geared to market opportunities in developed countries.⁸⁵

B. Reinforcing Autonomy Through Cooperative Ventures: Regional Suppliers of Last Resort

A more promising strategy is to think in regional or sub-regional terms, with a view to standardizing procedures, to lowering the transaction costs of all participating countries, and to stabilizing the availability of medical supplies that all the participating countries are likely to need. To this end, I propose that Regional Pharmaceutical Supply Centers (RPSCs) should be established (preferably in extra-territorial customs zones) that

⁸⁴ See most recently the dispute between Novartis and the Indian government concerning second uses of medicinal patents.

⁸⁵ See generally K. Outtersson, *supra* note 8.

would operate as the designated agents of participating national governments and of any regional cooperative entity they decided to establish.

The primary task of any given regional supply center would, of course, be to procure and distribute the needed supplies, according to schedules and modalities discussed below. In that sense, it would operate as a central exchange and distribution facility, in much the same way that single private suppliers currently provide discounted medicines to old-age homes, prisons, or other institutions in the United States. At the same time, the proposed RPSCs could serve to standardize regulatory procedures and stimulate increased investment either in existing production facilities located within the region or in new production facilities, possibly situated in Least-Developed Countries that would enjoy prolonged transitional immunities (until at least 2016) under the TRIPS Agreement and the Doha Declarations.⁸⁶

In the short and medium-term perspective, the Regional Pharmaceutical Supply Centers should concentrate on fulfilling their primary role as supplier of last resort to member countries seeking access to essential medicines at the lowest possible prices. As agents of the participating governments, whose Health Ministers would ideally constitute the Center's Board of Directors, the RPSC would possess a formidable array of strategic options.

First, countries interested in price regulation of pharmaceuticals as occurs under the Canadian system,⁸⁷ could harmonize and coordinate their policies in this regard. Second, with or without price regulation mechanisms, an advantage of the proposed regional approach is the opportunities it might create to provide incentives to the major pharmaceutical companies to themselves become the "low-bidders" under the supply contracts offered by the central procurement agency. Besides avoiding the imposition of compulsory licenses, for example, companies that cooperated with the regional entities would stand to preserve market share and to benefit from economies of scale and scope. In a cooperative game, the pharmaceutical companies could also seek to alleviate the threat of parallel imports from alternative general suppliers, especially if they committed to expanding local production facilities within the region itself.

A third option would be for the central procurement agency to manage jointly emitted compulsory licenses where needed, as more fully described below. To the extent that compulsory licenses were issued at the national level, the RPSCs should offer their services as a standard designated supplier under standard-form licenses. The RPSCs would then operate intra-regionally and, if necessary, inter-regionally to satisfy the needs of single members, with maximum emphasis on potential gains from technical cooperation between developing countries (TCDC).

⁸⁶ See Doha Declaration on Public Health, ¶7. The extra-territorial customs zone in which a given RPSC was located could itself pertain to an LDC. If developed countries helped such a center to gradually establish its own production and quality control capabilities over time, it could enable them to better discharge the transfer of technology obligations that article 66.2 of the TRIPS Agreement has so far mandated to little avail.

⁸⁷ See Reichman with Hasenzahl, *The Canadian Experience* (ICTSD/UNCTAD 2003).

A fourth option would arise from the central procurement agency's enhanced opportunities to stimulate local production of selected medicines. With or without compulsory licenses, cooperative relations between the regional supply centers and the major pharmaceutical producers could thus engender specific commitments to increase direct investment within the region and to heightened support for training and research that would enhance the region's own capabilities.

Cooperation should also lead to more and better technical assistance from developed countries, especially with a view to supporting public-private partnerships that could grow out of appropriate regional undertakings. This fifth option could become particularly important if developed country governments subscribed to a novel proposal to "buy out" the rights to supply developing country markets from the pharmaceutical companies themselves.⁸⁸

All these strategic options are examined in more detail below. Taken together, they exemplify the opportunities that the proposed Regional Pharmaceutical Supply Centers create for stakeholders to "bargain around the TRIPS Agreement"⁸⁹ in ways that could promote win-win situations for all concerned, if efforts to address access to essential medicines can move beyond a conflictual ethos to a more cooperative approach.

1. The Price Control Option

Many countries regulate the prices of pharmaceuticals sold to the public, a practice that remains unaffected by the TRIPS patent standards as adopted in 1994.⁹⁰ One of the most instructive examples of this practice is that of Canada, which had relied for decades on a system of automatic statutory compulsory licenses for patented pharmaceuticals.⁹¹ Because Canada instituted the Patented Medicines Price Review Board (PMPRB) in 1987, when the compulsory licensing scheme previously applied to medicines was abrogated under pressure from the United States,⁹² its experience seems particularly relevant to that of the developing countries in the post-TRIPS environment.

a. The Canadian Model

The PMPRB is empowered to order patentees to reduce excessive prices for medicines and to take other remedial measures that include ordering price reductions for

⁸⁸ See K. Outterson, *supra* note 8, 171-73 ("The Patent Buy-Out Proposal"); *infra* text accompanying notes

⁸⁹ See generally J. H. Reichman & David Lange, *Bargaining Around the TRIPS Agreement: The Case for Ongoing Public-Private Initiatives to Facilitate Worldwide Intellectual Property Transactions*, 9 DUKE J. COMPAR. & INT'L L. 11-65 (1998).

⁹⁰ That intellectual property rights confer a negative right to exclude competitors, but not a positive right to market the protected products, was recently confirmed by a WTO decision. See *EC—Trademarks and GIs* (WTO 2005) para 7. However, FTAs may link patents to regulatory approval and limit a state's freedom of action in this regard. See, e.g., Abbott, ____.

⁹¹ Reichman with Hasenzahl, *supra* note 87.

⁹² See *id.*

another of the patentee's medicines. However, it notably lacks the power to authorize a compulsory license after the legislative changes of 1992.⁹³

The PMPRB makes the determination of what constitutes an excessive price based on a comparison of several factors, including the price of the medicine in other selected OECD markets (reference pricing), the price of similar medicines in the Canadian market, and changes in the Canadian Consumer Price Index. In this connection, the Board may compel patent holders to provide a broad range of information about sales price, costs of making and marketing, competitors' prices and other matters. When the price requested by the manufacturer is deemed excessive, the PMPRB initially approaches the manufacturer requesting voluntary price reductions. Typically this has worked, even though the PMPRB itself lacks statutory authority to impose a compulsory license to remedy the situation. Needless to say, a regulatory scheme that could also dispose of compulsory licenses would give developing countries more bargaining clout with big pharmaceutical companies than the PMPRB.

In Canada, if the manufacturer refuses voluntary price reductions, the PMPRB may proceed with public hearings, which can result in sanctions, including ordering price reductions, ordering price reductions for another medicine produced by the patent holder, or assessing damages payable to the Crown.⁹⁴ This scheme is codified in the Canadian patent law, but developing countries would be well advised to include price regulation in either their health care or competition law statutes to avoid claims of discriminatory treatment of patented pharmaceuticals.⁹⁵ If so, the sanctions might fall under the traditional grounds of abuse, recognized in both the Paris Convention and the TRIPS Agreement, which further support the emission of compulsory licenses on more favorable terms, if needed.⁹⁶

b. A Model for Developing Countries

Developing countries participating in a regional procurement arrangement must first decide whether they will singly or collectively adopt price controls for essential medicines. In so doing, they must also decide whether or not to retain a compulsory license as a sanction for failure to comply with a pricing board's decisions. With these choices out of the way, the regional entity could be empowered to conduct a pricing review along the lines suggested above, with a view to establishing a quasi-generic manufacturing price for original producers valid for the regional market as a whole (or at least for those states willing to participate in the exercise).

This approach could conceivably alleviate the need to resort to compulsory licensing in most situations. For example, Al Engelberg, a patent attorney known for his efforts on behalf of the U.S. generic drug industry, suggests that a structure similar to the Canadian model could be adapted for developing countries, with a view to limiting

⁹³ *See id.*

⁹⁴ Reichman with Hasenzahl, ICTSD/UNCTAD Study (2003).

⁹⁵ *See* TRIPS Agreement, *supra* note 3, art. 27.

⁹⁶ *See* Paris Convention, art. 5A; TRIPS Agreement, *supra* note 3, art. 31(k).

encroachments on IPRs as such. In his view, the best solution is to persuade the patent holder to deal on reasonable terms, which avoids the logistical difficulties and lack of efficiency that compulsory licensing may entail.⁹⁷ Such a model law could also address the lack of pharmaceutical manufacturing capacity in many of the Least-Developed and developing countries, a problem that is specifically noted as an area for study in the Doha Declaration on Public Health.⁹⁸

In this regard, Engelberg stresses the principle that a patent on a pharmaceutical does not give the patent owner absolute control over pricing, which is well established and does not violate the TRIPS Agreement.⁹⁹ Moreover, the argument that the pharmaceutical companies need higher prices to cover research costs seldom applies to developing countries – at least at the present time – because the companies’ investment calculus was based on the expected return from the sale of most new and existing products in the developed nations.¹⁰⁰

Professor Outterson’s recent study largely confirms Engelberg’s earlier insight. He found that, with regard to global diseases, “a robust level of research is assured by high-income markets alone” and that relevant decisions to commit resources to R&D remain largely unaffected by any prospects of cost recovery from low- and middle-income countries.¹⁰¹ According to Outterson, the “powerful lure of high-income markets—particularly the U.S., the EU, and Japan—draw R&D funds to global diseases, without much regard for the market potential in countries like Brazil or Costa Rica.”¹⁰²

The extent to which this phenomenon results from a lack of adequate intellectual property protection, as Professor Sykes contends,¹⁰³ or is mainly the product of poverty as Outterson claims,¹⁰⁴ remains an open question that I will return to later in this paper.¹⁰⁵ For present purposes, it suffices to note that both Engelberg and Outterson conclude that programs to secure access to essential medicines at prices people in developing countries can afford, such as those under review here, will not undermine R&D incentives in global diseases generally. For that reason,

a strong economic and moral argument can be made that the price of a drug in a developing nation should not include any direct or indirect development costs. In short, developing nations, like developed nations, should be allowed to control the price of a pharmaceutical and, in doing so, can set a price which is *based on the cost of goods plus a reasonable manufacturing profit* rather than on a western-based value system.¹⁰⁶

⁹⁷ Letter from Al Engelberg; see also, Sykes, *supra* note 13.

⁹⁸ See Doha Declaration on Public Health, Para. 6.

⁹⁹ See *supra* note ___ and accompanying text.

¹⁰⁰ See Engelberg, *supra* note 97; K. Outterson, *supra* note 8, at 163

¹⁰¹ K. Outterson, *supra* note 8, at 163.

¹⁰² *Id.*

¹⁰³ See Sykes, 3 CHI. J. INT’L L. 47, 58-62 (2002).

¹⁰⁴ See K. Outterson, *Pharmaceutical Arbitrage*, *supra* note 12.

¹⁰⁵ See *infra* text accompanying notes ____.

¹⁰⁶ Communication from Al Engelberg (emphasis supplied)

Of course, this situation could change over time, as worldwide patent protection gave producers new incentives to focus research on the needs of developing countries.¹⁰⁷ For this and other reasons, Outterson proposes that developed country governments, or public-private partnerships, simply buy out any R&D cost recovery components attributable to developing country markets in advance.¹⁰⁸

In the meanwhile, Engelberg suggests that, under a price regulation scheme tailor-made for developing countries, a five per cent royalty added to the marginal cost of generic production would suffice to support a right of first refusal afforded patentees. In his view,

once a price that has been based on cost of production is set, a patent owner willing to sell at that price should retain exclusivity. In short, the patent owner should have a right of first refusal to sell a patented product anywhere in the world at the lowest price that the product could be purchased from a third party anywhere in the world (with, perhaps, a modest up charge of 5 per cent or less on that price as a reasonable royalty).¹⁰⁹

Without necessarily going this far, I am persuaded that analogous pricing mechanisms can be used at regional levels, and if necessary, they can be reinforced by compulsory licensing powers. At the very least, a combination of price regulation and compulsory licensing affords a set of legal tools that can be used to break the log jam impeding access to essential medicines in specific cases, and the Doha Declaration on TRIPS and Public Health has further potentiated these tools.

To be sure, nothing prevents a national government from conducting its own price regulation exercise; but the regional entities' clout could be greater and the incentives to settle might also prove more attractive to the rightholders. For example, if a patentee agreed to become low bidder at prices acceptable to the regional agency, it might become willing to organize local production by licensing a small pharmaceutical company in the region and by supplying both technical expertise and key active ingredients. It might then legitimately seek to obtain concessions immunizing it from parallel imports and from competition from other external generic suppliers outside the region.¹¹⁰

If the patentees failed to comply or to agree to an acceptable regulated price, then it would free the RPSC to seek supplies at satisfactory prices from any potential suppliers within the region that were willing and able to meet its conditions. In this connection, RPSC could seek to construct chains of compulsory licenses to support these

¹⁰⁷ See, e.g., Sykes, *supra* note 13; Cottier, *supra* note 47.

¹⁰⁸ See K. Outterson, *supra* note 8.

¹⁰⁹ Communication from Al Engelberg.

¹¹⁰ If production by local entities proved infeasible, then a second solution would be to encourage the foreign patentee to produce the target drug somewhere within the region.

suppliers, if necessary.¹¹¹ If no supplies were available from within the region at the target prices, RPSC may seek to import the products from any foreign source or to stimulate local production, either in some regional facility or under its own means, if it manages to acquire the necessary production capabilities.¹¹²

2. Cumulative Compulsory Licenses

Suppose that twelve countries in Sub-Saharan Africa decide to form a loose regional trade agreement to qualify under article 31*bis*(3).¹¹³ Assume that at least six of these countries are Least-Developed Countries, whose governments further decide to establish a Regional Pharmaceutical Supply Center on the territory of one or more of those same LDCs.

The Board of Directors of the RPSC should ideally consist of the Health Ministers of the twelve member states. This Board decides which essential medicines the region as a whole will seek initially to obtain at low, affordable prices from either local or foreign suppliers, after assessing their existing manufacturing capacities, or especially the lack thereof.¹¹⁴

Once these decisions are taken, all the participating governments then proceed to emit the necessary compulsory licenses under article 31*bis*(2) (assuming a demonstrable lack of manufacturing capacity). The local governments then endorse their respective compulsory licenses over to the RPSC, as their designated agents, and charge it with organizing procurement or production of the drugs in question.

Here, use of a TRIPS-compliant standardized license is assumed.¹¹⁵ However, I am begging the question of the grounds underlying the issuance of these licenses, which could vary from generic “public interest,” to extreme urgency, to anti-competitive practices, or even “governmental use,”¹¹⁶ depending on the facts at hand, on the domestic laws of the countries authorizing the licenses, and on policies yet to be developed. In practice, the choice of grounds would influence the number and nature of pre-conditions that issuing states would have to meet,¹¹⁷ with maximum flexibility accruing from

¹¹¹ See *infra* ____

¹¹² See *infra* text accompanying notes ____.

¹¹³ See art. 31*bis*(3), *supra* note 30. In practice, Professor Coenrad Visser advises that use of existing Customs Zones or Unions affords many advantages, including the means to avoid import duties on medicines under existing laws. See Coenrad Visser, Comments (on this paper) presented to the Conference on Trade, Development and Intellectual Property Rights, Chicago-Kent School of Law, October 10-11, 2006.

¹¹⁴ As previously discussed the Board may also wish to consult on common regulatory pricing mechanisms, like those adopted by the PMPRB in Canada, if they can bring themselves to follow the policies adopted in many OECD countries despite WHO’s questionable advice to the contrary. See J. H. Reichman with C. Hasenzahl, *Non-voluntary Licensing of Patented Inventions, Part II: The Canadian Experience*, UNCTAD-ICTSD, Geneva, 2003. See Rovira, *supra* note 5.

¹¹⁵ The World Bank has reportedly been working to formulate standard form licenses for this purpose.

¹¹⁶ See TRIPS Agreement, *supra* note 3, art. 31; Reichman with Hasenzahl, Part I, *supra* note ____.

¹¹⁷ See TRIPS Agreement, *supra* note 3, arts. 31(a)-(b) (requiring notice, good faith negotiation, and adequate compensation except in cases of emergency).

compulsory licenses rooted in refusals to deal, excessive pricing, or other aspects of competition law.¹¹⁸

Efforts would then be made to pool all the separate compulsory licenses issued for the product in question into a *de facto* region-wide compulsory license, which the RPSC would undertake to satisfy. This puts the Health Ministers, *qua* Directors of RPSC, in a position to engage in tough and strategic negotiations with pharmaceutical companies, with lots of options, backed by a variety of carrot and stick approaches.

The RPSC would proceed to tender offers seeking to fulfill these needs as agents of the governments emitting the compulsory licenses. In executing its mandate, the regional supplier should normally first seek to meet its needs through voluntary purchases of genuine goods from authorized distributors operating within the region, on the condition that such providers made their products available at acceptable, negotiated prices, notwithstanding any legal monopolies they possessed. The regional entity, negotiating on behalf of its buyer governments would thus conduct price negotiations, with a view to inducing rightholders to become low bidders on the project.¹¹⁹

If such a deal were concluded, the rightholders would themselves supply the entire regional market under the auspices of the RPSC at the agreed prices, which would apply market-wide or in negotiated tiers. Ideally, such a settlement could envision licensing, technical assistance, and the provision of key active ingredients to a local partner, which would obviate the need for imports from beyond the region.

In these negotiations, the patentees know that a supply of generics may otherwise be commissioned from low-cost suppliers elsewhere, say, in India, China, or Brazil. The foreign patentee also understands that in dealing positively with the RPSC, it stands to enhance its trademark and to preserve market share in the entire region against future competitors, while still selling at a price sufficiently above marginal costs of production to justify that effort.¹²⁰

Alternatively, the Directors of the RPSC may offer the foreign patentee the possibility of selling the patented products at better than rock bottom prices if it will establish local production facilities in a designated LDC territory, a territory that need not protect pharmaceuticals until 2016 (and by dint of recent action at the Hong Kong Ministerial Meeting in 2005, need not even provide any patent protection at all until 2013 (up from 2010)).¹²¹ Here the obvious carrot is that the foreign producer who establishes a manufacturing foothold in the territory is rewarded by a more favorable remuneration

¹¹⁸ See *id.*, art. 31(k).

¹¹⁹ For price guidelines see *supra* text accompanying notes ____.

¹²⁰ While Big Pharma could, in principle, threaten to walk away, as they have in the past, recent statements by Harvey Bale, spokesman for the industry, have revealed a more cooperative attitude with assurances that the companies would not walk away from these markets. See I.P. Watch (2006). This attitude may reflect a more realistic assessment of the potential future value of the African market and of the growing capacity of others to watch it.

¹²¹ See S. Musungu, *supra* note ____ (citing authorities).

package and by the prospects of supplying the entire regional market.¹²²

More subtle incentives are that the foreign producer may benefit from tax and other benefits if its own government views this investment as falling under its duties to help establish a viable technological base in, Least Developed Countries under TRIPS article 66.2. Of particular interest here is the possibility that the patentees' own government might be willing to "buy out" any demonstrable R&D cost recovery component that the pharmaceutical company might otherwise lose on such a deal, in keeping with Professor Outtersson's proposals as discussed below in greater detail.¹²³

If the foreign patentee opts to locate in the region, either directly, or through a local partner, the RSPC obtains a reliable, quality local producer, with the possibility of real transfers of technology and know-how over time and of long-term collaboration with the RSPC, which should be of reciprocal interest to all concerned. However, the sticks under this scenario are that if the foreign patentee declines the invitation to produce locally, despite appropriate incentives, the RSPC can either purchase the needed products abroad, under the compulsory licensing system of article 31*bis*, or attempt to entice foreign generic producers in India, China, Brazil and elsewhere, to establish local production facilities in the selected LDC territory under article 31*bis*(3). In that case, even if Big Pharma leaves town, which its spokesmen now profess reluctance to do,¹²⁴ or insists on staying away, Small Pharma may become willing to set up production facilities that could expand over time and compete with Big Pharma in local markets.

Let me reiterate that whoever is induced to establish local production facilities under these measures in Least-Developed Countries remains free of patent regulation until 2013 for all inventions and until 2016 for pharmaceuticals. Hence, a local producer, once it has established quality controls and sufficient manufacturing capacity, could become a formidable supplier of low-cost generics to a large area even without resort to compulsory licenses. In other words, local producers working closely with RSPCs could create in Africa something akin to the highly successful generic production base that was previously developed in India, prior to the TRIPS Agreement in 1994. Over time, moreover, disgruntled Big Pharma firms might rethink premature decisions to stay away and decide that the preservation of future market shares, among other considerations, might be a sufficient reason not to default a vast continental market to Small Pharma competitors.

Disgruntled OECD governments, finally, should console themselves with the thought that they were finally able to fulfill some of their obligations under TRIPS article 66, which are to help provide least-developed countries with a viable technical base and transfer of technology. This could become a win-win situation that avoided future complaints about OECD countries not fulfilling these obligations, and it could become a positive tool of development assistance if developed country governments opted into a

¹²² Cf. James Love, *Four Practical Measures to Enhance Access to Medical Technologies*, in NEGOTIATING HEALTH, *supra* note 5, at 241, 246-47.

¹²³ See *infra* notes ____ and accompanying notes.

¹²⁴ See recent remarks of Harvey Bale, *supra* note ____.

“buy out” scheme that indemnified pharmaceutical companies against losses of R&D cost recovery.¹²⁵

3. Other Options

The scenarios outlined above are illustrative of a broader array of options that cannot all be covered here for lack of time and space. Nevertheless, it is worth pausing to note a few additional scenarios that more fully illustrate the potential gains that could accrue from a wholehearted embrace of the concept of Regional Pharmaceutical Supply Centers.

a. Initiating Local Production Without More

In each of the previous scenarios, local production has been put forward as one of several variables attendant upon either a price regulation scheme or a compulsory licensing scheme or some combination of the two. Here it suffices to note that the mere existence of a RPSC, with its aggregate potential buying power, makes it potentially feasible for the entity to consider promoting local production of needed pharmaceuticals from the start, regardless of the availability of other options.

In other words, stimulating local production should always be a high priority of these regional organizations whenever the capability problems can realistically be addressed. Because these problems are likely to loom very large at the outset, I have relegated direct production by the Centers or their agents to the list of “other options” at the moment. Over time, however, as these agencies accumulated skills and practice, this option should acquire an ever increasing priority.

Of course, doubters may argue against this goal on the grounds that African countries lack comparative advantages in this area. This view overlooks the need for a certain level of autonomy in maintaining the supply of public health as a public good that all governments must envision. Moreover, the negative view overlooks the potential comparative advantages that Africa could eventually derive from its stores of biogenetic diversity and traditional knowledge, once a viable technological base was established.

b. The “Buy Out” Option

As noted earlier, Professor Kevin Outterson has recently launched a “patent buy-out proposal,” which merits more detailed discussion here. In effect, this proposal seeks to assure healthy levels of innovation “by reimbursing the [pharmaceutical] companies for all lost R&D recoveries in those [developing country] markets” where the scheme is put into practice.”¹²⁶ Costs of the scheme are low, because pharmaceutical companies currently do not look to these markets for recuperating research expenditures on global

¹²⁵ See K. Outterson, *supra* note 8.

¹²⁶ K. Outterson, *supra* note 8, at 171. this proposal represents a specific adaptation of more general proposals first put forward by James Love. See ____

diseases,¹²⁷ and risks “are minimized because the present IP system is retained for more than 80% of the global patent-based cash flow of the pharmaceutical companies.”¹²⁸

Under this scheme, purchasers—who could be governments (such as the U.S. or the EU), intergovernmental organizations (such as WHO, UNDP, or the Global Fund), or private foundations—would acquire patent rights for specific medicines for a particular geographic market. The purchasers would then offer “an open, nonexclusive, no royalty license to any legitimate generic manufacturer, but only for sale in the target markets.”¹²⁹ The patent owner is compensated under a buy-out formula, “which mimics the lost R&D cost recovery from the foregone sales.”¹³⁰

What makes the project feasible is that R&D cost recovery from developing countries is so low under current projections that buy outs would be extremely cheap compared to other methods of assistance. Once a buy out occurs,¹³¹ and the license is issued, competition is expected to “drive the unit price down towards the actual marginal cost of production.”¹³²

Outterson’s scheme, which is further nuanced in ways that cannot be explored here,¹³³ is put forward as an alternative to compulsory licensing, in the hopes that pharmaceutical companies might more readily support it.¹³⁴ I consider it a particularly valuable option when combined with the rationalized procurement policies that become possible through the Regional Pharmaceutical Supply Centers proposed in this article. In this context, developed country support of RPSCs through buy outs along these lines could greatly attenuate the need for developing countries to resort to compulsory licenses, which, however, would remain valuable tools to augment their “threat” capacity when circumstances so required.

Another important benefit of Outterson’s buy out proposal is that it would discourage the production of counterfeit pharmaceuticals, “which are greatly encouraged by the high price discrimination ratios made possible by IP laws.”¹³⁵ Generic pricing tends to eliminate the incentive to counterfeit drugs in low- and middle-income countries.¹³⁶

c. Growth Opportunities for States that Issue Patents and Possess Local Production Facilities

This scenario turns all the others on its head. It assumes that, in some

¹²⁷ *Id.*, at 163.

¹²⁸ *Id.*, at 171.

¹²⁹ *Id.*, at 171. OECD countries would continue to practice normal patent-based pricing. *Id.*

¹³⁰ *Id.*

¹³¹ For workable formulas, *see id.* at 173.

¹³² *Id.* at 173.

¹³³ *Id.* at 171-73.

¹³⁴ *Id.* at 171.

¹³⁵ *Id.* at 164.

¹³⁶ *Id.*

circumstances, at least one or more participating countries within the region possessed local production capabilities that may or may not be subject to a patentee's control. The point of the exercise is to show that whoever possesses such capabilities stands to benefit from growth opportunities within the kind of regional framework outlined above.

If local supplies are available and the product is covered by patents, this government can, in principle, meet its own needs without reference to the regional supply mechanism. Its success, however, will depend on its ability to negotiate affordable prices with the local manufacturer without causing it to shut down.

Here the availability of a regional supply entity can play a dual role. On one hand, the regional supply center can exert external pressures on the local company to lower its prices in order to avoid facing the procurement alternatives that the entity might bring to bear. On the other hand, the regional entity can leverage the local supplier with regard to prices in exchange for allowing it to supply the pooled demand of those seeking supplies in other countries, whether under voluntary or compulsory licenses or under any applicable price controls.

The existence of local supply capabilities may also enable the relevant government to better assist the regional supply entity in determining fair and reasonable prices, because it may have better access to data concerning actual costs of manufacture. In any event, those countries that have acquired manufacturing capabilities in pharmaceuticals stand to benefit from a regionalized approach, to the extent that they could emerge as trusted suppliers of the regional entity. In Africa, for example, plants in South Africa, Kenya, and Nigeria might benefit from these measures and could become focal points for future growth.

C. Objections and Limitations

In the following section, I wish to briefly anticipate some of the problems that the proposed Regional Pharmaceutical Supply centers might encounter in practice. Without minimizing these objections, I will also briefly suggest responses to them.

1. Quality Controls

No one familiar with the problem of meeting quality standards for the production of pharmaceuticals in developing countries could underestimate this obstacle. Considerable institutional efforts would have to be focused on this problem, including support for WHO's Prequalification Program.¹³⁷ Nevertheless, I maintain that this problem, along with related problems of market intelligence, necessarily become more manageable when handled by repeat performers, such as the RPSCs, than by single governments acting on an ad hoc basis.

2. Enabling Legislation

¹³⁷ See, e.g., OSI Draft Report, *supra* note 1, at 14.

To the extent that compulsory licensing under amended article 31*bis* of the TRIPS Agreement becomes essential to the overall success of the RPSCs, it cannot become fully operational without the support of the developed countries, which must enact enabling legislation. So far, this response has been slow—only four countries are known to have adopted legislation. At least one of these countries—Canada—has imposed a time frame that limits the capacity of generic companies there to establish long-term supply arrangements where feasible and desired by developing countries.

3. Discouraging Patent Incentives

While there is little evidence that patent incentives for R&D on global diseases are currently affected by developing country markets (and, by definition there are no such incentives at work on so-called “neglected diseases”). This possibility could change as the “incipient transnational system of innovation” that TRIPS inaugurated¹³⁸ more fully integrates pharmaceutical production after January 1, 2006. this situation requires monitoring lest the fears expressed by Professors Sykes and Cottier concerning inadequate patent incentives for private sector investment should materialize later on.¹³⁹

On balance, there is reason to hope that drug companies in developing countries would respond to the newly instituted patent incentives by developing medicines for developing country markets that are not currently available. Nothing should be done in these markets to discourage such efforts, nor do the proposals set forward here, if implemented, have that effect.

On the contrary, if companies in developing countries conduct R&D to address the needs of these same countries, their business models would presumably be based on mass production of the resulting medicines for sales in poor countries. Prices would accordingly be geared to the buying capacities of local populations, as reinforced by tiered pricing and product differentiation. If so, there is little or no need for the use of compulsory licensing, while the very existence of RPSCs should create marketing tools that reinforce, rather than discourage, patent incentives.

There is no reason to presuppose that regulatory authorities in developing countries, including price regulators, would be more hostile to local innovators and the positive effects of R&D incentives than their counterparts in developed countries. On the contrary, RPSCs would have every reason to support and encourage local innovators in order to achieve desired levels of national and regional autonomy with respect to meeting public health goals.

If, however, local firms succeeded in developing global drugs of interest to developed countries, then regulators in developing countries would have to remain vigilant that the prices practiced in developing countries were affordable and not mere vehicles for rent-extraction from affluent circles. One can only hope that production in Africa, for example, would quickly advance to the point where this problem became

¹³⁸ See Maskus & Reichman, *supra* note ____

¹³⁹ See Sykes, *supra* note __; Cottier, *supra* note ____.

relevant. For the foreseeable future, however, it is the failure of the worldwide patent system to meet the public health needs of developing countries that one must actually confront.

4. Sustaining the Plan

The proposed RPSCs will need institutional and financial support from developed countries, governments, IGOs, and nongovernmental organizations. Foundations should also assist the pioneers in this effort, in order to achieve self-sustaining levels of activity over time.

5. Re-Exports

The amended TRIPS Agreement and its progeny mandate extraordinary efforts to ensure that medicines produced for poor countries under its more favorable terms do not end up in developed countries, where they would destabilize the existing R&D structure. Every RPSC must make strenuous efforts to ensure that these and related rules are strictly enforced.

6. Local Opposition to Foreign Suppliers

I have emphasized the need to stimulate local production, wherever possible, and to prioritize the role of local producers and suppliers generally. Nevertheless, the scheme can only work if the threat to resort to willing foreign suppliers, when needed, becomes credible.

Needless to say, as RPSCs become successful, they may possess funds to improve local capacity, especially when compulsory licenses are deemed necessary. Spending seed money on local capacity building to enhance the threat of compulsory licensing, where needed for public health purposes, has been successfully practiced in Brazil, for example. Nevertheless, participating governments must take pains to ensure that local producers do not engage in protectionist and obstructionist tactics that could lessen the effectiveness of RPSCs, once they got underway.

7. Local Distribution Complexities

Local distribution of medicines in Africa is unduly complex, and the presence of many middlemen often adds to costs while detracting from efficiency. The advent of RPSCs should not make these problems worse and might provide a focal point for considerable improvement and rationalization along regional lines.

8. Governance and Political Instability

As Professor Coenrad Visser has pointed out, the real problems these proposals face are rooted in the high levels of corruption that plague many developing countries and in the political and ethnic tensions that often impede cooperative efforts, particularly in

Africa.¹⁴⁰ I have no silver bullet for overcoming these difficulties in this context. One would hope that self-preservation and common humanitarian concerns, united around a common regulatory framework overseen by the Ministries of Health plus other contributing ministries, would provide a foundation for dealing with these problems. To the extent that IGOs and developed country governments provide funds to make such ventures work, they can and should build in performance standards to deal with these risks.

9. Comparative Advantage

In the course of this paper, I have already rejected arguments based on the lack of comparative advantage in African countries with respect to the production of pharmaceuticals. As previously observed, the need for a minimum level of national autonomy to provide public health as a public good overrides this consideration, and the contrary policy of dependence seems repugnant, if not immoral. Nevertheless, concerns about relative comparative advantage must be taken into account when evaluating public investments in the pharmaceutical sector, even if market factors should naturally adjust private sector investment in this regard.

Let me reiterate that knowledge is a public good and that comparative advantages evolve with spillovers and capacity building over time. In particular, there is a vast potential for genetic resources and traditional knowledge in Africa that could become a basis for future comparative advantages, if a proper foundation can be laid.

III. Concluding Observations

If there are few countries with local production facilities within a given region or subregion, the proposed Regional Pharmaceutical Supply Centers are designed to address their collective procurement problems in the short and medium terms. Over time, moreover, regional supply entities should cooperate with one another and consider “cross-licensing” when appropriate. In other words, cooperative agreements could enable external regional suppliers to emit compulsory licenses to alleviate serious public health problems in another region, in return for promises of similar help in the future.

Let me stress that the regional supply entities need not be elaborate operations and that regional cooperation need not engender complex bureaucratic structures. The initial object is to procure the needed medicines wherever they are available, and once facilities are provided and appropriate legal arrangements are in place, actual distribution could be achieved with the help of NGOs and relief agencies. A shack in the woods with “RPSC” painted on the roof might suffice to enable serious NGOs to use it as a warehouse and redistribution point, while any efforts to disrupt its operations could be open to immediate press coverage and public censure.

If, overtime, a less rudimentary regional structure emerged, it might provide additional efficiency gains, so long as bureaucratic sclerosis were avoided. For example,

¹⁴⁰ See C. Visser, Comments, *supra* note ____.

threats by single pharmaceutical companies, or by a group of them, to reduce investments in the face of regulatory pressures would become less effective if regional markets were at stake and if central supply entities were organized to procure substitute products wherever they might be available. Indeed, the existence of an effective regional market should become a fillip to direct foreign investment in local production in order to keep costs down and remain competitive within the regional market. At the same time, any organized boycotts or concerted action to undermine the work of RPSCs should be prosecuted as antitrust violations, including criminal conspiracies where indicated.

The TRIPS Agreement, by its nature, is an agreement of balance and compromise, and this proposal seeks to maintain the balance of rights and obligations that imbue the normative provisions. This proposal seeks to improve access to essential medicines for developing and Least Developed Countries, while attempting to limit the abrogation of patent rights by creating an environment for market-based solutions. The primary function of the proposed regional supply centers is to meet needs that member countries cannot satisfy on a purely territorial basis. An important secondary function is to induce patentees to participate in a more cooperative game, to the mutual advantages of all the stakeholders.

This proposal would also benefit from the creation of an independent scientific body, guided by specified criteria, to determine the list of essential medicines of primary interest to countries that qualify to participate in the plan. Clearer criteria on what constitutes an essential medicine need to be developed, while use of the centers should be limited to specific terms and conditions consistent with the spirit of the Doha Declarations. The proposed RPSCs should become vehicles for maximizing incentives to invest, invent and produce over time, not the other way around.

One of the primary goals of this proposal is to produce a market-based solution by providing a collective supply and distribution body that would encourage the pharmaceutical industry to engage in more constructive and expeditious price reduction negotiations with developing countries. Essentially, the procurement centers could provide a powerful incentive for patentees to voluntarily bring prices down and thereby avoid compulsory licensing in all but the most critical instances. At the same time, it could put a stop to dilatory action by producers engaging in endless litigation in single territories. Above all, it could provide a major fillip to expand local production capabilities and to channel public and private funds in this direction.

In the medium and long-term perspective, the creation of regional procurement centers potentially offers pharmaceutical manufacturers an attractive business opportunity. The companies might find that direct access to a regional market reduced the transaction costs of establishing relationships on a country-by-country basis, and they should be encouraged to license local producers as the most favored option. Voluntary participation by the patent holding pharmaceutical manufacturers in schemes to improve access to essential medicines in such a framework could ultimately build a substantial market share for them in the regions themselves, while greatly expanding local capacity and building a foundation for greater local autonomy.

Are these scenarios nonetheless just another pipedream? Would political pressures, incompetence and corruption kill them in practice? No one knows the answer to that. UNCTAD has expressed interest, and some governments have funded feasibility studies. For our purposes today, what you can see is that the legal landscape has been radically reshaped since 1995; and that developing and Least-Developed Countries that get their acts together now have unprecedented opportunities to solve some of their most pressing public health problems by their own self-help regulatory initiatives.