

Policy Department External Policies

ACCESS TO ESSENTIAL MEDICINES: LESSONS LEARNED SINCE THE DOHA DECLARATION ON THE TRIPS AGREEMENT AND PUBLIC HEALTH, AND POLICY OPTIONS FOR THE EUROPEAN UNION

INTERNATIONAL TRADE

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ABSTRACT

The study evaluates the impact of the TRIPS agreement on access to medicines in developing countries and analyses the evolving legal framework. Special emphasis is given to the issue of compulsory licensing, including recent cases in Brazil and Thailand. The EU's own implementing regulation is also presented, as well as the considerations for any TRIPS-related provisions in bilateral trade agreements of the EU and the US. The TRIPS agreement and its amendment are discussed in light of the various public health, commercial, legal and economic considerations and interests. The study also sets out conclusions and concrete recommendations to improve the overall framework of the TRIPS agreement and access to medicines.

Executive Summary

1. The WTO TRIPS Agreement that entered into force on January 1, 1995, fundamentally altered the policy environment in which developing (and developed) countries operate with respect to producing and distributing pharmaceutical products needed to protect public health. The TRIPS Agreement requirement to provide pharmaceutical product patent protection establishes the basis for market dominance (regarding newer products) by originator companies that are almost exclusively based in the OECD, including in the European Union. Important policy space for developing countries was made available in the form of a transition period that extended until January 1, 2005. India and its generic producers took good advantage of that space, which has now largely been closed (although Least Developed Countries (LDCs) continue to benefit from a transition arrangement).
2. Compulsory (including government use) licensing is a critical tool for promoting effective price negotiations with patent holders, and for enabling local production, importation and distribution of patented medicines at affordable prices. However, a technical rule of the TRIPS Agreement threatened to make use of compulsory licensing extremely difficult for many developing countries after January 1, 2005, when availability of pharmaceutical patents would be required in all countries, except LDCs. This technical rule (Article 31(f)) limited use of compulsory licensing for the predominant supply of the domestic market of the country issuing the license. Countries without adequate production capacity, and without access to imports of off-patent medicines from other countries (such as from India), would be unable to effectively use compulsory licensing.
3. As part of negotiations regarding the Doha Declaration on the TRIPS Agreement and Public Health, developing countries sought a solution to the looming problem of effective use of compulsory licensing that would have been administratively straightforward and expeditious. The European Union (EU) and United States, reflecting the position of their originator pharmaceutical industries, rejected a straightforward solution in November 2001 at Doha. Instead, a programmatic formula was established that led to two years of further negotiations on a “waiver” (Decision of August 30, 2003) (“Decision”), followed by a proposed amendment (Article 31*bis*) of the TRIPS Agreement (“Amendment”), ratification and acceptance of which by the EU is now being assessed by the European Parliament (EP).
4. All parties to the negotiations resulting in the proposed Amendment recognize that it is not the straightforward and expeditious solution initially sought by developing countries. The administrative formalities and substantive restrictions imposed by the proposed Amendment include, for many cases, the requirement of double (or “back-to-back”) compulsory licensing, as well as various notification, quantity, product identification and destination control requirements. Many, if not most, of these formalities and restrictions were proposed and championed by the EU in WTO negotiations. Therefore, in assessing whether to renegotiate the Amendment, the EP is in substantial measure asking whether the EU is prepared to renegotiate with itself.

5. This report includes an element-by-element assessment of the proposed Amendment and concludes that, while there are no doubt significant impediments to expeditious use, on the whole it would provide a “net benefit” in respect of access to medicines in developing (including LDC) countries. There are mechanisms that can be used to overcome certain of the administrative obstacles. In its adoption of an implementing regulation for the Decision and Amendment, the EU has in fact taken good advantage of the possibilities for encouraging effective use of the new system. The authors believe Article 31*bis* can be made functional, even if imperfectly, through a combination of political will, good lawyering, financial support for appropriate implementation efforts and collective action.
6. A key question before the EP is whether delay of acceptance, or proposal for renegotiation, is likely to improve upon the present framework. It is extraordinarily difficult to make a sound prediction concerning the results of pursuing the options of delay or renegotiation. While efforts by NGOs and some governments to improve the negotiating climate through forums such as the Intergovernmental Working Group (IGWG) at the WHO may succeed, it is hard to make an advance assessment of that.
7. The authors of this report regard the most likely result of attempts at renegotiation as an “impasse”. While there is the possibility that terms of the Amendment could be improved in the sense of eliminating unnecessary and counterproductive administrative procedures and substantive limitations, there is an almost equal possibility that a renegotiated solution would impose new substantive limitations (such as limitations on the “scope of diseases” or eligible importing countries). The authors’ assessment of future prospects is based, *inter alia*, on their evaluation of the reaction of certain powerful political and economic operators, and prominent media outlets, to the recent use by certain governments of TRIPS flexibilities. The authors concede, however, that such assessments are necessarily subjective, and that “reasonable minds” can differ concerning the prospects based on delay or renegotiation – in either a more flexible or more restrictive direction.
8. The Decision (i.e., the waiver) is legally designed to remain in effect until an amendment is accepted by all WTO Members. Therefore, from a strictly legal standpoint there is no apparent risk from delay (or rejection) of the Amendment. However, the authors have serious concerns that industry interests and supporting governments would use delay or failure of acceptance of the Amendment as the basis for an aggressive lobbying campaign intended to undercut the vitality of the waiver. Moreover, there is anecdotal evidence that some governments have taken a “wait and see” attitude toward implementation of the Decision pending formalization via the Amendment. These factors also incline toward a more positive view of acceptance of the Amendment, again, with appropriate caution that reasonable minds may reach another conclusion.
9. Nevertheless, the EP could decide to postpone assent to ratification of the Amendment while seeking to negotiate a suitable program of action with the Commission and Council that would color the EU’s future outlook and conduct relevant to implementing the Amendment. For example, once the Commission and Council accepted to pro-actively support the IGWG process, refrain from negotiating TRIPS-plus provisions affecting public health in the EPAs and other bilateral

agreements with developing countries, discussed the use of Article 30 by the member states as an alternative approach to authorizing exports and took into account some of the proposals that the Committee on International Trade put forward in regard to the implementing regulation, the EP might conclude that the package negotiated with Commission and Council was a significant improvement over the status quo, even if the text of the Amendment remained unchanged. However, care must be taken with the message conveyed by the EP, and the timing of its decisions, so that the fundamental force of the Decision and Amendment are not undermined.

10. The report lays out possible mechanisms for enhancing the effectiveness of the Amendment, including in some detail the possibilities inherent in regional cooperation toward joint procurement and joint administration of compulsory licensing efforts. These mechanisms may assist developing countries in achieving economies of scale in purchasing or production that are important to controlling costs, and consequently to reducing medicines prices.
11. The report emphasizes the importance of promoting capacity for the development and production of pharmaceutical products in developing countries and LDCs, and encourages the EU and its member states to take a more active role in concrete technology transfer and physical infrastructure capacity building efforts. The authors emphasize that related measures such as pooling of essential medicines patents, the buying out of patent rights for developing country markets and/or the geographic (or other market, *e.g.*, public-private) segmentation of patent rights, may be very important tools for promoting pharmaceutical research and development, and for the establishment of production facilities, including for active pharmaceutical ingredients (APIs).
12. The report carefully addresses the need to preserve incentives for research and development (R&D) for new medicines. At the present time, originator pharmaceutical companies based in the OECD recover the great part of their R&D expenditures in the more affluent OECD markets, and invest a small part of their R&D budgets on diseases of special relevance to developing countries. Consequently, the use by developing countries of compulsory licensing to ensure public access to affordable medicines is unlikely to have a material effect on the level of research currently undertaken in the OECD. If pharmaceutical companies, either in OECD countries or elsewhere, respond to TRIPS patent incentives by investing in R&D that pertains to poverty-related, tropical and neglected diseases of primary concern to developing countries, then resort to compulsory licensing may require a different calculus. Depending on the type of financing mechanism employed for research (*e.g.*, public or private), the originators may have to seek their returns on investment in the affected countries, and calculations regarding whether and how to use compulsory licensing should take account of the altered landscape.
13. During the negotiations on the Decision and Amendment, many stakeholders argued that WTO Members seeking to assist developing countries through exports of needed medicines could accomplish the same goal by proceeding under Article 30 of the TRIPS Agreement, which authorizes exceptions to the patentees' exclusive rights. While the EP expressed interest in this approach, the U.S. government was strongly opposed, and was joined in opposition by the Commission and Council. The EP and

Council might adopt a joint policy statement to the effect that EU member states are free to proceed by the Article 30 route under their domestic patent laws, and recommend that the Commission refrain from taking action to interfere with such proceedings. This alternative, favored by some influential NGOs, is not without corresponding risks. For example, industry pressures at the member state level might inhibit some governments from proceeding under Article 30, despite such an enabling policy statement, and state practice could vary considerably throughout the EU. But the continued availability of Article 31*bis* would attenuate these risks.

14. Brazil and Thailand have recently issued government use licenses on important antiretroviral treatments (ARVs), as well as treatment for coronary disease (in the case of Thailand). These licenses promise to significantly promote and improve public health interests in the respective countries. One of the objectives of the recent actions by Brazil and Thailand was to move pharmaceutical production and distribution from a “high margin, low volume” model to a “low margin, high volume” model, more attuned to the needs and interests of a large part of their populations. An important goal in cautiously supporting the proposed Article 31*bis* Amendment is to reinforce the tools that can help shift the patentees’ marketing strategy in this direction, in addition to stimulating greater local production capacity in the developing world. In overcoming political resistance to taking such measures, Brazil and Thailand may have in fact improved the prospects for effective implementation of the Amendment, by demonstrating that compulsory licensing “can be done”, and that the sky will not fall as a consequence.
15. In principle, there is no compelling reason why originator companies, as well as the generic sector, could not prosper in such a “low margin, high volume” environment. Yet to date, this marketing approach has not appealed to the originator sector. This is one reason that government use and compulsory licensing remains a vital alternative for the supply of public goods in the form of medicines.
16. Recent discussions at IGWG have focused on proposals that would re-examine the link between pricing and the cost of R&D, with a view to devising workable new models. There is also growing interest in forming patent pools to deal with poverty-related, tropical and neglected diseases, with the participation of public-private partnerships, such as UNITAID. The authors urge the European Parliament to monitor work at IGWG and to lend their support to such proposals.
17. The European Union has nominally adopted a policy of not pursuing pharmaceutical-related TRIPS-plus commitments in its negotiations with developing countries, while nonetheless “free riding” on the pharmaceuticals commitments obtained by the United States through operation of the TRIPS Agreement most favored nation treatment (MFN) rule. However, it is not really the case that the EU foregoes additional pharmaceutical-related commitments in its bilateral and regional negotiations. For example, the European Union is effectively seeking to burden the ACP countries with the duty to implement the terms of its Intellectual Property Enforcement Directive. A developing country that enters into an FTA with the United States and an EPA with the EU along the lines of those presently proposed will be constrained to provide a very strong market dominant position for pharmaceutical originator companies, and thus to create substantial obstacles to the introduction of generic products. The

authors believe that EPAs should refrain from imposing any new intellectual property obligations on APC countries that could affect their public health programs. Indeed, the European Parliament should encourage the EU expressly to endorse full implementation in APC and other developing countries of the flexibilities in the TRIPS Agreement as recognized in the Doha Declaration “to promote access to medicines for all”.

18. The report concludes with a series of recommendations directed toward EU institutions that are intended to promote research and development on treatments directed to people in need in developing (and developed) countries, and to promote affordable access to medicines.

I. Impact of the TRIPS Agreement on Access to Medicines in Developing Countries

Before the TRIPS Agreement of 1994 entered into force, developing country governments retained relatively unrestricted power to regulate public health, with little interference from international intellectual property law. The exercise of this power was part of their broader duties to maintain the supply of essential public goods generally, including education, nutrition and agriculture, environmental safety, scientific research and industrial policy (including the promotion of a competitive rather than a command economy, where so desired).¹

Within this traditional framework, international intellectual property standards affecting the developing countries' ability to supply essential public goods, especially public health, were rudimentary at best. Although the decolonization process saddled many (if not most) developing countries with membership in the Paris Convention for the Protection of Industrial Property of 1886, as amended in 1967, the provisions of that Agreement concerning patented inventions dealt mainly with rules of priority and national treatment. It otherwise left states free to devise and implement their own patent systems and, as many chose to do, even to deny any patent protection for pharmaceuticals at all.

In this environment the ability of developing and Least-Developed Countries (LDCs) to obtain essential medicines varied with respect to their procurement methods, local production capabilities, public health policies, and general financial resources. The chief limitations on supply were not of a legal character, but rather depended on the reverse-engineering capacities of generic suppliers and their pricing policies; on the availability of key active ingredients (APIs) on the world market; on the pricing policies of the big pharmaceutical companies (and any countervailing local regulatory framework); and on the well-known failure of the research-based pharmaceutical industries in the OECD countries to invest in R&D directed at diseases that primarily afflicted the poorer countries. The growing ability of some middle-income developing countries to produce low cost generic medicines under these regimes – notably in Argentina, Brazil, Chile, India, Thailand, Egypt, Indonesia, Taiwan and South Korea – made it increasingly possible for even very poor states to obtain certain low cost generic medicines on the world market, whether such products were on or off patents.

Once the TRIPS Agreement of 1994 took effect, however, and its limited transitional periods expired in 2005, this situation changed radically. All developing countries (but

¹ See e.g., Keith E. 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 INTELLECTUAL PROPERTY REGIME 3-45 (K.E. Maskus & J. H. Reichman, eds., Cambridge U. Press, 2005).

not the LDCs) became liable to adopt and enforce all the TRIPS patent standards, and these standards necessarily applied to medicines in all WTO member countries (except LDCs) from 2005 on. With the passage of time (and the opening of the “mail boxes” holding pharmaceutical patent applications during the transitional periods), more and more essential medicines (for example, so-called second and third line HIV drugs) will be on patent in all countries capable of supplying them to the world market, at least until the relevant patents expire in those countries.

The availability of these drugs will thus depend on the pricing strategies of patent holders and the countervailing regulatory measures states may adopt to influence them. Moreover, further efforts to tighten international intellectual property standards continue today under the Substantive Patent Law Treaty (SPLT) negotiations ongoing at WIPO, and especially under Free Trade Agreements and Bilateral Trade Agreements, which adversely affect Ministries of Health (such Ministries often remaining powerless to modify or block problematic demands in response to “take it or leave it” negotiating pressures).

Meanwhile, in an effort to bolster the vertical powers of poor countries to maintain the supply of essential medicines as part of their public health responsibilities, despite elevated international intellectual property standards, the WTO Ministerial Conference adopted the Doha Declaration on the TRIPS Agreement and Public Health in November 2001. This Declaration reconfirmed the so-called flexibilities built into the TRIPS Agreement and amplified them further by establishing legal machinery to enable countries lacking the capacity to manufacture generic substitutes for costly patented medicines under domestically issued compulsory licenses to obtain imports from countries able and willing to assist them without interference from the relevant patent holders. This solution, initially embodied in a waiver known as the Decision of August 30, 2003, would be rendered permanent in the form of an Amendment to the TRIPS Agreement, known as Article 31*bis*, whose ratification is currently under consideration by the European Parliament.

How the developing countries adapt the TRIPS flexibilities to the needs of their national and regional systems of innovation will ultimately determine both the direction of future R&D in the global pharmaceutical sector and the extent to which all WTO Members, and especially the developing and Least-Developed Countries, will be able to provide essential medicines at affordable prices under their domestic public health programs. In this calculus, the potential role of the proposed Article 31*bis* Amendment to shift the pharmaceutical companies pricing strategies from a “low volume, high margin” approach to a “high volume, low margin” approach is of primary importance. We have, accordingly, focused the bulk of this report on issues surrounding the viability of the pending Amendment and on ancillary actions the European Parliament might take to help attain the goals it is meant to promote.

In what follows, we will first depict the evolving legal infrastructure affecting the supply of pharmaceuticals to developing countries, in which the Protocol of Amendment concerning Article 31*bis* is a major component. We shall then evaluate the prospects for

implementing the amended flexibilities with some hope of success, and we shall also consider certain alternative or complementary strategies. Finally we shall draw conclusions and make recommendations concerning these and other related issues covered in the report, which the European Parliament may wish to support.

II. The Evolving Legal Infrastructure

A. The WTO August 30, 2003 Decision and the Protocol of Amendment

A principal objective of this Committee review is to consider whether the European Communities should ratify and accept the Amendment to the TRIPS Agreement adopted by WTO Members on December 6, 2005² that would formally amend the TRIPS Agreement to add a new Article 31*bis*.³ Proposed Article 31*bis* reflects the terms of the WTO Decision of August 30, 2003 (hereinafter the "Decision").⁴ It established a waiver of certain obligations under the TRIPS Agreement for the purpose of permitting exports of medicines under government use and compulsory licenses that might otherwise be prevented by the terms of the TRIPS Agreement as it entered into force on January 1, 1995.

1. The EU Position as Key Determinant of the Terms of the WTO Measures

As will be shown, the EU was the key architect of most of the bureaucratic limitations incorporated into the Amendment. To the extent that the Amendment may be criticized for imposing obstacles to the effective use of compulsory licensing by countries with inadequate production capacity, the criticism may largely be directed at the EU. At the same time, the EU has adopted a Regulation to implement the Decision that shows a strong appreciation for the flexibilities that remain open to countries in making use of the system.

The EU does not have experience with the operation of the Decision or the implementing Regulation, and there are limitations on the extent to which the effectiveness of the system can at this stage be accurately assessed. There is neither a strong experiential basis for recommending acceptance of the Amendment, nor of declining to accept it. The question is largely political, asking whether, and from whose perspective, an "improved" Amendment might be negotiated or the chances for its effective implementation might be strengthened.

² The "European Communities" is the formal Member of the WTO, along with each of the member states of the European Union. Presumably it is the "European Communities" that would submit an instrument of acceptance to the WTO regarding the Amendment on behalf of the "regional entity in Europe".

³ WTO General Council Decision of 6 December 2005, Amendment of the TRIPS Agreement, WT/L/641, 8 Dec. 2005, with attachment "Protocol Amending the TRIPS Agreement" (with Annex setting out Article 31*bis* (and associated Annex) to the TRIPS Agreement [hereinafter "Protocol of Amendment" or "Amendment"].

⁴ Implementation of Paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health (Aug. 30, 2003), Doc. WT/L/540 (Sept. 1, 2003) [hereinafter "Decision"].

The authors are inclined to believe there is not much room in the present global political environment for negotiating a different deal from the one presently on the table. They are also inclined to believe that the Amendment can play a net positive role from the standpoint of public health, even if it is not the optimal solution from the perspective of any interested stakeholder. Finally, while it is virtually impossible to predict whether the negotiating environment will change in the direction of improving the terms of the Amendment, there is a possibility that time will work against the existing waiver solution, notwithstanding the legal commitment by WTO Members that it will continue in effect indefinitely (until an Amendment is accepted by all Members). This may ultimately argue in favor of ratifying and accepting the Amendment, imperfect though it may be.

A full appreciation of the terms of the August 30, 2003 Decision, and subsequent Amendment, requires understanding that the Decision was the result of a long and complex negotiation among a substantial number of interested stakeholders, many of whom had widely different perspectives regarding the optimal outcome. The Amendment represents a formal lowering of intellectual property (IP) protection standards imposed by the TRIPS Agreement. The traditional *demandeurs* of high standards of IP protection lose something they gained in the GATT Uruguay Round negotiations.

The Decision is not the optimal solution for stakeholders seeking the most administratively simple or expeditious mechanism for permitting exports under compulsory license. None of the parties involved in the negotiations are under the impression that this was the result achieved. This is not because the negotiators failed to appreciate that a more user-friendly or expeditious process was possible. It is instead because the WTO Members negotiating on behalf of the originator pharmaceutical industry *demandeurs* would not accept that solution. And, while the European Union may not (or may) have been the most patent-protective WTO Member in the negotiations, its negotiating position was well on the side of the originator-IP holder industry. There is limited reason to conclude that the member states and the European Union have changed their perspective from the time the Decision was adopted. The current G-8 focus on IP enforcement led by the German presidency, and as reflected in negotiating texts of EU Economic Partnership Agreements, might lead to the conclusion that the EU would not negotiate again today certain more permissive aspects of the Amendment.

2. India and the Problem of Exports under Article 31(f)

To set the Amendment in context, the potential problem posed by Article 31(f) of the TRIPS Agreement was identified prior to the decision by developing countries to initiate, in June 2001, a review within the TRIPS Council of the effects of the agreement on public health. While Article 31 generally permits WTO Members to issue compulsory licenses, subject to certain procedural requirements, on virtually any grounds, Article 31(f) sharply limits exports under these licenses by requiring that “any such use shall be authorized predominantly for the supply of the domestic market of the Member authorizing such use.”

The core of the problem was recognition that on January 1, 2005, India would be required to implement pharmaceutical product patent protection, and to review the pharmaceutical patent applications that were collected in its "mailbox" between January 1, 1995 and December 31, 2004. Because India -- unlike most developing countries -- had taken advantage of the ten-year transition period for providing pharmaceutical product patent protection, it had developed and maintained a world-class generic production capacity with respect to drugs that were otherwise on-patent in developed (and many developing) countries. It was this unique generic production capacity that enabled Indian manufacturers to break the price stranglehold of the originator companies with respect to key antiretroviral (ARV) treatments.⁵

Once India was forced by the TRIPS Agreement to provide pharmaceutical product patent protection,⁶ new drugs developed after January 1, 2005 would be protected, so that new second or third line ARVs, for example, would not be available in generic form. A more complicated situation would be created with respect to ARVs invented prior to January 1, 2005.⁷ The net result with respect to HIV-AIDS treatment was that with some certainty "new" second and third line treatments would be patentable and unavailable at generic prices, and that some first line ARVs might become subject to essentially late-stage patent protection. The precise effects of the January 1, 2005 transition in India would depend to a significant extent on the terms and implementation of India's amended Patent Act.

From the earliest days of developing country consideration of the Article 31(f) problem, moreover, there was wide recognition that the need for low-cost generic supplies of newer medicines in developing countries extended well beyond ARVs, or treatment for malaria, tuberculosis and other infectious diseases. Coronary disease, cancer, diabetes, asthma and other disorders are major causes of morbidity and mortality in developing countries, as is made clear in WHO statistical reports. There was, therefore, a wide recognition that a solution to the Article 31(f) problem must necessarily extend beyond HIV-AIDS.

It is very important to public understanding of the ultimate terms of the Decision and Amendment that developing countries were acutely aware of the importance of establishing a straightforward and expeditious solution, as reflected in the initial non-

⁵ CIPLA offered annual per patient ARV treatment at about US\$350 when the originator prices were in the \$10,000 range. This revolutionized the HIV-AIDS treatment environment in the developing world. See Medecins Sans Frontieres (MSF), *Untangling the web of price reductions, a pricing guide for the purchase of ARVs for developing countries*, 8th ed., at pg. 10, available at < <http://www.accessmed-msf.org/documents/untanglingtheweb%208.pdf>>

⁶ See Frederick M. Abbott, *The WTO Medicines Decision: World Pharmaceutical Trade and the Protection of Public Health*, 99 AM. J. INT'L L. 317, 320-24 (2004) (hereinafter "Abbott, WTO Medicines Decision").

⁷ It appeared that a substantial part of the first line ARV drug library was invented and patented outside India prior to initiation of the mailbox requirement on January 1, 1995, and those drugs (at least in non-combination form) would not be subject to patenting. There was some question with regard to combinations, such as the widely used "Combivir" patented outside India by Glaxo. The potential for patenting of combinations may depend on interpretation of the specific terms of India's new patent legislation. For a few ARVs, there might be issues regarding the appropriate filing and/or priority date that would influence whether or not the drugs would come under patent.

paper draft for a Ministerial Declaration on the TRIPS Agreement and Public Health circulated to the TRIPS Council on September 19, 2001, prior to adoption of the Doha Declaration.⁸ This developing country draft proposal embodied several administratively efficient solutions. First, based on the underlying concept of "comity" familiar to international lawyers, paragraph 3 of the solution would have authorized WTO Members to "give effect" to compulsory licenses issued by other members, and to export pursuant to those licenses.⁹ There would be no requirement for back-to-back licensing. This would have been an expeditious and straightforward solution to the problem of countries that could not themselves manufacture medicines the production of which was authorized under license.

Second, paragraph 9 of the developing country draft would have recognized that WTO Members are able to use the Article 30 exception provision to authorize production and export "to address public health needs in importing Members".¹⁰ Finally, in paragraphs 7 and 8, the developing country proposal made clear that the data protection and exclusive marketing rights provisions would not become an obstacle to giving effect to compulsory licenses.

However, both the United States *and* the European Union rejected the proposal by the developing countries to resolve the Article 31(f) problem at the Doha Ministerial Conference in November 2001, instead negotiating the well-known Paragraph 6 formula. Paragraph 6 formed the basis of two years of further negotiations leading to the adoption of the Decision in August 2003, followed by the adoption of the Protocol of Amendment in December 2005. In other words, the United States and EU could have taken on board a straightforward and expeditious solution in late 2001, but chose not to do so, and the complications that emerged in the Decision and Amendment were the joint product of their negotiators¹¹ who rejected Article 30 as the basis for a simple solution.

⁸ General Council, Council for Trade-Related Aspects of Intellectual Property Rights, Proposal by the African Group, Bangladesh, Barbados, Bolivia, Brazil, Cuba, Dominican Republic, Ecuador, Haiti, Honduras, India, Indonesia, Jamaica, Pakistan, Paraguay, Philippines, Peru, Sri Lanka, Thailand and Venezuela, IP/C/W/312, WT/GC/W/450, 4 October 2001 (01-4803), available at <http://www.wto.org>.

⁹ See suggestion in Communication from the European Communities and Their Member States, The relationship between the provisions of the TRIPS agreement and access to medicines, IP/C/W/280, 12 June 2001 and EU Commission, Compulsory Licensing and Data Protection, Legal Issues related to Compulsory Licensing under the TRIPS Agreement (referenced in para. 13 of Communication to TRIPS Council), *id.* See further elaboration in Frederick M. Abbott, *The TRIPS Agreement, Access to Medicines and the WTO Doha Ministerial Conference*, Quaker United Nations Office (QUNO), Occasional Paper 7, Sept. 8, 2001, at pgs. 13-15 (also published in 5 JWP 15 (2002)), and Frederick M. Abbott, *Compulsory Licensing for Public Health Needs: The TRIPS Agenda at the WTO after the Doha Declaration on Public Health*, QUNO Occasional Paper No. 9, Feb. 2002, at 29.

¹⁰ Article 30 of the Agreement allows members to "provide limited exceptions to the exclusive rights conferred by a patent, provided that such exceptions do not unreasonably conflict with a normal exploitation of the patent and do not unreasonably prejudice the legitimate interests of the patent owner, taking account of the legitimate interests of third parties." Because the assisting country would export needed medicines to the importing country, there should be no significant economic impact on the local market of the exporting country.

¹¹ In fact, the bureaucratic complications which are ultimately reflected in the Amendment largely emanated from the European Commission. Consider, for example, the proposal from the EC to the TRIPS Council in

At a critical juncture in the negotiations, the EC proposed that the solution be confined to “grave” public health problems, raising the specter of WTO intervention to determine when a public health problem was serious enough to warrant attention. The same EC proposal sought to require that formulation of active ingredients into final products was to take place in the importing Member if it maintained the capacity for formulation. This would in some cases require territorial division of the manufacturing process in a way that would make little sense from a cost-efficiency standpoint. The EC further sought to require that the patent holder should always have the right to make an offer of products at “strongly reduced prices,” which could be rejected on “reasonable grounds.”

At the same time, the United States tried to restrict the scope of the solution to addressing HIV-AIDS, malaria, tuberculosis and a potentially restricted group of other infectious diseases, while limiting the countries that would benefit from the solution. This strategy proved difficult to maintain, however. There is no public health justification for refusing to allow patients to have access to treatments for certain diseases because trade officials have decided that that some diseases should be on (or off) an official list. Developing countries firmly rejected the idea of restricting the solution to a limited scope of diseases.¹²

It is worth noting that the United States initially proposed limiting permissible exporting countries to developing countries, but this was not strongly pursued. Moreover, the United States, like the EU, was opposed to allowing the presumptively more liberal Article 30 approach, as distinct from using the presumptively more restrictive Article 31 approach. At the end of the day, many or most of the key restrictions in the August 30 Decision and the Protocol of Amendment originated with, or were strongly supported by the European Union, after considerable internal deliberation.¹³

3. Terms of the WTO Measures

One of the authors of this report has published a detailed analysis of the negotiating history of the August 30 Decision,¹⁴ as well as a set of model implementing legislation prepared on behalf of the World Bank.¹⁵ Copies of these documents have been furnished

June 2002, Communication from the European Communities and their Member States, Paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health, IP/C/W/352, 20 June 2002.

¹² Substantive and Procedural Elements of a Report to the General Council under Paragraph 6 of the Declaration on the TRIPS Agreement and Public Health, Non-Paper Submitted to the Council for Trade-Related Aspects of Intellectual Property Rights by South Africa, 4 Nov. 2002, WTO Ref: Job(02)/156. For list of supporting countries, see Abbott, *WTO Medicines Decision*, at pgs. 328-29.

¹³ The proposal circulated by the EC on November 2 was subject to an extensive internal consultation in the 133 Committee of the European Council, *see, e.g.*, MD: 494/02 REV 1, dated 29.10.2002, with interlined suggestions from the Commission.

¹⁴ Frederick M. Abbott, *The WTO Medicines Decision: World Pharmaceutical Trade and the Protection of Public Health*, 99 AM. J. INT’L L. 317 (2004). The same author has in draft form a more detailed step-by-step recount of the negotiations, as yet unpublished.

¹⁵ Frederick M. Abbott and Rudolph van Puymbroeck, *Compulsory Licensing for Public Health, A Guide and Model Documents for Implementation of the Doha Declaration Paragraph 6 Decision*, World Bank Working Paper No. 61 (2005) [hereinafter “World Bank Models”].

to the Committee staff. In the interests of conciseness, this report will not recount the step-by-step process that ultimately produced the specific terms of the Decision. However, the key elements and issues raised by those elements are discussed below.

a. Scope of Covered Diseases

In defining “pharmaceutical product”, both the Decision and pending Amendment establish a broad subject matter scope of the medicines and related supplies that may be furnished pursuant to the system.¹⁶ The definition refers to products “of the pharmaceutical sector needed to address the public health problems as recognized in paragraph 1 of the Declaration on the TRIPS Agreement and Public Health.” Paragraph 1 of the Doha Declaration does not contain any limitation on the application of the Declaration to specific diseases or medicines. The definition of pharmaceutical product expressly extends to active ingredients, as well as to diagnostic kits used for determining whether pharmaceutical treatments are needed. The definition is broad enough to include vaccines because vaccines are “products of the pharmaceutical sector”.

Despite the intensive and extensive negotiations on the subject of “scope of diseases”, the outcome has not prevented business-oriented publications, such as the *Financial Times* and the *Wall Street Journal*, from recently opining, in response to the grant of a compulsory license on Plavix (clopidogrel bisulfate) by Thailand, that WTO compulsory licensing rules were never intended to cover conditions such as heart disease. EC officials have reportedly made similar assertions to NGO personnel. Although these opinions were offered in the context of Thailand’s use of Article 31 of the TRIPS Agreement, and not the August 30 Decision, they provide continuing evidence that Pharma’s advertising and lobbying efforts will seek to distort the plain language of the TRIPS Agreement and Doha Declaration if it suits their purpose.

b. Notification and Eligible Importing Countries

There are several forms of notification contemplated by the Decision and Amendment. The first is a general notification of intent to make use of the system as an importing country, which notification is required from all countries that use the system other than Least-Developed Countries (LDCs).¹⁷

(1) General Notice of Intent to Use

As an administrative matter, there would be almost no concrete transaction cost for a country in making this initial notification of intent to use. No special information is required and the World Bank models present readily usable forms for this purpose. It remains, of course, a pointless exercise, which follows from the EU line of loading-up the Decision and Amendment with bureaucratic requirements.

¹⁶ Para. 1(a), Decision; para. 2, Article 31bis Annex to TRIPS Agreement [hereinafter “Art. 31bisAnnex”].

¹⁷ Para. 1(b), Art. 31bis Annex.

Least-Developed Members are exempt from this general notification requirement, which means that more than 30 WTO Members already are eligible to use the system. Some commentators have wondered why no other country has so far made the general notification of intent to use the system to the TRIPS Council. Since negotiation of the Decision and Amendment was a priority for developing countries, the absence of notifications could be viewed as: (1) evidence of lack of confidence in the system itself, or (2) reflection of concern on the part of developing countries that they will be criticized, and perhaps penalized, by the major OECD powers for having indicated an intention to use it.

Whether governments are neglecting to make notification because of a lack of confidence in the system is a very difficult matter to assess. It would become clearer if a country that considered using the system had rejected such use because of potential obstacles, but the authors are not aware of any such case.

The second possibility reflects a potential line of OECD criticism, to the effect that "Country X has evidenced that it is hostile to foreign direct investment by threatening inviolable rights in patents. It is not a full-fledged participant in globalization, and it will suffer adverse economic consequences". Industry groups in the OECD and parts of the media have deployed this rhetoric in reaction to the recent grants of compulsory licenses by Thailand and Brazil.

Whether adverse press of this kind would pragmatically translate into a palpable reduction in foreign direct investment is another matter. The authors of this report have their doubts about that. Would, for example, a manufacturer of computer equipment decide not to invest in an otherwise attractive business environment because the host country had taken steps to protect the public health of its citizens, even if this included the grant of a compulsory license? That same company might just as well view measures taken for the protection of public health as a positive inducement, in part because company health expenditures might be lowered.

Nevertheless, in requiring eligible importing countries to deposit a general notification of intent to use, the European Union may have accomplished its objective. This pragmatically irrelevant formality may in fact impose a political barrier that limits the use of the system.

(2) Self-Declaration of Non-Use or Limited Use

The Decision and Amendment also provide that a WTO Member may notify the TRIPS Council that it does not intend to use the system as an importing country, or that it intends to use it only in a limited way.¹⁸ Practically all (if not all) OECD countries have made a notification of their intention not to use the system, including the European Communities and each of its member states, or to use it in a limited way.

¹⁸ *Id.*

While the EU decision to reject eligibility to use the system seems bizarre, and obviously contrary to the public health interests of the inhabitants of the European Union in view of recent concerns about Avian influenza, for example, we lack space to analyze it here. We note that on the subject of compulsory licensing for public health, the United States authorities threatened such action with regard to stockpiling Cipro for an anthrax scare, and according to the testimony of Health and Human Services Secretary Leavitt, regarding access to Tamiflu as well.¹⁹ We also note that France and Belgium have recently enacted statutes permitting accelerated compulsory licensing of pharmaceuticals when needed. The official positions hostile to compulsory licensing are intended to inhibit action by foreign governments, but they are not actually considered to constrain the EU or the United States. In fact, the United States makes greater routine use of compulsory licensing of patent inventions for a variety of government purposes than most other countries combined.²⁰

Whether a government could later withdraw its own self-declaration of intention not to use the system in response to changed circumstances presents an abstract legal question for which no clear answer exists. As a practical matter, however, it is doubtful that any country would seriously oppose such a retraction, and the question seems more political than legal in character.

c. Determination as to Insufficient or No Capacity

In order to be eligible to import medicines in a given case, a country must either (1) be a Least Developed Country, or (2) make a determination that it has insufficient or no manufacturing capacity for the product in question.²¹ The determination regarding capacity, which is made by the importing country, excludes production facilities that the patent holder owns or controls. It applies to the specific product in question, and not generally to the country's pharmaceutical industry.²² Once the importing Member has developed its own adequate capacity, it is expected to cease use of the system.

This requirement imposes no significant burden on a prospective importing Member. When there is adequate domestic capacity to produce the product in a way that would reasonably satisfy the country's needs, there is no reason to obtain supplies elsewhere. Developing WTO Members succeeded on this issue, despite the EU's proposal to divide the API and formulation markets (which might have created significant inefficiencies).

¹⁹ U.S. Representative Joe Barton (R-Tx) Holds a Hearing on Pandemic Flu Preparedness, House Energy And Commerce Committee, FDCH Political Transcripts, Nov. 8, 2005, exchange between HHS Sec'y Michael Leavitt and Representative Tom Allen, Lexis-Nexis News database.

²⁰ See generally Reichman with Hasenzahl, *Non-Voluntary Licensing of Patented Inventions: The Law and Practice of the United States*, Part III (ICTSD/UNCTAD 2003) (citing authorities).

²¹ Para. 2(a)(ii), Article 31bis Annex, and Appendix to Annex.

²² The "Chairperson's Statement", discussed *infra*, indicates that "To promote transparency and avoid controversy, notifications under paragraph 2(a)(ii) of the Decision would include information on how the Member in question had established, in accordance with the Annex, that it has insufficient or no manufacturing capacities in the pharmaceutical sector." Irrespective of the legal status of the Chairperson's Statement, this adds nothing material to the Amendment. A statement that the importing country had examined relevant available data would suffice.

d. Licensing and Conditions

The procedural and substantive requirements that govern the issuance of compulsory licenses by importing (where applicable) and exporting countries, as well as the conditions and notifications connected with that licensing, constitute the principal potential obstacles to effective use of the Amendment.

(1) Importing Members

An importing member need not issue a domestic compulsory license when there is no applicable patent. Because Least-Developed Members are authorized to disapply patent protection, they also do not need to issue domestic compulsory licenses if they choose to disapply the relevant patent(s). An importing member that is not exempt (per the above) must issue a compulsory license prior to importation, and it must notify the TRIPS Council of its intent to issue (or its issuance of) the license.²³

While compulsory licensing may entail various administrative complications, there are legitimate ways to avoid a substantial part of them. For example, a license issued for public noncommercial use or for national emergency or circumstance of extreme urgency does not require prior negotiation with, or even notification of, the patent holder (pursuant to Article 31(b), TRIPS Agreement, which applies to the Amendment procedure).²⁴ Only in the case where a party is seeking a compulsory license for ordinary commercial use do the requirements of prior negotiation with the patent holder and prior notification apply. It is therefore possible to structure action on the importing side (as well as on the exporting side) to take place in an expeditious manner.

It is worth noting that action to remedy anticompetitive practices also dispenses with the need for prior negotiation with the patentee and with the limits on exports under article 31(f),²⁵ which would otherwise require recourse to the Amendment. However, actions to correct anticompetitive practices require some judicial or administrative process,²⁶ which takes time. Once the process is completed, the prosecuting government is also freed from the duty to provide adequate compensation and may, instead, penalize the patentee for its conduct.²⁷ In this connection, the Italian Competition Commission has issued three compulsory licenses against major pharmaceutical companies for refusals to deal in the past year, and it has imposed royalty-free licenses to boot.²⁸

²³ *Id.*, para. 2(a)(iii)

²⁴ *See, e.g.*, para. 2(a)(iii), *id.*, for continued applicability of Article 31, except as otherwise amended. In addition, the possibility for injunctive relief need not be available with respect to government use licenses (pursuant to Article 44.2, TRIPS Agreement).

²⁵ TRIPS Agreement, art. 31(k).

²⁶ *Id.*

²⁷ *Id.*

²⁸ *See, e.g.*, Press Release, Pharmaceuticals: Antitrust Authority Rules Merck Must Grant Free Licences For The Active Ingredient Finasteride, A364 - Merck - Active Ingredients (Conclusion Of Investigation), http://www.agcm.it/agcm_eng/COSTAMPA/E_PRESS.NSF/92e82eb9012a8bc6c125652a00287fbd/28653b373e56772ac12572ab003a4d68

Under Article 31*bis*, the importing Member must specify the name of the product(s) and the expected quantities to be imported, and make notification of that to the TRIPS Council.²⁹ While some commentary on the Amendment has suggested that the requirement to indicate expected quantities inhibits effective use of the system, this is not necessarily true. The Amendment does not demand a particular fixed formula with respect to indication of expected quantity. There are a variety of ways that a relatively subjective indication can be expressed (e.g., the quantity needed to treat an approximate sized group of patients over an approximate period of time), and there is nothing in the Amendment that prevents a Member from modifying the quantity over time.³⁰ While it would have been simpler to avoid a statement of expected quantity, this requirement, standing alone, does not necessarily constitute a significant inhibition.

Also criticized is the requirement that prospective suppliers in exporting Members are only able to produce on a case-by-case, license-by-license basis. Prospective exporters accordingly find it harder to make decisions and investments necessary to scale-up production because there is no assurance of import markets. This issue will be further addressed in the context of the requirements imposed on exporting Members. However, so long as “predominant” exports are considered a form of “exception” under Article 31(f) that requires specific procedural attention, investment planning may be problematic unless action to pool compulsory licenses in appropriate procurement cases—as explained below—suffices to address the problem.

(2) Exporting Members

The exporting Member is required to issue a compulsory license with conditions.³¹ The authorized manufacturer should only export the quantities needed (and notified) by the importing Member(s).³² Product should be clearly identified as having been produced under this system, including by special packaging and/or labeling, and/or special shaping or coloring, if the distinctions are feasible and do not have a significant impact on price.³³ The exporting licensee is required to post destination and identification information regarding shipments on a web site.³⁴ The exporting Member is required to notify the TRIPS Council of the issuance of the license and conditions, including the expected quantities of production and destination(s).³⁵

As with respect to the importing Member, a compulsory license issued by the exporting Member for public noncommercial use or for national emergency or circumstance of extreme urgency does not require prior negotiation with, or notification of, the patent

²⁹ *Id.*, para. 2(a)(i)

³⁰ *See, e.g.*, World Bank Models, at pgs. 23-24.

³¹ *Id.*, para. 2(b).

³² *Id.*, para. 2(b)(i).

³³ *Id.*, para. 2(b)(ii). This provision is also addressed in the Chairperson Statement. Irrespective of the legal and status of the Chairperson Statement, it is unlikely to be an inhibiting influence with respect to this aspect of the Amendment.

³⁴ *Id.*, para. 2(b)(iii).

³⁵ *Id.*, para. 2(c).

holder.³⁶ Thus, in the circumstances addressed in Article 31(b) of the TRIPS Agreement, a compulsory licensing transaction may be pursued expeditiously through back-to-back licenses that take advantage of "fast-track" possibilities.³⁷

It is self-evident from the entire object and purpose of negotiation of the Decision and Amendment that the exporting Member may make use of the "fast-track" procedure to address a situation of emergency, extreme urgency or public noncommercial use in the eligible importing Member. The whole process is obviously designed to meet the pressing needs of the importing country that lacks manufacturing capacity.

The authors of this report would not bother to mention this self-evident matter of interpretation, except that the government of Canada has publicly expressed the view that the fast-track procedure cannot be used in Canada under the Decision and Amendment because there would be no public health emergency in Canada -- most recently stating this as the formal position of their Ministry of Justice.³⁸ While this position has been rejected by other governments in their implementing legislation (see discussion *infra*), it suggests that at least some OECD governments are prepared to act in "less-than-good" faith with respect to implementation of the Amendment, and it may undermine the extent to which developing country governments believe they can rely on the good faith of negotiators at the WTO.

As a general matter, the information required by the TRIPS Council concerning the grant of a compulsory license should not be difficult for the exporting Member to assemble. As to the burden on an exporting producer to provide notification of the shipments and intended destinations, reputable pharmaceutical producers generate detailed production and shipping records in the ordinary course of business, and posting such information on the Internet should be a minor matter.

Similarly, while there might be some cases where specially identifying a product would impose difficulties, in the ordinary case this seems unlikely. Finished product packaging is relatively easy to modify, and identification through such packaging or labeling is acceptable under the terms of the Amendment. Whether it will be cost-prohibitive to modify the color or shaping of a product will depend on the individual case. The language of the Amendment suggests that a producer should not be required to purchase

³⁶ See, e.g., para. 2(a)(iii), *id.*, for continued applicability of Article 31, except as otherwise amended.

³⁷ The "fast-track" terminology in this regard was initially adopted by the European Commission TRIPS negotiating team and used in an article on the Decision published subsequent to its adoption. Paul Vandoren and Jean Charles Van Eeckhaute of the European Commission suggested the term "fast track" to describe the emergency/public noncommercial use option under Article 31(b) of the TRIPS Agreement. Paul Vandoren & Jean Charles Van Eeckhaute, *The WTO Decision on Paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health: Making It Work*, 6 J. WORLD INTELL. PROP. L. 779, 783 (2003) (noting that under Article 31 "procedures to grant compulsory licences are not necessarily cumbersome and lengthy" but, rather, "minimal and flexible").

³⁸ See Abbott, *WTO Medicines Decision*, at 342, for earlier reference to this Canadian position. The position was reiterated, and attributed to the Ministry of Justice, at a public meeting on review of Canada's legislation held in Ottawa on April 19-21, 2007 (author's notes).

new formulation or stamping equipment solely for this purpose, but might make some adjustments to existing production processes.

A potentially more serious obstacle for the prospective exporter is the requirement to produce only amounts needed to satisfy the requirements of licensees or other importers (e.g., Least-Developed Members operating under an exemption) as notified to the TRIPS Council. Prospective producers in exporting countries may thus be deterred from constructing new facilities "on speculation" that a sufficient number of orders will be received in the end.

However, there are factors that may ameliorate this potential problem. As with any production venture, the plant owner may seek to visit prospective purchasers prior to undertaking capital expenditure to obtain indications of intention to purchase and/or commitments. Moreover, the recipient of a compulsory license under this system is not precluded from also obtaining a license for supply of its domestic market.

Pooled procurement strategies may well be used by countries or groups of countries with long-term needs that can be identified in advance, which may facilitate long-range planning for potential exporters. For example, a group of countries in the Caribbean may know that they have a long-term need for second or third line antiretroviral treatment and that they would wish to contract for purchase with an Indian or Brazilian supplier. This approach will be addressed further in discussion of Regional Supply Centers below.

Existing pharmaceutical production facilities may in some cases be modified to produce different drugs. It will not always be the case that to meet the requirements of an importing country (or countries) that a manufacturer will need to build a new facility. In some cases, the transition costs may be modest.

Finally, a producer in a country such as India or Brazil might initiate relatively small-scale production under compulsory license for supply of the domestic market, and later solicit orders that will require it to make use of the Amendment. The costs of ramping up production in such cases may be lower than start up costs from "scratch".

Disregarding the prospects for stimulating production in response to procurements under pooled compulsory licensing strategies, it seems fair to conclude that the Amendment does not encourage "speculative" construction of facilities by prospective exporters under compulsory licenses. However, this outcome is consistent with respect for the rights of patent holders under the terms of the TRIPS Agreement; which are unlikely to be substantially modified in this respect. As matters stand, most systems that provide an "exception" to the rights of patent holders are likely to discourage "speculation" by capital investors.

e. Remuneration

One potential consequence of the issuance of double compulsory licenses in the importing and exporting Members was that the remuneration provided for under Article

31(h) of the TRIPS Agreement would be paid twice. The Amendment avoids this consequence by providing that adequate remuneration need only be paid in the country of export, taking into account the economic circumstances of the importing country.³⁹ This reasonable solution to the remuneration issue will not likely lead to difficulties.

f. Measures to Prevent Diversion and Non-Authorized Importation

The Amendment obligates importing Members to take reasonable and proportionate measures to prevent diversion or re-exportation of pharmaceutical products received under the system.⁴⁰ There is provision for potential assistance from developed to developing Members in implementing an anti-diversion system, if requested. This provision is directed to governments and, in that sense, adds an obligation to those that already exist under the TRIPS Agreement. It need not materially inhibit use of the system or impose unreasonable costs. Drug importation should ordinarily be subject to close supply chain management, and steps taken to ensure the integrity of supply are likely to prove useful from a public health perspective as well.

The Amendment requires Members to provide means for patent holders to protect against unauthorized importation of products produced under the system and diverted into their markets.⁴¹ However, Members are not required to establish mechanisms beyond those already available under the TRIPS Agreement. Implicit in this scheme is an understanding that products produced under the relevant compulsory licenses should not be treated as "lawful parallel imports" after having initially been placed on the market. This result follows logically from the design of the system, which limits exports to the intended destination (although another approach to re-exports might reasonably have been pursued).

g. Special Regional Treatment

The Amendment makes special provision for Members that belong to regional trade agreements of which at least half the members "currently" are Least-Developed Countries.⁴² This provision permits pharmaceutical products imported into one Member of the group under a compulsory license to be re-exported to other Members of the group without additional *export* licensing. However, it does not exempt the importing countries from issuing separate compulsory licenses where otherwise applicable (i.e., when there is a patent or, in the case of a Least-Developed Member, when it has not elected to disapply the patent). There is also some provision for developed country assistance in establishing systems for the grant of regional patents to facilitate use of this concession.

However, this provision for special treatment of a regional alliance remains severely restricted. The European Union, which was instrumental in imposing these limitations during the negotiations, insisted that the solution be limited to what is effectively sub-

³⁹ *Id.*, para., Article 31bis.

⁴⁰ *Id.*, para. 3

⁴¹ *Id.*, para. 4.

⁴² *Id.*, para. 3.

Saharan Africa, and it rejected proposals that would have made it unnecessary for importing countries to issue compulsory licenses when re-exportation was otherwise enabled.⁴³

There were few aspects of the negotiations more frustrating to developing countries than the refusal by developed countries to permit more flexible implementation of a regional solution. Caribbean negotiators -- whose countries are experiencing major HIV-AIDS problems -- were particularly disappointed, and remain so at the present time. Notwithstanding the foregoing, the authors of this report will suggest the use of regional mechanisms that may enable cooperating governments to overcome these restrictions.

h. Non-Violation Causes of Action

The Amendment expressly precludes nonviolation nullification or impairment causes of action, and situation causes of action, from being initiated in dispute settlement with reference to the Amendment.⁴⁴ This prohibition is important because the general situation regarding nonviolation complaints under the TRIPS Agreement remains uncertain, and the possibility of such complaints might create substantial insecurity for countries inclined to use the system.

i. Non-Prejudice to Other Rights and Non-Members of the WTO

The Amendment expressly provides that WTO Members are not precluded from exercising other rights under the TRIPS Agreement. Therefore, if production and export by third parties of products under patent are deemed permissible under Article 30, which deals with exceptions rather than compulsory licensing, this possibility has not been foreclosed by the Amendment. As discussed further below, the authors (along with many NGOs) view this as an option that the European Parliament may wish to consider. The Amendment also makes it clear that countries are not precluded from exporting under compulsory licenses within the otherwise applicable limitations of Article 31(f) (i.e., less than a predominant part of production), without resort to the special legal machinery envisioned by the Amendment.

The continuing applicability of Article 30 also permits exports to countries that are not members of the WTO, including a number of the poor countries of the world that may particularly need to import medicines under compulsory licenses. There is no reason why an exporting WTO Member cannot extend the availability of the solution to an importing non-member as a limited exception to the rights of the patent holder in the exporting country, especially if the importing non-member provides a diplomatic representation that it will abide by the conditions of the Amendment. Several WTO Members have already implemented availability of the Amendment for non-members of the WTO.

⁴³ The provision for assistance in regional patenting was viewed by developing country negotiators as part of an EU strategy for making it easier for EU pharmaceutical companies to control the market.

⁴⁴ Para. 4, Article 31*bis*.

j. The Chairperson's Statement

In December 2002, the United States blocked adoption of the draft text of the Decision because it refused to accept an open-ended solution with respect to "scope of diseases".⁴⁵ For the next seven months, the United States sought agreement on limitation of the scope of diseases, or restriction of the solution to countries of sub-Saharan Africa, which ultimately failed. (At one stage, the EU proposed as a compromise that countries wishing to use the system would need approval of the WHO with respect to diseases they were addressing outside a list of diseases that were presumably covered.)

Developing countries made clear that they were not going to accede to the US demands to limit the "scope of diseases". As the Cancun Ministerial Conference approached in September 2003, neither the WTO Secretariat nor key developed country actors wished to see the Ministerial dominated by the public health issue. Some face-saving formula was required to allow the United States to sign off on the Decision, which ultimately resulted in a statement read out by the Chair of the General Council prior to adoption of the Decision on August 30, 2003, and again prior to adoption of the Protocol on December 6, 2005 (the Chairperson's Statement).

As a practical matter, the only controversial provision of the Chairperson's Statement is the shared understanding that,

First, Members recognize that the system that will be established by the Decision should be used in good faith to protect public health and, without prejudice to paragraph 3 of Article 31*bis* of the amendment [or paragraph 6 of the Decision], not be an instrument to pursue industrial or commercial policy objectives.

During negotiation of this provision, the United States had initially proposed that use of the Decision should be "not for commercial gain," but this was promptly rejected by developing country negotiators. The final formula indicates that the intention of the system is to support public health needs, and not merely to advance industrial policy objectives. The authors of this report do not consider that this statement will in fact inhibit use of the system, whatever its legal status may ultimately be determined to be.⁴⁶ It seems unlikely that any WTO Member issuing a compulsory license for export of a pharmaceutical product to assist needy countries would be failing to advance the objectives of public health.

In the recitals of its Regulation implementing the Decision (*see analysis infra*), the European Union has referred to its adoption "in the light of the statement read out by [the WTO General Council] Chairman". Also in the recitals to the Regulation, it has included

⁴⁵ For details, including US statement to TRIPS Council, *see* Abbott, *WTO Medicines Decision*, *supra* note 6, at 331.

⁴⁶ Nonetheless, there is considerable controversy concerning the legal status of the Chairperson's Statement.

language regarding use in “good faith” adapted from that statement. Such references may represent a form of subsequent state practice in application of the Decision (see Article 31(3)(b), Vienna Convention on the Law of Treaties), and might add some weight to an argument that the statement was intended to influence interpretation of the Decision. However, the practice of one state (or region) party to the Decision would not be decisive in establishing the legal character of the statement, particularly since that practice in this instance does not involve application of the Decision to a compulsory license (or application), but merely recitation in the preamble to the implementing legislation. Moreover, the EU’s recital adds no greater substantive bite to the statement itself on this matter, which does not seem to present any serious obstacle at present.

k. Technology Transfer

The Amendment recognizes the desirability of improving pharmaceutical production capacity in countries with insufficient or no capacity, and it encourages Members to “use the system in the way which would promote this objective”.⁴⁷ It also includes an “undertaking” by Members to address this situation as part of Article 66.2 of the TRIPS Agreement, and related commitments to Least-Developed Members. The German government, in association with UNCTAD, UNIDO and the UK Department for International Development (DFID), is undertaking a program to improve production capacity in certain Least Developed Countries of Africa and elsewhere (*see infra*), which represents an example of positive implementation of this undertaking. As another example, the United States has also provided some funding for the study of transfer of technology options for the pharmaceutical sector in Latin America, one of which studies is being undertaken by an author of this report.⁴⁸

What these initiatives have suggested to the authors of this report is that there are quite concrete mechanisms by which the European Union might support the improvement of pharmaceutical research, development, and production capacity in developing countries. Moreover, the EP’s Committee on International Trade expressly recommended that the Community should “encourage...the transfer of technology, research, capacity strengthening, regional supply systems and help with registration in order to facilitate and increase the production of pharmaceutical products by the developing countries themselves.”⁴⁹ Yet very limited financial resources are so far committed to such endeavors. The implementing Regulation for the Decision, discussed *infra*, pays scant attention to issues of technology transfer and capacity-building, merely paraphrasing at Recital 13 some general language of the Decision.

⁴⁷ Para. 6, Article 31*bis* Annex.

⁴⁸ Frederick Abbott is serving as technical expert for a project funded by USAID regarding transfer of technology in the pharmaceutical sector with respect to Colombia, which project has also involved extensive consultations in Brazil.

⁴⁹ See European Parliament, Committee on International Trade, Report on the Proposal for a regulation of the European Parliament and of the Council on compulsory licensing of patents relating to the manufacture of pharmaceutical products for export to countries with public health problems (Com (2004) 0737-C6-0168/2004-2004/0258 (COD), A6-0242/2005, at 7 [hereinafter EP Committee on International Trade, Report (2005)].

We emphasize that building up pharmaceutical-related capacity in developing countries is quite *practicably achievable*. The question is not *whether* it can be done, but whether developed country governments are *genuinely prepared* to promote such objectives.

1. Provisions for Review

The Amendment includes provision for annual review of the functioning of the system by the TRIPS Council, with a view toward “ensuring its effective operation,” and it presupposes an annual report on its operation to the General Council. If the Amendment enters into force, the annual review should provide a platform for considering whether any modifications are desirable. It should be evident, however, that achieving a new consensus with respect to changes to the system will be difficult. Therefore, a decision to accept the Amendment in its present form must be understood as a serious commitment to the system in that form.

4. The EU Implementing Regulation

As noted at the outset of this report, governments involved in the negotiation of the Decision and Amendment are well aware that it was not designed to provide the maximum flexibility and administrative simplicity in favor of countries seeking to protect public health. Given the deliberate limitations built into the Amendment, the question from a public health standpoint is whether it can and will be implemented in a manner that enables countries without adequate production capacity to make effective use of compulsory licensing.

The initial proposal for an implementing regulation from the European Commission contained a number of restrictions and limitations that would have substantially inhibited effective use of the Decision and Amendment. Among the most important deficiencies, that proposal did not acknowledge the possibility for use of the fast-track procedure.⁵⁰ Notwithstanding the problematic initial proposal, and through successful intervention by the European Parliament, the EU ultimately adopted an implementing Regulation that takes a largely positive approach.⁵¹

The following list briefly summarizes what the authors view as the most promising aspects of the Regulation:

⁵⁰ Proposal for a Regulation of the European Parliament and of the Council on compulsory licensing of patents relating to the manufacture of pharmaceutical products for export to countries with public health problems, Brussels, COM(2004) 737 final, 29.10.2004. One of the authors of this report provided comments on the initial Commission proposal to Professor Carlos Correa, at his request, in connection with his assessment prepared for the European Parliament. For observations by Professor Abbott in this regard, see *Assessing the European Draft Regulation for Implementation of the WTO Decision of August 30, 2003*, Response to questions by Prof. Frederick M. Abbott, January 19, 2005 (email to Prof. Correa). See Professor Carlos M. Correa, Policy Paper, *Assessment of the Proposed EU Regulation on the Compulsory Licensing of Generic Drugs for Export to Developing Countries*, Policy Department, European Parliament, EP/ExPol/2004/07 01/02/2005.

⁵¹ Regulation of the European Parliament and of the Council on compulsory licensing of patents relating to the manufacture of pharmaceutical products for export to countries with public health problems, 2004/0258 (COD), PE-CONS 3674/05, Brussels, 12 April 2006 [update cite].

- It mandates the grant of a compulsory license for export by the member state authority when the appropriate conditions are fulfilled.⁵²
- The definition of a pharmaceutical product extends to any product of the pharmaceutical sector, including vaccines.⁵³
- The Regulation extends to less advantaged non-members of the WTO.⁵⁴
- Use of the system is not limited to government authorities, but extends to "any person", albeit with some qualification regarding authorization from an importing country.⁵⁵
- The Regulation expressly recognizes the option for Least-Developed Countries to disapply patents.⁵⁶
- The Regulation sets a safe harbor for prior negotiation with the patent holder in ordinary commercial cases, i.e. a 30 day period.⁵⁷
- The Regulation waives the requirement of prior negotiation in situations of national emergency, other circumstances of extreme urgency, or in cases of public non-commercial use under Article 31(b) of the TRIPS Agreement.⁵⁸
- The Regulation establishes a maximum royalty for products exported in situations of emergency or for public non-commercial use (under Article 9(2)) of 4% of the total price paid by the importing country.⁵⁹
- The royalty to be paid in the exporting country in otherwise "ordinary" circumstances will take into account "humanitarian or non-commercial circumstances."⁶⁰
- Specific provision is made for expedited increase of the quantities to be supplied beyond those originally set forth in the license application.⁶¹

⁵² *Id.*, art. 1.

⁵³ *Id.*, art. 2. See discussion of relevant cross-referenced EU legislation in Abbott, *WTO Medicines Decision*, *supra* note 6, at 333.

⁵⁴ *Id.*, art. 4(c) & 5.

⁵⁵ *Id.*, art. 6(3)(f).

⁵⁶ *Id.*, art. 8(b).

⁵⁷ *Id.*, art. 9(1).

⁵⁸ *Id.*, art. 9(2). Obviously, the Regulation is not requiring that the condition of waiver needs to be present in the European Union, which would produce an absurd result in context, particularly given that the EU has opted-out of using the Amendment as an importing country/region, and thus could not be acting in the face of its own emergency or public non-commercial use.

⁵⁹ *Id.*, art. 10(9)(a). If further evidence that the waiver of prior negotiation reflects the situation in the importing country is needed (to satisfy Canadian authorities), the fact that the royalty limit (in Article 10(9)(a)) applies with respect to the price paid by the "importing country" makes clear that it is the importing country which is relying on the emergency or public non-commercial use.

⁶⁰ *Id.*, art. 10(9)(b).

⁶¹ *Id.*, art. 16(4). See also EP Committee on International Trade, Report (2005), *supra* note 49, at 17 (mandating this result). As noted earlier, *supra* text accompanying note 30, the terms of the Amendment appear to permit a subjective form of statement of quantity that takes appropriate account of public health needs, e.g., "a quantity of pharmaceutical product 'x' sufficient to treat 'y' patients over 'z' period". See World Bank Models, at doc. 2, pg. 20. Presumably, the EU Regulation does not foreclose the use of such subjective formulas, which may be the most appropriate to medium to longer term treatment of disease, in addition to use for shorter term treatment. The reference in Article 16(4) of the Regulation to a requirement for negotiation with the patent holder regarding added quantities in excess of 25% of the amount stated in the original license (when a TRIPS Article 31(b) waiver does not apply under Article 9(2) of the

- Procedures are included for expedited regulatory approval of products previously not registered,⁶² while marketing exclusivity rules that might otherwise impede the registration, production and export of products under compulsory license are waived.⁶³
- Provision is made for periodic review of the operation of the Regulation, including specific aspects where problems might logically arise.⁶⁴

Given that the European Union was working within the limitations imposed by the text of the Decision and Amendment, it has certainly done a creditable job in giving effect to the flexibility inherent in the system. Until the Regulation is used, it is hard to assess whether there may be some "hidden defect" that will present a significant barrier to effective use. The authors of this report do not suggest that there is literally no room for improvement in the Regulation,⁶⁵ but the potential improvements appear to lie at the margins of an otherwise positive effort, which the EP's Committee on International Trade seems to have influenced.

5. Provisional Evaluation of the Pending Enactments

One of the common criticisms directed at the Decision (and Amendment) is that its legal machinery has not been used despite its adoption in the waiver of August 2003. It seems to logically follow that because the Decision has not been used, it is ineffective. The authors of this report believe this particular line of criticism to be both premature and unconvincing.

While the Decision and Amendment may not have been formally invoked by any WTO Member to date, this does not mean that the Decision has failed to play a significant role in influencing access to essential medicines. In 2005, as worldwide concerns about the spread of a deadly form of Avian flu increased, Taiwan announced that it would issue a compulsory license for the local production of Roche's patented Tamiflu (oseltamivir) antiviral.⁶⁶ Following expressions of concern by other countries regarding potential limits on the availability of Tamiflu from Roche, the Swiss pharmaceutical company issued voluntary licenses to a number of producers to permit stockpiles to be increased,⁶⁷

Regulation) should presumably not be understood to limit the type of quantity formula included in the original license. If it were so understood, this would suggest the need to revisit the terms of the Regulation.

⁶² *Id.*, art. 18(1).

⁶³ *Id.*, art. 18(2).

⁶⁴ *Id.*, art. 19.

⁶⁵ For example, nongovernmental organizations require evidence of government authorization to make use of the system. Such a limitation may impose unjustified constraints on the activities of NGOs, particularly those working in least developed countries.

⁶⁶ Kathrin Hille, *Taiwan employs compulsory licensing for Tamiflu*, FT.com, Nov. 25, 2005. The report notes that Taiwan issued a domestic license with a number of limitations.

⁶⁷ Roche Media News, *Roche update on Tamiflu global supply to meet future world demands – from partnerships to regional sub-licenses*, Basel, Dec. 12, 2005 (reporting voluntary license to Shanghai Pharmaceutical Group, and identification of twelve potential sub-licensees); Roche, Factsheet Tamiflu, 17 Nov 2006, at http://www.roche.com/med_mbtamiflu05e.pdf.

including producers in China (two suppliers), India and South Africa.⁶⁸ Although Roche was said to have entered into voluntary licensing agreements with U.S. generic manufacturers to increase production under pressure from members of Congress,⁶⁹ Roche itself reports that it has stepped up its own controlled production in the United States at the request of the Department of Health and Human Services.⁷⁰

Roche's actions with respect to the supply of Tamiflu were taken in the shadow of the Decision and Amendment, which would have permitted the export of its product under compulsory license to countries without adequate manufacturing capacity. A producer acting under compulsory license in Taiwan, China or India could fulfill orders from developing countries around the world (most developed countries have opted out of the Amendment-based system). Compulsory licensing has traditionally served as an effective threat against which price reductions or voluntary licenses may be negotiated,⁷¹ and it seems likely that the Decision played that role in the case of Tamiflu.

Even if one discounts the role of the Decision in the Tamiflu situation, it is nevertheless unsurprising that the Decision has not yet been used. The factual basis on which negotiation of the Decision and Amendment was predicated was the transition to take place in India on January 1, 2005. After that date, pharmaceutical mailbox patent applications would be processed and new pharmaceutical products would become subject to patenting. While a resulting curtailment of generic supplies to world markets from India was anticipated, this impact was not expected to be, and is not, immediate.

Indian patent offices must process the mailbox applications, which has been slow. Moreover, India's Patent Act amendments permit generic producers to continue supplying products already in production on January 1, 2005, upon payment of a reasonable royalty, and Glaxo decided against pursuing its Indian patent application for Combivir.⁷²

The consequence of these factors is that Indian generic production and supply to world markets has yet to be curtailed. There has not been a newly arising need for prospective

⁶⁸ The Chinese license was reportedly issued under threat of compulsory license. See James Packard Love, Recent Examples of the Use of Compulsory Licensing on Patents, KEI Research Note 2007 (2), revised as of 6 May 2007, available at http://www.keionline.org/misc-docs/recent_cls.pdf.

⁶⁹ See, e.g., California State Senate Health Committee Staff Analysis of Senate Bill 1763, April 2006, noting that, "On October 26, 2005 ten members of Congress sent a letter to Health and Human Services Secretary Michael Leavitt noting that compromising public health needs to protect patent rights is 'inexcusable' "and requesting the immediate issuance of compulsory licenses for Tamiflu and Relenza so that generic manufacturers could begin producing necessary drugs to meet stockpile goals. In December of 2005, Roche reached a voluntary agreement with two U.S. generic drug companies to increase production of Tamiflu." See <http://info.sen.ca.gov/pub/05-06/bill/sen/sb_1751-1800/sb_1763_cfa_20060424_152009_sen_comm.html>.

⁷⁰ Roche recorded conference call MP3 file, April 26, 2007, from http://www.roche.com/home/media/med_events/med_events_mb0407.htm.

⁷¹ See J.H. Reichman with Cathy Hasenzahl, *Non-Voluntary Licenses of Patented Inventions: Part I, Historical Perspective, Legal Framework Under the TRIPS Agreement and an Overview of the Practice in Canada and the United States* (ICTSD/UNCTAD 2003).

⁷² GlaxoSmithKline Press Release, August 10, 2006, GSK patents and patent applications for *Combivir*, <http://www.gsk.com/ControllerServlet?appId=4&pageId=402&newsid=874>.

importing countries to issue compulsory licenses for fulfillment by Indian producers. While use of the system established by the Amendment could have been undertaken in respect to other prospective exporting countries, or for other reasons, these facts help to explain why the system has not yet been used.

The conclusion should not be drawn that the system is therefore unimportant. As countries face the growing need to supply second and third line antiretroviral treatments, which are and will be patented in the principal countries of potential supply, such as China and India, demand for generic products should become intense. In that context, governments may well be prepared to overcome political inhibitions and seek to make use of the system. The recent issuance by Brazil and Thailand of compulsory licenses on Merck's patented Efavirenz drug evidences the growing pressure that is being imposed on public health budgets.

B. The Recent Grants of Compulsory Licenses in Brazil and Thailand

Recent grants of compulsory licenses in two middle-income developing countries have riveted attention on this legal device and heated up the political atmosphere, which indirectly affects the prospects for implementation of the pending Amendment. A brief survey of these developments is set out below.

The Decision does not apply to the government use licenses issued by Brazil and Thailand, nor would the Amendment (if and when it enters into force), at least as matters now stand with respect to foreign requests for supply. Neither Brazil nor Thailand issued its license(s) for the purpose of exporting a predominant part of production to a country or countries without adequate pharmaceutical production capacity, which is the situation covered by the Decision and Amendment. These licenses were instead issued within the legal framework established by Article 31 of the TRIPS Agreement, and reaffirmed by the Doha Declaration, in a manner legally consistent with that framework. Nonetheless, the public health circumstances surrounding the issuance of the licenses, as well as the political reactions, are relevant to assessment of the utility of the Amendment.

1. The Case of Brazil

Few countries in the world -- and certainly among developing countries -- have devoted more attention to the problem of access to medicines than Brazil, and there is a comprehensive academic literature describing in detail the steps the Brazilian government and research institutions have taken to this end.⁷³ To be clear, the government has been criticized for previous legislation favoring multinational over domestic industry, which created serious problems. A number of steps now being taken in Brazil are designed to

⁷³ See, e.g., INTELLECTUAL PROPERTY IN THE CONTEXT OF THE WTO TRIPS AGREEMENT: CHALLENGES FOR PUBLIC HEALTH, (J. Bermudez & M.A. Oliveria eds. 2004), and particularly chapters 7-9; Claudia Ines Chamas, *Developing Innovative Capacity In Brazil To Meet Health Needs*, MIHR report to CIPIH, April 2005WHO Ref. CIPIH Study 10d (DGR); O. Fabienne, D. Cristina, L. Hasenclever and C. Benjamin, *Trips-Post 2005 in Southern Countries: The Sustainability of Public Health Policies at Stake*, DIME Conference, London, Sept. 2006, and Luciana Xavier de Lemos Capanema, *A Indústria Farmacêutica Brasileira e a Atuação do BNDES*, 23 BNDES Setorial 193 (2006).

rebalance the situation, so that there is greater local participation in more innovative parts of the pharmaceutical sector.

Brazil was among the group of developing countries that strongly resisted incorporation of "trade-related intellectual property rights" into the GATT Uruguay Round. Prior to entry into force of the TRIPS Agreement on January 1, 1995, Brazil's domestic industry had produced the bulk of active pharmaceutical ingredients (APIs) used in products sold on the national market. Because Brazil did not provide pharmaceutical product patent protection at the time the TRIPS Agreement entered into force, it could have taken advantage of the same ten-year transition period that India used.⁷⁴ However, in a decision strongly criticized by Brazilian public health experts, the government chose not only to provide pharmaceutical product patent protection from 1996 on, but it also voluntarily provided "pipeline" protection that permitted the extension of patent protection beyond that which would ordinarily have been available to holders of foreign patents.⁷⁵

As a consequence of these decisions, between 1996 and 2005 Brazil lost almost all of its API production capacity, though not the basic technology that might be needed to reestablish that capacity. Today, virtually all APIs used in the Brazilian pharmaceutical sector are imported. There has been a staggering increase, far in excess of that generally applying to other sectors, in Brazilian expenditures on imports of pharmaceutical products.

At the same time, Brazil led the world in establishing universal public access to antiretroviral treatment for HIV-AIDS. As part of a comprehensive strategy, Brazil relied on a system of public manufacturing facilities to produce ARV treatments that were not covered by patents. Through this strategy, Brazil was largely able to provide treatment at a cost reasonably affordable to the government, with one significant problem that emerged. Several important ARVs, particularly those used as second line treatment (i.e., when resistance to first-line treatment develops) were patented in Brazil by foreign multinational producers, and they could not be produced locally without infringing the patents.

The cost to the Brazilian public health sector of purchasing the patented ARVs far exceeds the cost of purchasing locally produced (or imported) generic ARVs, and it is placing a significant burden on the public health sector. Moreover, because resistance to first-line ARVs among the group of patients treated in Brazil will increase over time, and because side-effect profiles of newer generation ARVs may be better than first-line treatments, reliance on newer treatments seems likely to increase, with corresponding increased pressure on the public health budget.

For these reasons, the Brazilian government has used the threat of compulsory licensing to pressure foreign multinational patent holders to significantly lower the prices charged for ARVs. Up until April 2007, Brazil had not formally granted a compulsory license because the government had reached negotiated settlements with foreign suppliers. The

⁷⁴ Article 65.4, TRIPS Agreement.

⁷⁵ Provided that their products had not been previously introduced on the Brazilian market.

decision to pursue voluntary settlements had been criticized by important actors in the Brazilian public health sector because (1) in some cases, the results were perceived as too favorable to the foreign supplier and too restrictive on Brazilian public health authorities, and (2) because the failure to initiate production in Brazil limits the learning experience and capacity of public and private pharmaceutical producers. In the end, reliance on foreign patent-holding suppliers continues at the present time.

However, in April 2007, the Brazilian government⁷⁶ followed through with granting a compulsory license for public use of Merck's⁷⁷ Brazilian patent on the ARV Efavirenz.⁷⁸ This ARV is used in the treatment of approximately 75,000 of 200,000 patients under treatment in Brazil.⁷⁹ Merck offered to lower the annual per patient price of its drug from \$580 to \$400, but there are generic versions available from India at \$165 per patient per year. Brazil estimates a cost-saving of \$30 million per year to its public health procurement budget from shifting to generic imports.⁸⁰

In addition, Brazil's national pharmaceutical laboratory and producers plan to transition to local production.⁸¹ It is useful to note that the U.S. President's Emergency Plan for AIDS Relief (PEPFAR) authorizes the purchase of generic Efavirenz from at least one Indian supplier (Aurobindo), and that the latest report from PEPFAR explains the substantial cost saving the U.S. government is achieving in its treatment program through a shift from originator to generic ARVs (including Efavirenz).⁸²

2. The Case of Thailand

Thailand covers a large part of its population with universal access to medicines through publicly funded government organizations.⁸³ Included among these programs is universal access to HIV-AIDS treatment. Since the entry into force of the TRIPS Agreement, Thailand's budget expenditures for the provisions of medicines have increased dramatically, now constituting approximately ten per cent of the government budget.

⁷⁶ See Q&A from the Brazilian MoH on the Efavirenz CL - official translation from the MoH available on www.aids.gov.br, posted on IP-Health List Serve, April 26, 2007.

⁷⁷ In Brazil, through its affiliate "Merck Sharp & Dohme". *Id.*

⁷⁸ "Efavirenz is in the class of drugs called non-nucleoside reverse transcriptase inhibitors (NNRTIs), which helps keep the AIDS virus from reproducing in cells. This antiretroviral drug is used in combination with other antiretroviral agents for the treatment of HIV-1 infection." US Food and Drug Administration, FDA Tentatively Approves Generic Efavirenz – Product Eligible To Be Considered Under the President's Emergency Plan for AIDS Relief, FDA News, June 24, 2005.

⁷⁹ See Brazil MoH, *supra* note 76, and Joe Cohen, *Brazil, Thailand Override Big Pharma Patents*, SCIENCE MAGAZINE, May 11, 2007, at 816.

⁸⁰ *Id.*

⁸¹ Marcia Wonghon, *Brazil Decides to Make Own AIDS Drug After Talks With Merck Collapse*, Brazil Mag., May 3, 2007, available at <http://www.brazzilmag.com/content/view/8220/54/>.

⁸² See, e.g., PEPFAR, Critical Intervention in the Focus Countries: Treatment, at, e.g., Tables 2.8 & 2.9, referring, *inter alia*, to generic versions of Efavirenz, <http://www.pepfar.gov/documents/organization/81024.pdf>.

⁸³ A comprehensive description of Thailand's public health system approach to provision of medicines can be found at Ministry of Public Health and National Health Security Office, Thailand, Facts and Evidences on the 10 Burning Issues Related to the Government Use of Patents on Three Patented Essential Drugs in Thailand, Feb. 2007, ISBN 978-974-94591-5-7 [hereinafter the "Thai White Paper"].

Among countries in Asia, Thailand provides the largest percentage of HIV-AIDS patients with antiretroviral treatment. However, due to the high costs of some patented ARVs, the Thai public health system may need to provide lower-cost alternatives that increase the risk of side effects.

From November through February 2007, the government of Thailand issued compulsory (“government use”) licenses on three patented pharmaceutical products.⁸⁴ Two of these are antiretroviral treatments: (1) Kaletra (Lopinavir and Ritonavir) (patented in Thailand by Abbott Laboratories), and (2) Efavirenz (patented in Thailand by Merck). The third is Plavix (clopidogrel bisulfate), a product used for the treatment of coronary disease, patented in Thailand by Sanofi-Aventis. The licenses will initially be used for the importation of generic products from India, but the government production facility (GPO) plans to initiate local production in the future.

The government has proposed payment of a royalty of 0.5% to the patent holders, but has indicated (and provided in legislation) that this rate is open to further negotiation and review. The Thai government did not attempt to negotiate voluntary licenses with the aforementioned patent holders prior to issuing the government use licenses. However, the government had unsuccessfully attempted to negotiate price reductions from the patent holder-suppliers over a prolonged period of time prior to issuance of the licenses.

When the government issued its public use license for Efavirenz, Merck’s price was approximately double that of the Indian generic price. Merck later offered to substantially reduce its price for Efavirenz to about 20% above the Indian generic price.⁸⁵ The Thai government expects to reduce the price of purchasing Kaletra to about 20% of the current price charged by Abbott Laboratories. The Thai government indicates that it will be able to reduce its costs for clopidogrel (Plavix) by a factor of 10.⁸⁶

The Thai authorities stress that the “government use” licenses issued for supply through its public health care system will not be used to supply the comparatively small segment of the “private” Thai commercial pharmaceuticals market, where products are sold at the patentee’s prices. Spokesmen for the Health Ministry have publicly declared at several conferences that their goal was to move the pharmaceutical companies from a “low volume-high margin” price strategy to a “high volume-low margin” alternative approach..

Because Thailand already contracted for several months supply of Efavirenz from an Indian generic supplier, the government has not yet considered it necessary to make a decision regarding future purchases from Merck at its reduced offer price. The Thai government continues to hold discussions with Abbott Laboratories and Sanofi-Aventis. Meanwhile, Abbott Laboratories has withdrawn a number of applications for regulatory approval of drugs that were pending at the time the government use license on Kaletra was issued.

⁸⁴ Documents evidencing the grants of the compulsory license are attached to the Thai White Paper.

⁸⁵ Thai White Paper, pg, 29 and Document 21, Merck Press Release.

⁸⁶ Thai White Paper, pgs. 14-15.

3. Foreign Reaction

The multinational pharmaceutical companies affected by the Brazil and Thailand compulsory licensing decisions have reacted by asserting that these decisions will have a negative effect on research and development for new medicines and, at least in the case of Abbott Laboratories and Merck, have strongly condemned the actions.⁸⁷ Pharmaceutical industry groups, and more broadly-based industry chambers of commerce, have likewise reacted quite negatively to these developments.⁸⁸

At least in the case of Thailand, the reaction by United States government authorities has been somewhat uncharacteristically ambivalent. On one hand, USTR Susan Schwab assured a substantial number of concerned members of Congress that her agency appreciates that the actions taken by the government of Thailand appear to be within WTO rules, and that USTR was not directly involved in addressing this situation. On the other hand, USTR placed Thailand under 2007 Special 301 “Priority Watch List” surveillance, stating:

[I]n Thailand, in late 2006 and early 2007, there were further indications of a weakening of respect for patents, as the Thai Government announced decisions to issue compulsory licenses for several patented pharmaceutical products. While the United States acknowledges a country’s ability to issue such licenses in accordance with WTO rules, the lack of transparency and due process exhibited in Thailand represents a serious concern. These actions have compounded previously expressed concerns such as delay in the granting of patents and weak protection against unfair commercial use for data generated to obtain marketing approval.⁸⁹

The authors of this report have thus far found little public evidence of negative European governmental reaction to the issuance of government use licenses by Brazil or Thailand.

Thailand has received a statement of support from the head of UNAIDS, Dr. Peter Piot.⁹⁰ The Director-General of the WHO, Dr. Margaret Chan, was reported to have sharply criticized the Thai government for its actions (at a meeting in Thailand following issuance of the licenses). Director General Chan shortly thereafter dispatched a letter

⁸⁷ See, e.g., Nicholas Zamiska, *Abbott Escalates Thai Patent Rift, Firm Pulls Plans To Offer New Drugs In Spat With Regime*, WALL ST. J., March 14, 2007; Merck & Co., Inc. Statement on Brazilian Government's Decision To Issue Compulsory License for STOCRIN™, May 4, 2007, available at <http://www.merck.com/newsroom/press_releases/corporate/2007_0504.html>.

⁸⁸ See, e.g., PhRMA Press Release, *Protecting Patent Rights in Thailand*, Dec. 1, 2006, and PhRMA Press Release, *PhRMA Response to 2007 Special 301 Report*, Apr. 30, 2007, available at <http://phrma.org> and; U.S. Chamber of Commerce Press Statement, *Brazil Takes Major Step Backward on Intellectual Property Rights, Says U.S. Chamber*, May 4, 2007.

⁸⁹ USTR 2007 Special 301 Report, available at <http://www.ustr.gov/assets/Document_Library/Reports_Publications/2007/2007_Special_301_Review/ass_et_upload_file230_11122.pdf>.

⁹⁰ Thai White Paper, Document 23.

supporting the Thai government's right to issue the compulsory licenses, claiming that the media had misrepresented her initial condemnation.⁹¹

4. Preliminary Observations

The highly visible issuance by Brazil and Thailand of compulsory licenses on patented medicines may represent a turning point in government willingness to exercise rights under the TRIPS Agreement, as confirmed by the Doha Declaration. Prior to these actions, developing country governments had been extremely reluctant to make use of these TRIPS flexibilities, presumably out of concern over adverse reaction from major trading partners, and possibly out of concern about evidencing an inhospitable environment to foreign direct investment.

The ambivalent reaction of the U.S. government may signal at least a modest change in the international environment. Part of this change may reflect the reality of substantially wider public understanding of the rules of the TRIPS Agreement. In 1997, the United States and European Union wrongfully condemned South Africa for public health legislation alleged to be inconsistent with the TRIPS Agreement. At that time, there was not a wide public understanding of the rules of that agreement. It was comparatively easy for governments and industry to misrepresent the rules without strong adverse public reaction.

Today the situation is different. Media outlets, such as the *Wall Street Journal* and *Financial Times* can go only so far in misrepresenting international legal rules. At some point, critical reaction from NGOs forces them to acknowledge that their position is political, not legal. Moreover, Thailand has stated its intention to bring a claim for WTO dispute settlement if trade sanctions are wrongfully imposed. There is little doubt that Thailand would win a dispute settlement claim based on the TRIPS-compliance of its government use licensing.

If the actions by Brazil and Thailand are successfully maintained, this may improve the climate for use of the Article 31*bis* Amendment. If it also stimulates all the pharmaceutical stakeholders to review their pricing strategies in the developing countries, the end result could lead to a win-win approach for all sides, as further discussed below.

C. Multilateral Negotiations on a Substantive Patent Law Treaty (SPLT)

As previously reported, India recently undertook the arduous task of conforming its patent law to the norms of the TRIPS Agreement, a process that has generated much controversy and still uncertain results. Like all developing countries, India had to reconcile the international minimum standards of intellectual property protection with its own cultural and technical assets, with a view to minimizing the social costs and

⁹¹ Letter from WHO Director General Dr. Margaret Chan to Thailand Minister of Health, Mr. Mongkol Na Songklha, dated Feb. 7, 2007, *id.*, at Document 13.

maximizing the potential gains in trade.⁹² Making this assessment with regard to the needs of India's public health sector proved especially daunting because of tensions between the pro-competitive outlook of its robust generic pharmaceutical industry and the more protectionist views of its growing research-based pharmaceutical sector.

This legislative exercise has produced a novel and ingenious mix of domestic and international provisions, whose economic effects remain to be seen and whose legal validity has already been challenged by major pharmaceutical companies in the *Novartis* case and questioned by the U.S. Trade Representative.⁹³ Because India remains the largest alternative supplier of generic drugs to the world market at the present time, the results of its legislative balancing act at home could affect the availability and affordability of essential medicines in all developing countries for a considerable period of time.

The legal challenge to India's statute mounted by Novartis is emblematic of the political difficulties facing developing countries in making use of TRIPS flexibilities, and is strongly reminiscent of the unsuccessful effort by major originator pharmaceutical companies to derail South Africa's progressive Medicines and Related Substances Control Amendment Act of 1997. The South Africa case riveted public attention because it was wrongfully pursued under the TRIPS Agreement in the face of a mushrooming HIV-AIDS pandemic, and it appeared to show a blatant disregard for the public health consequences of pursuing enforcement of international trade and patent rules (without legal justification).

Novartis is challenging Article 3(d) of the amended India Patents Act as being inconsistent with Article 27.1 of the TRIPS Agreement.⁹⁴ What is particularly troubling about this cause of action is that India, following the British Commonwealth constitutional model, does not permit the direct effect of treaties (such as the WTO and TRIPS Agreements). This means that Novartis has no legal grounds under Indian law to challenge the TRIPS-consistency of the Indian legislation. Novartis appears to have acknowledged this point in the course of the litigation, but has sought to justify its action as a convoluted exceptional case under the Indian Constitution, which argument is highly unlikely to succeed. In effect, Novartis is attempting to stretch the rules of public international law and Indian constitutional law for the purpose of limiting TRIPS flexibilities, when WTO Members have already expressly encouraged the use of TRIPS flexibilities in the Doha Declaration. This was, to be clear, the main object and purpose of the Doha Declaration exercise at the WTO.

⁹² See generally J.H. Reichman, *From Free Riders to Fair Followers: Global Competition under the TRIPS Agreement*, 29 N.Y.U. J. INT'L L. & POL. 11 (1997).

⁹³ See, e.g., Janis M. Mueller, *Taking TRIPS to India—Novartis, Patent Law, and Access to Medicines*, 356 NEW ENGLAND J. MEDICINE 541 (Feb. 8, 2007); Janis M. Mueller, *The Tiger Awakens: The Tumultuous Transformation of India's Patent System and the Rise of Indian Pharmaceutical Innovation*, Aug. 16, 2006, available at <http://ssrn.com/abstract=923538>.

⁹⁴ Amended Article 3(d) of that Act denies patentability for claims of modifications to previously known pharmaceutical substances that do not demonstrate significant enhancement in "efficacy". In layman's terms, under amended Article 3(d), to obtain a patent on a modification to an already known product, the applicant must show that the change improves the treatment. This is hardly a startling proposition.

The highly publicized debate about domestic patent reform in India is emblematic of a similar if quieter process that has been taking place in all developing countries (except for the Least-Developed Countries) over the past few years. How all these countries implement the TRIPS standards into their domestic laws will determine the balance between private incentives to innovate and the public interest in free competition, with enormous short and medium term implications for economic growth and development. This process manifestly requires time, capacity building, and cumulative technical expertise, as well as a suitable business infrastructure, to succeed in the end.⁹⁵

Yet, time and patience is exactly what the OECD countries are determined not to grant the developing world in this respect. On the contrary, the OECD countries, grouped within WIPO's Standing Committee on the Law of Patents (SCP), have pressed the developing countries to adhere to a draft Substantive Patent Law Treaty (SPLT).⁹⁶ This proposed treaty represents an attempt "to pursue a 'deep harmonization' of both the law and practice" concerning not just the drafting, filing and examination of patent applications, but also cornerstone requirements of patentability, such as novelty, non-obviousness, sufficiency of description, and drafting and interpretation of claims.⁹⁷ Notably, through the efforts of the so-called Group of Friends of Development,⁹⁸ this initiative is also being tested against the drive for a more development-friendly agenda at WIPO, with a view to ensuring consideration of the needs of all nations, whatever their technological capacities may be.⁹⁹

⁹⁵ See, e.g., Maskus & Reichman, *supra* note 1.

⁹⁶ See Standing Committee on the Law of Patents, (SCP), Draft Substantive Patent Law Treaty (SPLT), 10th Sess., May 10-14, 2004, WIPO doc. SCP/10/2, 30 Sept. 2003; Standing Committee on the Law of Patents, (SCP), Information on Certain Recent Developments in Relation to the Draft Substantive Patent Law Treaty (SPLT), 10th Sess., May 10-14, 2004, WIPO doc. SCP/10/8, 17 March 2004; Standing Committee on the Law of Patents, (SCP), Report, 10th Sess., May 10-14, 2004, WIPO doc. SCP/10/11, 1 June 2005.

⁹⁷ Karen M. Hauda, *The Role of the United States in World-Wide Protection of Industrial Property*, in THE FUTURE OF INTELLECTUAL PROPERTY IN THE GLOBAL MARKET OF THE INFORMATION SOCIETY 91, 97 (2003) ("This approach was adopted in an attempt to avoid the controversial hurdles to agreement that were found in the past."). See also Philippe Baechtold, *The Future Role of WIPO, in the Area of Industrial Property*, *id.* at 139, 142-43 (highlighting the need to cover other topics such as patentable subject matter, the requirement of technical character of an invention, exceptions from patentability, novelty grace period and issue of equivalents). All of these issues constitute "flexibilities" under the TRIPS Agreement, of which compulsory licensing is but one very important component. See generally CARLOS CORREA, TRADE-RELATED ASPECTS OF INTELLECTUAL PROPERTY RIGHTS: A COMMENTARY ON THE TRIPS AGREEMENT (Oxford U. Press 2007).

⁹⁸ On October 4th, 2004, the General Assembly of the World Intellectual Property Organization agreed to adopt a proposal presented by the Group of Friends of Development (namely: Argentina and Brazil), for the establishment of a Development Agenda for WIPO, Doc. WO/GA/31/11. Since then, many other proposals have been presented and discussed, see e.g., Provisional Committee on Proposals Related to a WIPO Development Agenda, Proposal for a Decision of the PCDA on the Establishment of a WIPO Development Agenda, PCDA/2/2 (June 22, 2006), available at <http://www.stakeholderforum.org/22june2006.html>. See also James Boyle, *A Manifesto on WIPO and the Future of Intellectual Property*, 2004 DUKE L. & TECH. REV. 9 (2004).

⁹⁹ See generally papers presented at the World Intellectual Property Organization's Open Forum on the Draft Substantive Patent Law Treaty (SPLT), International Conference Center (ICC), Geneva, Switzerland, March 1-3 2006 [hereinafter WIPO Open Forum], available at http://www.wipo.int/meetings/en/2006/scp_of_ge_06/scp_of_ge_06_inf1.html.

In a widely circulated and soon to be published article, Professors Reichman and Dreyfuss demonstrate the likely adverse affects a further round of patent harmonization would have on the developing countries.¹⁰⁰ These include:

- Erosion of whatever flexibilities these countries still retain under the TRIPS Agreement.
- The risk that virtually every pro-competitive option still left open—from exceptions to patentability, limitations on exclusive rights, and the possibility of imposing compulsory licenses—would shrink or disappear.¹⁰¹

They conclude that what developing countries most need is a “period of calm and stability in which to devise intellectual property strategies consistent with both the TRIPS Agreement and the needs of their own emerging national and regional systems of innovation... They cannot succeed if, at the international level, a new round of multilateral intellectual property negotiations threatens to raise the technological ladder once again before they even get a solid foot hold on it.”¹⁰²

The authors of that new article also argue that a premature patent harmonization exercise of this kind could seriously harm the very developed countries that are pushing it forward at WIPO. They contend that developed patent systems are under serious stress everywhere owing particularly to the emergence of information technologies and biotechnologies, among others, that do not fit within classical patent theory and practices. They point out that there is no consensus on how the patent law should address these new challenges, and that, at the very moment when USTR is seeking to “export a dysfunctional system to the rest of the world,”¹⁰³ the U.S. Supreme Court has radically been reshaping that very system.¹⁰⁴ The European Patent Office, which has increasingly experimented with new approaches to new technologies that deviate from U.S. practice, has recently issued its own cautionary views on the future of patent law.¹⁰⁵

While the authors of this report lack space to explore these matters in depth, we endorse the view that “any attempt to achieve deep harmonization of world patent law at the present time, such as that contemplated by the SPLT, is premature.”¹⁰⁶ What is needed, instead, is a period of experimentation in which different countries at different levels of

¹⁰⁰ Jerome H. Reichman & Rochelle Dreyfuss, *Harmonization without Consensus: Critical Reflections on Drafting a Substantive Patent Law Treaty*, DUKE L. J. (forthcoming 2007).

¹⁰¹ Id. See also *supra* note 97 and accompanying text.

¹⁰² Reichman & Dreyfuss, *supra* note 100. See also Maskus & Reichman, *supra* note 1; Joseph Stiglitz, The Economic Foundations of Intellectual Property, Frei Lecture, Duke University School of Law, Feb. 16, 2007, available at <http://www.law.duke.edu/webcast/>; Margaret Chon, *Intellectual Property and the Development Divide*, 27 CARDOZO L. REV. 2821 (2006).

¹⁰³ Maskus & Reichman, *supra* note 1.

¹⁰⁴ See, e.g., *E-Bay v. MercExchange*, 126 Sup. Ct. 1837 (2006); *Merck v. Integra Lifesciences*, 125 S. Ct. 2372 (2005), and *KSR v. Teleflex*, 127 Sup. Ct. 1727 (2007).

¹⁰⁵ EPO, THE FUTURE OF PATENT LAW (2007).

¹⁰⁶ Reichman & Dreyfuss, *supra* note 100.

development seek to adapt the traditional patent system to their own needs, taking into account the challenges of new technologies and of the emerging transnational system of innovation as a whole that TRIPS brought into existence.¹⁰⁷ For this and other reasons, the European Parliament should exercise oversight in these matters, with a view to restraining the ability of a special interest lobby of knowledge goods distributors to ratchet up existing international patent standards at the expense of real innovators everywhere.

D. The Problem of the Free Trade Agreements

The originator pharmaceutical industry based in OECD countries has not been satisfied with the terms of the TRIPS Agreement negotiated in the GATT Uruguay Round. It has also realized that increased protection for this industry is not a realistic negotiating objective at the WTO, at least in present circumstances, and that further harmonization under the SPLT at WIPO has encountered mounting opposition. As a "second best" solution for obtaining enhanced protection, U.S. pharmaceutical originators (represented by PhRMA) have intensively lobbied USTR and other parts of the U.S. government (including Congress) to incorporate higher levels of industry protection in bilateral and regional free-trade agreements (FTAs).¹⁰⁸ The European Union originator pharmaceutical companies are similarly lobbying the European Commission and EU institutions (and member state governments), perhaps so far with somewhat less overall success.

1. Agreements of the United States

A modest level of enhanced protection (above that provided by the TRIPS Agreement) was incorporated into NAFTA. However, the trend towards high protection commenced in earnest with negotiation of an FTA with Jordan in 2001, and has progressed through a series of FTAs with developing and developed countries, including Chile, Australia, Singapore, Morocco, Central America (including Costa Rica, El Salvador, Guatemala, Honduras, Nicaragua and the Dominican Republic) ("CAFTA-DR"), Bahrain, Oman, and in signed, but not yet ratified, agreements with Panamá, Peru, Colombia and South Korea.¹⁰⁹

Although the patent and pharmaceutical regulatory terms of the FTAs vary with the different agreements, they follow a common template. The main objectives are to:

- Extend the scope of patent protection to cover new uses of known compounds, and plants (and, on occasion) animals;
- Provide patent term extensions to offset regulatory delay;

¹⁰⁷ Maskus & Reichman, *supra* note 1.

¹⁰⁸ For economic assessment, see Carsten Fink and Patrick Reichenmiller, Tightening TRIPS: The Intellectual Property Provisions of Recent US Free Trade Agreements, World Bank Group, International Trade Development, Trade Note 20, Feb. 7, 2005. See legal analysis and additional references in Abbott, *WTO Medicines Decision*, *supra* note 6 at 349 et seq. and Frederick M. Abbott, *Intellectual Property Provisions of Bilateral and Regional Trade Agreements in Light of U.S. Federal Law*, UNCTAD - ICTSD Project on IPRs and Sustainable Development, Issue Paper No. 12, Feb. 2006.

¹⁰⁹ Texts generally available at <<http://www.ustr.gov>>.

- Limit the scope of permissible exceptions to patent rights;
- Provide fixed periods of marketing exclusivity for a broad class of previously unapproved products, based on submission of regulatory data (especially clinical trial data), or reliance on foreign marketing approval or foreign submission of regulatory data;
- Prohibit effective granting of marketing approval by the health regulatory authority during the patent term without the consent or acquiescence of patent holders (“linkage”);
- Authorize nonviolation nullification or impairment dispute settlement claims;
- Prohibit parallel importation (in some cases);
- Limit the grounds for granting compulsory licensing (in higher income countries).

The combined impact of these various restrictive provisions is to significantly strengthen the position of originator-patent holder pharmaceutical enterprises on national markets, and thereby to impose substantial obstacles to the introduction of generic pharmaceutical products.

One major concern with several of the foregoing restrictive measures is that they could effectively preclude use of compulsory licensing because they contained no provision expressly for exceptions in such cases. All (or virtually all) countries require a medicine to be approved and registered by the public health authority before distribution on the market. The provisions of the FTAs for patent linkage make no provision for registration of generic products produced under compulsory licenses, while otherwise requiring the consent of the patent holder for marketing approval. In response to objections from NGOs and members of Congress, USTR appended "side letters" to the FTAs intended to give the appearance of addressing this problem. But USTR refused to acknowledge that these attachments resulted in any exception to the express terms of the agreements.¹¹⁰

While the European Union’s pharmaceutical originator enterprises are not direct participants in these FTA negotiations, they remain indirect beneficiaries of their terms once concluded. This result follows from Article 4 of the TRIPS Agreement, which requires the extension of most favored nation (MFN) treatment to all WTO Members.¹¹¹

After the Democratic Party gained control of the Congress beginning in 2007, certain changes have been agreed upon between the Executive (represented by USTR) and congressional leaders with respect to signed, but not yet ratified, FTAs (with developing countries).¹¹² These changes include limiting the grant of marketing exclusivity to a

¹¹⁰ See Abbott, *WTO Medicines Decision*, *supra* note 6, at 352-53, discussing USTR’s position regarding legal effect of public health side letters.

¹¹¹ Regional agreements entered into subsequent to entry into force of the TRIPS Agreement do not enjoy an exclusion from the requirement of extending MFN (pursuant to Article 4(d) of the TRIPS Agreement). For extended analysis of Article 4(d) of the TRIPS Agreement, see UNCTAD-ICTSD RESOURCE BOOK ON TRIPS AND DEVELOPMENT, at 77-82 (Ch. 4, Part. 3.2). For discussion of question whether FTA pharmaceutical-related provisions constitute a “benefit” to third countries, or in some important circumstances a trade barrier, see Abbott, *WTO Medicines Decision*, *supra* note 6, at 357.

¹¹² See, e.g., USTR, *Bipartisan Agreement on Trade Policy: Intellectual Property*, May 2007, Trade Facts, available at <<http://www.ustr.gov>>.

period contemporaneous with that obtained in the United States; eliminating provision for patent term extension based on approval delay; eliminating the express linkage between patents and marketing approval; and incorporating express provision for use of compulsory licensing notwithstanding existing marketing exclusivity.

The foregoing changes without doubt will represent an improvement over the current situation. However, it must be noted that additional obligations have been proposed to reduce the magnitude of the changes. Patents and marketing exclusivity are to be expressly de-linked, but signatories will be obligated to provide transparent and expeditious mechanisms for initiating patent infringement litigation. Direct patent term extension will be eliminated, but obligations will be added to ensure expeditious processing of applications for patents and marketing approval. While marketing exclusivity obligations may be limited to periods contemporaneous with those running in the United States, the basic requirement of marketing exclusivity remains a substantial TRIPS-plus obligation, which in effect introduces another exclusive property right by the back door.¹¹³

2. Agreements of the European Union

The European Union has nominally adopted a policy of not pursuing pharmaceutical-related TRIPS-plus commitments in its negotiations with developing countries, while nonetheless "free riding" on the pharmaceuticals commitments obtained by the United States. In this sense, further negotiations on this subject matter by the EU could be superfluous (at least in so far as the EU and United States are negotiating with the same parties). However, it is not really the case that the EU foregoes additional pharmaceutical-related commitments in its bilateral and regional negotiations.¹¹⁴

First, in its proposed Economic Partnership Agreements (EPAs) with the African, Caribbean and Pacific (ACP) countries, the EU is negotiating for adherence to or acceptance of the obligations of the Patent Cooperation Treaty (PCT) and the Patent Law Treaty (PLT). These procedural treaties facilitate obtaining patents in the countries that are party to them. Given a recent trend of substantial increase in the number of pharmaceutical patent filings in developing countries, an obligation to participate in the PCT and PLT may have a significant impact on the number of patents on pharmaceutical products and processes granted in the ACP countries. At the very least, it affords originators a 30 month priority period during which investors in generic products cannot readily enter local markets even if no patent applications have been filed.¹¹⁵

¹¹³ See Jerome H. Reichman, *The International Legal Status of Undisclosed Clinical Trial Data: From Private to Public Goods?*, in *NEGOTIATING HEALTH—INTELLECTUAL PROPERTY AND ACCESS TO MEDICINES* (P. Roffe *et al*, eds. Earthscan 2006), 133-46.

¹¹⁴ And this is leaving aside the fact that the European Union has required countries joining the Union to accept the full panoply of EU regulations respecting pharmaceuticals, which in some cases (*e.g.*, Hungary) has had a substantial impact on local generic producers.

¹¹⁵ See Maximiliano Santa Cruz S., *Intellectual Property Provisions in European Union Trade Agreements*, ICTSD Issue Paper No. 20 (2007).

Second, and more important, the European Union is effectively seeking to burden the ACP countries with the duty to implement the terms of its Intellectual Property Enforcement Directive.¹¹⁶ As should be well known here, the Enforcement Directive requires the EU member states to ensure that IPR holders have access to evidence regarding the activities of alleged infringers. Member states must make available provisional measures, including preliminary injunctions to prevent “imminent infringement,” and to make that remedy available without the appearance of the alleged infringer, in particular when any delay would cause irreparable harm. The directive specifies that member state judges must be authorized to remove from commerce and destroy infringing goods, to issue permanent injunctions, and to assess damages, taking into account “all appropriate aspects,” including lost profits. The unsuccessful party generally bears the legal costs of the proceeding. Judicial authorities may also order dissemination of information concerning the decision at the expense of the infringer.

One enforcement provision of a draft EPA proposed by the Commission¹¹⁷ requires that competent judicial authorities, “even before the commencement of proceedings on the merits of the case”, on the basis of “reasonably available evidence to support [a patent holder’s] claims” ... may “order prompt and effective provisional measures”... including “the physical seizure of the infringing goods, and, in appropriate cases, the materials and implements used in the production and/or distribution of these goods”. Such a provision, with a very low evidentiary standard and lacking a temporal limitation, may have a strong chilling impact on producers of generic medicines who are threatened with seizure of products and production equipment on the basis of “reasonably available evidence” in advance of a determination as to the validity of the evidence. The seizures could last for an extended duration and cripple the business without any meaningful judicial process.

Article 4 of the EU Enforcement Directive, replicated in draft EPAs, provides that:

Member States shall recognise as persons entitled to seek application of the measures, procedures and remedies referred to in this chapter: ... (d) professional defence bodies which are regularly recognised as having a right to represent holders of intellectual property rights, in so far as permitted by and in accordance with the provisions of the applicable law.

By endeavoring to incorporate this Enforcement Directive obligation (among the panoply of enforcement obligations in the EPAs), the EU aims to provide “friends of Pharma” with an explicit right to initiate legal claims against generic producers seeking entry into the national market. There are various other enforcement provisions in the draft EPAs strongly favoring the interests of patent holders, without correspondingly strong protections for the generics sector. Yet, the European Parliament has recently adopted a report on EPAs, which asked the Commission not to include IP provisions that could adversely affect access to essential medicines.

¹¹⁶ Directive 2004/48/EC of the European Parliament and of the Council of 29 April 2004 on the enforcement of intellectual property rights, OJ L 195/16, 2.6.2004.

¹¹⁷ The authors have received draft texts in confidence from negotiators and do not consider that further identification of source is necessary or appropriate here.

A developing country that enters into an FTA with the United States and an EPA with the EU along the lines of those presently proposed will be constrained to provide a very strong market dominant position for pharmaceutical originator companies, and thus to create substantial obstacles to the introduction of generic products. The ameliorated U.S. template discussed above will improve this situation somewhat, but the extent of the improvements should not be exaggerated. Replacing express linkage with accelerated patent infringement litigation may be a step in the right direction, but the new obligations will pose significant problems for both developing country governments and generic producers.

Imposing a requirement on a developing country party to an FTA to reform its administrative and judicial processes to improve the prospects for patent infringement causes of action may result in significantly strengthening the position of patent holders on the market, depending on the precise terms and conditions of the implementing legislation and rules. The United States government may play a substantial role in proposing and reviewing the rules – which is consistent with U.S. practice concerning oversight of the implementation of FTA obligations. It will be very important for developing countries parties to these FTAs to review carefully – where appropriate with the assistance of development-friendly technical advisers – the proposals of the United States (and the EU in the case of the EPAs). In light of the importance of the implementation process, it is difficult to assess the “softer” new U.S. FTA policy while the details are not yet developed and public.

The authors believe that EPAs should refrain from imposing any new intellectual property obligations on APC countries that could affect their public health programs. Indeed, the European Parliament should encourage the EU expressly to endorse full implementation in APC countries of the flexibilities in the TRIPS Agreement as recognized in the Doha Declaration “to promote access to medicines for all.”

E. The World Health Organization’s Intergovernmental Working Group on Public Health, Innovation and Intellectual Property (IGWG)

Under pressure from developing country governments and NGOs, the World Health Organization (WHO) has initiated a process to assess the global situation concerning public health, innovation and intellectual property, and to recommend an action plan geared to its findings.¹¹⁸ Meetings bearing on the Intergovernmental Working Group (IGWG) are taking place in Geneva, and the prospective impact of this ongoing work at the WHO remains hard to predict. Nonetheless, the WHO was absent during the GATT Uruguay Round negotiations, and over the past decade its leadership has played a modest role in global debates concerning intellectual property and access to medicines. That these issues appear to have gained greater prominence in WHO discussions is a positive development.

¹¹⁸ Documents available at <http://www.who.int/phi/en/>.

Brazil, Kenya, Thailand and other developing countries have urged the WHO to adopt an action plan that would encourage research and development on medicines important for developing countries and that would improve access to medicines for a much wider part of the world's population. This plan should embrace not only "neglected" or "developing country" diseases, but also diseases common to developing and developed countries, such as cancer and coronary disease.¹¹⁹ These countries want to see concrete measures for transfer of technology to improve the capacity of poor countries to participate fully in the development and production of medicines.

Recent discussions at IGWG have focused on proposals that re-examine the link between pricing and the cost of R&D, with a view to devising workable new models. There is also growing interest in forming patent pools to deal with poverty-related, tropical and neglected diseases, with the participation of public-private partnerships, such as UNITAID. The authors urge the European Parliament to monitor work at IGWG and to lend their support to such proposals.

The European Union and the United States are each playing a rather ambiguous role in these discussions. The EU makes references to limiting "TRIPS-plus" obligations on developing countries, but it also aims to ensure that the WHO does not become a primary forum for consideration of IP-related issues.¹²⁰

The WHO might better be viewed as a primary institution for negotiating over patents and other intellectual property rights because IPRs affect members' ability to maintain adequate supplies of medicines as a public good. The WHO is the designated international governance agency for public health. Nothing has so disrupted the National Health Ministries' traditional roles in this regard as the top-down, private law codifications of intellectual property rights rammed through other international forums with little inputs from them.

While the GATT and WTO were conceived to promote reduction of trade barriers and the free flow of goods and services, patents create trade barriers, they are designed to inhibit market entry. Whether the WTO, which nominally promotes "free trade", should be developing and enforcing rules that restrict trade remains an open question, regardless of

¹¹⁹ See, e.g., Submissions of Brazil, Kenya, Thailand and others regarding /PHI/IGWG/1/5, available *id.*

¹²⁰ See, e.g., Comments by the European Union, Consultations on "Elements of a global strategy and plan of action (A/PHI/IGWG/1/5), 28/02/2007, available *id.* This document also states, *inter alia*:

"The EU feels that the action point 'Management of intellectual property' (and to a lesser extent the action point 'Transfer of Technology') runs roughly parallel with WTO and WIPO's work within the Provisional Committee on Proposals related to a WIPO Development Agenda (PCDA). ...

It is important that WIPO, WHO and WTO/TRIPS cooperate closely, and WHO's role in monitoring the impact of IPR on access to healthcare is recognized, in order to ensure that these two ambitious initiatives do not run counterproductive to one another. In doing so we ensure that innovative incentives for R&D *are in accordance with international intellectual property framework.*" [italics added]

one's views about needed incentives to innovate under free market condition. Patents impose significant public health costs, by fostering high medicines prices, even as they promote private sector efforts to discover new medicines. Are patents "more relevant" to the WTO than to the WHO?

There is not a greater "inherent connection" between patents and trade than between patents and public health. The WHO has an interest in patents at least as great as that of the WTO. The EU might accordingly devote more of its efforts at the WHO to developing an IP environment that promotes public health, without unduly dampening R&D incentives, and spend less time engaging in "damage control" with respect to rules previously negotiated at the WTO and WIPO.

III. Making the Amendment System Work

While the compromise accepted in the Decision of August 30 and the corresponding Amendment is cumbersome, we have showed that it was the best available at the time and better than alternatives then on the table. Without understating its formalistic nature and built-in administrative roadblocks, there is reason to believe it can be made workable. To this end, countries needing assistance must muster the political will and skill to use the system, and countries able to supply needed drugs must enact suitable legislation without too many additional limiting wrinkles imposed by special interest lobbying, as occurred in Canada.

In this connection, the Indian enabling legislation appears complete and unambiguously supportive of the goals behind the Amendment.¹²¹ Moreover, the Secretary-General of the Indian Pharmaceutical Alliance is on record as expressing the willingness of his constituency to respond to requests for assistance by other developing countries, and a spokesman for the European generics industry has also expressed interest. Whether the countries with the greatest capacity will in fact respond depends on a number of imponderables, including the size of the market, the procurement guarantees, and the stability of local conditions at any given time. Nonetheless, given the legal infrastructure and the known capacities and interest of the Indian and European generic companies, prospects for fruitful collaboration seem reasonably promising.

In practice, converting this promise to reality could largely depend on the strategies of the would-be user countries. In particular, aside from major autonomous markets in middle-income countries, such as Thailand and Brazil, much could depend on whether the effort to obtain any given drug is initiated by single countries, each going its own way, or by a number of countries willing and able to pool their single compulsory licenses in a consortium that could afford greater buying power and offer suppliers sounder incentives to invest in production.

In what follows, we outline a blueprint for effective implementation based on what the evolving legal infrastructure makes possible. While real world obstacles abound, our

¹²¹ However, this conclusion could be affected by Indian implementing regulations if and when such are adopted.

primary task here is to emphasize what could be done with willpower, skill and resources. The European Parliament and member governments could themselves play a role in transforming possibilities into practice, given the political will to do so.

A. Goals and Limits of Compulsory Licensing

Existing WTO jurisprudence suggests that when tensions arise between the Members' efforts to provide domestic public goods, such as public health, and the private rights of patentees, Members should look to both the codified exceptions to those rights under Article 30 and to the broad possibilities for imposing compulsory licenses under Article 31 and Amendment Article 31*bis*, before invoking still untested claims for waivers under the hardship escape clauses of articles 7 and 8.

In the public sector, developing countries resort to compulsory licensing—either by threat or actual imposition—in order to persuade pharmaceutical companies to lower the prices of specific medicines to the point where they become available to mass market consumers in need of them and not just to affluent members of any given community. Such licenses are a critical tool for promoting effective price negotiations with patent holders and for enabling local production, importation and distribution of patented medicines at affordable prices. In Thailand, for example, a compulsory license was issued on Plavix, a heart medicine, in order to make it affordable for eighty percent of the population that could not pay existing prices. The Thai authorities disavow an intention to disturb the market segment in which twenty percent of the population purchases the products at monopoly prices.

Where public health authorities directly undertake the provision of medicines to meet important public health needs, including the HIV/AIDS pandemic, the obligation to match the costs of distribution with available public resources also exerts pressure to issue compulsory licenses. For example, the license recently issued in Brazil for Efavirenz was premised on the need to obtain the lowest cost generic available anywhere, which was significantly less than the reduced price offered by the patentee in negotiations.

One should note that, between unregulated monopoly pricing, on one hand, and compulsory licensing on the other, there exists intermediate regimes based on price regulation, which are widely practiced in OECD countries. An illuminating example is the case of Canada, which moved from a regime of routine compulsory licensing of patented pharmaceuticals to a regime of price controls in 1992.¹²² These price controls help Canada keep the costs of its socialized medicine program under control. On the whole, developing countries have not widely experimented with price controls on essential medicines, which controls might then affect the extent to which compulsory licensing is employed.¹²³

¹²² See Reichman with Hasenzahl, *Non-Voluntary Licensing of Patented Inventions: The Canadian Experience*, (ICTSD/UNCTAD 2003).

¹²³ Kevin Outterson, *Patent Buy-Outs for Global Disease Innovations for Low- and Middle-Income Countries*, 32 *AMERICAN J. LAW & MEDICINE* 159, 161 (2006).

When, instead, developing-country governments resort to compulsory licensing (or threats thereof), they typically seek to move the pharmaceutical companies away from a marketing strategy based on “low-volume, high margin returns” to a strategy based on “high-volume, low margin returns,” which is more characteristic of the generic industries. Given that generic industries operating under the latter strategy are profitable, one may ask why the big pharmaceutical companies do not voluntarily adopt similar pricing strategies on a voluntary basis in developing countries, given that they typically expect to recoup R&D costs plus the bulk of their profits in OECD markets.

There are different theories to account for this resistance. One is that because a patent monopoly gives control over prices, the lack of competition simply dulls any incentive to price-differentiate. A second theory is that the pharmaceutical companies fear a “reference pricing backlash,” which would occur if low prices in developing countries were used as benchmarks by price regulators in developed countries.¹²⁴ A third theory is that selling needed medicines to the affluent at very high prices in developing countries is objectively more profitable than mass-marketing at low prices that almost all could afford. A fourth theory is that pharmaceutical companies are concerned that parallel imported favorably-priced medicines would compete with higher priced offerings.¹²⁵ A fifth theory is that all the above four theories play some part in resistance to price discrimination.

Whatever the truth may be, we emphasize that the overall goal in evaluating the pending Amendment to the TRIPS Agreement is the extent to which it can help developing countries shift the patentees’ strategy to a “high volume—low margin” approach. The more that the system as a whole encourages pharmaceutical companies to adopt such a strategy voluntarily without government intervention, the less friction it will generate and the more successful it will be.

Here, however, a cautionary note is in order. The foregoing propositions rest on the premise that originator pharmaceutical companies typically recoup their R&D costs plus reasonable profits in OECD markets.¹²⁶ So long as this premise holds, experts in the field maintain that developing country governments that paid these companies their marginal costs of production plus a five per cent royalty would normally be providing generous compensation under either a price regulation scheme or a compulsory license.¹²⁷

¹²⁴ 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.

¹²⁵ See, e.g. Harvey E. Bale Jr., *The Conflicts Between Parallel Trade and Product Access and Innovation: The Case of Pharmaceuticals*, 1 J. INT’L ECON. L. 637 (1998).

¹²⁶ The authors of this report do not imply that originator practices in areas such as marketing and executive compensation are presently appropriate and reasonable, but rather they indicate a premise for discussion.

¹²⁷ See, e.g, Letter from Al Engleberg (on file with the authors).

If, instead, pharmaceutical companies either in OECD countries or elsewhere responded to the TRIPS patent incentives by investing in R&D that pertained to poverty-related, tropical and neglected diseases of primary concern to developing countries, then resort to compulsory licensing would require a different calculus. These companies would necessarily have to seek returns on investment in the affected countries, and *ex post* resort to compulsory licensing could skew the *ex ante* investment calculus that led to medical discoveries in the first place.¹²⁸

In such cases, much obviously depends on the extent to which government funding itself played a role in the R&D efforts and on the pricing strategies voluntarily adopted by the patent holder, whose interests may naturally lie in a “high-volume, low-margin” approach on the relevant markets. We shall return to these considerations later on. Nevertheless, we emphasize that care must be taken to focus on the facts of individual cases with a view to achieving win-win situations for all stakeholders over time, when possible.

B. The High Transaction Costs of Single State Action¹²⁹

Haphazard action by single states seeking to impose compulsory licenses on patented pharmaceuticals is limited by economic, legal and technical factors. While middle-income markets, such as those of Thailand and Brazil, are large enough to warrant investments in the production of generic drugs by potential suppliers, the same cannot be said of most other markets in the developing countries. Taken one by one, in other words, there are serious problems arising from a lack of economies of scale and scope.

Moreover, uncoordinated legal action by single states seeking compulsory licenses is reinforced by a territorial notion of international patent law and by the independence of patents doctrine.¹³⁰ These principles support the kind of market segmentation in which each new supply problem entails a new cat-and-mouse game between patentees and the local governments. 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—within the control of big pharmaceutical companies based in developed countries. As a result, these companies often influence the choice of rules under which specific legal contests will occur and the pace at which ultimate decisions will be made.

Strategies premised on national action alone could thus entail high transaction costs in overcoming an array of technical legal obstacles, and they could require levels of organizational and administrative skills and drive that are often lacking in smaller developing countries. Given a predictable lack of coordination among developing country governments, moreover, action by single states on a case-by-case approach will

¹²⁸ 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).

¹²⁹ This and the following sections are drawn from Jerome H. Reichman, *Procuring Essential Medicines Under the Amended TRIPS Provisions: The Prospects for Regional Pharmaceutical Supply Centers*, Paper prepared for the Seminar on Intellectual Property Arrangements: Implications for Developing Country Productive Capabilities in the Supply of Essential Medicines, United Nations Conference on Trade and Development (UNCTAD), Palais des Nations, Geneva, Switzerland, 18-20 October 2006.

¹³⁰ Paris Convention for the Protection of Industrial Property (1886), as revised 1967), arts. 2(1), 4*bis*(2).

remain vulnerable to strong legal and economic pressures by rights holders, in the form of defensive actions to choke off critical sources of supply. Even when single battles are won with regard to 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.

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.

C. The Potential Benefits of Pooled Procurement Strategies

As one of the authors of this report explained in a recent paper presented to an UNCTAD seminar on stimulating local production of essential medicines, 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. On this approach, a group of developing countries interested in price regulation of pharmaceuticals could harmonize and coordinate their policies in this regard. With or without price regulation, a pooled procurement strategy would provide incentives to the originator pharmaceutical companies themselves to become “low bidders” under supply contracts offered by a centralized procurement authority.

Companies that cooperated with such an authority could preserve market share and benefit from economies of scale and scope. If this cooperation was lacking, however, a centralized procurement authority could offer attractive investment opportunities to prospective generic suppliers who could gear production to the larger market that cumulative or pooled compulsory licenses made available.

A pooled procurement strategy would also greatly enhance the procurement agency’s opportunities to stimulate direct investment in local production facilities within the region and to obtain support for training and research to enhance that region’s own capabilities. Technical assistance of this kind could become particularly effective if developed country governments subscribed to a proposal to “buy out” the rights to supply developing country markets from the pharmaceutical companies themselves,¹³¹ pursued the establishment of essential medicines patent pools that would offer low (or no) cost

¹³¹ See K. Outtersson, *supra* note 123, at 171-73.

production licenses,¹³² or otherwise persuaded patent holders to permit the use of their technologies on preferential terms in developing country markets.¹³³

Ideally, a pooled procurement strategy, operating under the facilitations of Amendment Article 31*bis*, would offer the greatest benefits to a large number of cooperating countries, half of which were Least-Developed Countries. This model is particularly suited to conditions in Africa. As explained below, moreover, tangible benefits could nonetheless arise from much smaller arrangements between two or three countries, and even when none of the participating countries were LDCs.

1. A Large Regional Model With Many LDCs

Consider the possibilities that would arise if twelve African countries formed a loose trade association to qualify under Article 31*bis*(3), in which at least six of the participating countries were LDCs. Assume further that these countries established a Regional Pharmaceutical Supply Center (RPSC), which could organize the procurement of pharmaceuticals needed to fulfill the demand created by the emission of as many as twelve pooled compulsory licenses by all the participating states.

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 authority may 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 patents they possessed. The regional entity, acting on behalf of its buyer governments, could thus conduct price negotiations, with a view to inducing rights holders to become low bidders on the project.

If such a deal were concluded, the rights holders 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 could obviate the need for imports from beyond the region.

In these negotiations, the patentees know that if no agreement were reached, a supply of generics might 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 the effort.¹³⁴

¹³² See, e.g., various proposals by James Love, including Proposal for Patent Pool for Essential Medicines (PPEM), Addis Ababa – 3 March 2005, available at <http://www.cptech.org/cm/addisababa03032005.html>.

¹³³ The concept of territorial segmentation of patent rights was strongly advocated by Prof. Jean Lanjouw in various papers, and has since found its way into practical application by institutions such as the Drugs for Neglected Diseases initiative (DNDi) in licensing arrangements with originator enterprises.

¹³⁴ While Pharma enterprises could, in principle, threaten to walk away, as they have in the past, some recent statements by a spokesman for the industry have suggested a more cooperative attitude, with

Alternatively, the Directors of the RSPC (who could be proxies for the respective health ministries) may offer the foreign originator the possibility of selling the patented products at better than rock bottom prices if it established local production facilities in the region. Here the carrot is that the foreign producer who establishes a manufacturing foothold in the territory is rewarded by a more favorable remuneration package and by the prospects of supplying the entire regional market.¹³⁵ 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 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 either to sell at low prices or 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 regional territory under article 31*bis*(3). Here the preferred solution would be to locate such a production facility in a designated LDC territory that need not protect pharmaceuticals until 2016, if technical and logistic barriers can be overcome.¹³⁶

A local producer in such a territory, 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 of 1994. Given these prospects, moreover, Pharma firms may be more likely to decide that the preservation of future market shares, among other considerations, was a sufficient reason to cooperate with the RSPC and not default a substantial continental market to smaller generic competitors.

2. A Smaller Model with or without LDCs

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 enter it.

¹³⁵ Cf. James Love, *Four Practical Measures to Enhance Access to Medical Technologies*, in NEGOTIATING HEALTH, *supra* note 113, at 241, 246-47.

¹³⁶ WTO Ministers agreed in paragraph 7 of the Doha Declaration that Least Developed Members should not be obligated to implement or apply TRIPS provisions for pharmaceutical product patents or data protection until January 1, 2016. Just as important, they agreed that Least Developed Members already allowing for such protection did not need to “enforce” such rules until that later date. The TRIPS Council adopted a decision confirming this flexibility. Decision of the Council for TRIPS of June 27, 2002. The WTO General Council added a waiver of least developed members’ obligations regarding so-called exclusive marketing rights that might otherwise have been used as a substitute for patent protection to block production, import, and sale of medicines. WTO General Council, WT/L/478, 12 July 2002 Least-Developed Country Members — Obligations Under Article 70.9 of the TRIPS Agreement with Respect to Pharmaceutical Products, Decision of 8 July 2002.

While a pooled procurement strategy operating under a large regional model like that just described yields the maximum bargaining clout, much smaller variations on this theme will still give economies of scale and scope that should prove attractive to foreign suppliers and investors. For example, even a three-country model in Africa, where two of the participants were LDCs, could produce considerable bargaining power through pooled compulsory licenses. Under either the large or the small model, drugs shipped into or produced in any one of the participants could be re-exported to all the other participants without additional external compulsory licenses, given the facilitations afforded by pending Article 31*bis* to certain regional trade agreements.

If, instead, one looks to a region, such as Latin America, where there are many poor countries but few LDCs, a pooled procurement strategy still makes sense. Three small countries bargaining with either the patentees or potential generic suppliers under the double compulsory licensing system of Article 31*bis* could still muster a lot more bargaining power than any of the countries proceeding separately. On this scenario, however, there would exist technical obstacles to re-exporting the products from one participant to another, so shipments and other procedures would have to be coordinated.

3. Fulfilling Technology Transfer Obligations under Article 66.2

If the European Union supported the initiatives outlined above, it could provide grants, subsidies and tax concessions to pharmaceutical companies that cooperated with Regional Pharmaceutical Supply Centers. In so doing, the European Union would be fulfilling its duty to help establish a viable technological base in LDCs under Article 66.2 of the TRIPS Agreement. Of particular interest here is the possibility that the patentees' own governments might become willing to make patented technology available through buy-out, patent pool or arrangements for geographically segmented licensing.¹³⁷

It should also be noted that the German Development Agency, in cooperation with UNCTAD, UNIDO and DFID, has focused considerable efforts and funds to promote local production in LDCs during the lengthened transitional period that was recently established. The European Parliament should encourage all Member States to support this initiative and should instruct the Commission to devise a plan for so doing.

4. Technical Cooperation Between Developing Countries

The architecture of Article 31*bis* presupposes that poor countries lacking capacity to manufacture needed medicines under compulsory licenses would seek assistance from developed countries, or at least from large, middle-income developing countries, such as India, China and Brazil. In reality if efforts to expand local production capabilities succeeded, the number of potential assisting suppliers for any given product could multiply.

Any developing country with the capacity to produce a drug needed by another developing country could come to the assistance of the latter country under the double

¹³⁷ See text *supra* accompanying notes 131-33.

compulsory licensing system to be established by Article 31*bis*. Over time, this network of mutual assistance could grow into a formidable self-help production system, which could exert pressure on patentees everywhere to price discriminate on a “high volume-low margin” basis in developing countries generally.

D. The Overriding Importance of Stimulating Local Production

Disregarding the double compulsory licensing scheme envisioned by Article 31*bis*, the Ministerial action initiated in 2001 created unique opportunities for establishing local production of pharmaceuticals in Least-Developed Countries by exempting them from any duty to patent (or enforce patents on) medicines until 2016. As the German Development Agency has clearly recognized, this temporal window of opportunity makes it possible to recreate, on the territory of willing LDCs, the kind of generic pharmaceutical production base that was fostered in India, over a much longer period of time. Given the flexibilities sanctioned by TRIPS, Doha and the post-Doha regimes, moreover, the emergence of growing capacities in these countries (and in other cooperating developing countries) could be pooled and focused on spreading supplies of generic substitutes throughout the developing world at affordable prices.

Of course, doubters will argue that LDCs in Africa or elsewhere lack comparative advantages in this area, and would likely require substantial external assistance, which is correct. But 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 address. The negative view also ignores the potential comparative advantages that LDCs in Africa and elsewhere might eventually derive from stores of biogenetic diversity and traditional knowledge, once a viable technological base was established. If the European Parliament could help to enlarge the German initiative to the point where promoting local production in LDCs became a Community-wide commitment, the prospects for changing the facts on the ground during the LDC window of opportunity (at least until 2016) are endless.

In this connection, we stress that potential generic manufacturers locating in the LDCs do not need any compulsory licenses at all to operate until 2016. Moreover, through buy-outs, patent pools or similar arrangements, willing governments—or the Commission—could reimburse originator pharmaceutical companies for lost R&D recoveries that resulted from establishing production in poor countries and from assisting other such countries to obtain the relevant medicines. Precisely because pharmaceutical companies currently do not look to these markets for recuperating research expenditures on global diseases, costs of buy outs or pooling arrangements would be low and risks are minimized.¹³⁸

Under these types of proposals, the technology procurers—who could be governments (such as the EU), intergovernmental organizations (such as WHO, UNDP, or the Global Fund), or private foundations—could acquire and make available patent rights for

¹³⁸ See K. Outtersson, *supra* note 123, at 171, noting that under a buyout proposal “the present IP system is retained for more than 80% of the global patent-based cash flow of the pharmaceutical companies.”

specific medicines for particular geographic markets.¹³⁹ A patent owner could be compensated under a transfer of rights (including pooling) formula, “which mimics the lost R&D cost recovery from the foregone sales.”¹⁴⁰

R&D cost recovery from developing countries is so low under current projections that buy outs and essential medicines patent pooling arrangements would be extremely cheap compared to other methods of assistance. Once a transfer of rights occurs, and the license is issued, competition should “drive the unit price down towards the actual marginal cost of production.”¹⁴¹ Lower prices should discourage the production of counterfeit pharmaceuticals, limiting the incentive to counterfeit drugs in the low- and middle-income countries.¹⁴²

E. Obstacles to Obtaining Key Active Ingredients (APIs)

Much also depends on the ability of potential suppliers to obtain key active ingredients. The production of these ingredients is increasingly outsourced to firms in certain developing countries, but subject to patent rights and other pressures that effectively reduce their availability to would-be user countries.

This need for APIs, a problem in the best of situations, becomes more acute if originator enterprises retaliate against the issuance of compulsory licenses by refusing to register new drugs for market approval. In principle, this form of retaliation leaves affected countries free to obtain the products anywhere or to reverse-engineer them under compulsory licenses (possibly as a remedy for patent abuse) for local production. In practice, the task of reverse-engineering could be difficult and costly, entailing major funding to defray the medicinal chemistry involved. Skills might have to be provided by either existing generic suppliers (in India, Brazil, and China) or by a network of universities willing to work in this area. Indeed, Pharma companies may calculate that the costs of reverse-engineering would persuade governments to accept their higher price offers rather than assume these risks.

The potential difficulties and costs of reverse-engineering needed components of new drugs are increased by possible legal restrictions on research exemptions under the laws where that analysis occurs. Here much depends on the exceptions to the patent holder’s exclusive rights that may apply in the country where reverse-engineering takes place. Of course, any analysis of this kind conducted in LDCs should be free of patent protection, if the LDC has avoided enacting relevant patent laws under the extension or has moved to disapply its patent laws for medicines under the new dispensation. However, the available skills in these countries would be very weak, unless they were bolstered by

¹³⁹ *Id.* The purchasers would then offer “an open, nonexclusive, no royalty license to any legitimate generic manufacturer, but only for sale in the target markets.” OECD countries would continue to practice normal patent-based pricing.

¹⁴⁰ *Id.*

¹⁴¹ *Id.* at 173.

¹⁴² *Id.*

transplants from foreign universities and research institutes, or by transplanted generic industries, e.g., Indian generic producers in Bangladesh.

Technical assistance could come from a network of willing universities and research institutes in developed countries, especially if sufficient funds were made available for this purpose. However, the pharmaceutical companies would likely exert pressure on any universities that cooperated in such a venture.

F. Countervailing Pressures by Industry and Governments

Much depends on the attitude of OECD governments, including that of the European Union. If they support Pharma enterprises and put pressure on developing countries and Least-Developed Countries, their threats and other measures can divide local governments internally (e.g., Trade Ministry versus Health Ministry) and retard or suffocate efforts to use the TRIPS/Doha flexibilities and the Amendment to the full.

It is worth noting that countermeasures by some governments may cross the line of legality under international law. For example, the United States has put both Thailand and Brazil on its priority watch list under Section 301 of the Trade Act, and the Administration has allegedly withdrawn GSP privileges on certain Thai exports in retaliation for the three compulsory licenses that government has recently issued.

This approach may conflict with the duties of WTO members to avoid taking unilateral acts concerning impediments to their expected benefits under the WTO Agreement, as set out in Article 23.1 of the Dispute Settlement Understanding.¹⁴³ Query whether recent actions against both Brazil and Thailand are consistent with these undertakings, not to mention with the Doha Declaration on TRIPS and Public Health.

G. New Patent Incentives and Old Market Failures

In a recent article, Maskus and Reichman suggested that the TRIPS Agreement had given rise to “an incipient transnational system of innovation.”¹⁴⁴ As developing countries begin to harness some of the potential benefits that system provides, while struggling to contain its social costs, their entrepreneurs may respond positively to the incentive effects that a relatively harmonized, worldwide patent system affords.

1. Stimulating Private R&D Investment in Poverty-Related, Tropical and Neglected Diseases

In the pharmaceutical sector, developing countries having significant generic production capacities in place, along with a basic infrastructure geared to innovation, may witness a shift to more research-based investments in the future, in place of reverse-engineered substitutes for existing drugs. Some evidence suggests that India is moving in this

¹⁴³ See United States – Sections 301-310 of the Trade Act of 1974, Report of the Panel, WT/DS152/R, 22 Dec. 1999.

¹⁴⁴ Maskus & Reichman, *supra* note 1.

direction. Whether research-based investments in these countries would be directed to poverty-related, tropical and neglected diseases, as one would hope, or to health problems that affect lucrative markets in OECD countries, remains to be seen.

Should private sector investments actually lead to the discovery of new drugs aimed specifically at poverty-related, tropical and neglected diseases, the patent system would have achieved one of its goals, and the market failure currently experienced with regard to public health needs of the South might shrink. If this hypothesis materialized over time, which is certainly a possibility, developing country governments might have to adjust their public health policies and strategies with a view to encouraging rather dampening such initiatives.

Unlike the situation today, where the major pharmaceutical companies expect to recoup their investments in the OECD countries and developing country markets are relatively incidental to this goal, the hypothetical company that discovers a cure for neglected diseases in the future would have to recoup its costs and make a profit in the poorer markets where the disease was widespread. On this scenario, the need to encourage socially beneficial private investment must be reconciled with short and long-term public health needs, and a certain caution with respect to compulsory licensing might be in order, lest the incentive to invest be curtailed.

Much would depend on the marketing strategy of the patentee who discovered the cure for a neglected disease. Precisely because it is dealing with diseases of the poor, the company may voluntarily adopt a marketing strategy based on a high volume of sales and low marginal returns, in order to distribute the drug across the widest possible base of potential patients.¹⁴⁵ In that event, intellectual property rights in combination with socially desirable marketing strategies would have solved the problem, without government intervention. To the extent some government intervention might still be needed, price controls afford an intermediate option that has proved workable in many OECD countries.

If, instead, a developing country firm that discovers a cure for a widespread Southern disease engages in the “low volume, high marginal returns” marketing strategy that big pharmaceutical companies tend to pursue today, it would invite government scrutiny and the possible threat of compulsory licensing along the lines discussed above. In practice, however, one would hope that private-sector pharmaceutical companies dedicated to discovering cures for poverty-related, tropical and neglected diseases would find it in their self interest—both socially and economically—to pursue a strategy based on high volume and low margins. In that event, their financial success, if it materialized, might help persuade the big pharmaceutical companies to adopt similar strategies when marketing their products to poor countries, in which case many of the current problems would be solved.

2. Changing the Marketing Model

¹⁴⁵ See, e.g., the approach of DNDi.

From the foregoing analysis, it should be clear that the overall objective of the flexibilities envisioned in Amendment article 31*bis* is not to drive the originator companies out of these markets, nor is it to reduce the incentive effects that stronger patent protection may have on stimulating R&D outside the OECD countries. What, instead, the use of TRIPS flexibilities needs to achieve is to persuade Pharma to change its marketing strategy in poor countries from a low volume-high margin approach to a high volume-low margin approach.

Given the size of these potential markets, there is no reason why the originator companies could not make profits on this strategy in the same way that Indian generics have done, all the more so if the bulk of R&D is funded by and recouped in OECD markets.

In a long-term perspective, moreover, more thought must be given to lessening the private sector's burdens with respect to clinical trial costs, and to the potential advantages likely to accrue from treating these costs instead as a global public good, whose benefits would also be shared by scientists and researchers worldwide.¹⁴⁶ While we lack the space to elaborate on this proposal here, it is clear that many of the inequities, hardships, and bureaucratic obstacles being imposed on developing countries in order to defray the growing financial burden that clinical trials places on the shoulders of the private sector could be relieved by a more rational reform based on the recognition that governments are in the best position to provide and regulate essential public goods.

3. The Continuing Role of Public-Private Partnerships

As matters stand, however, we remain a long way from seeing private sector remedies for diseases afflicting poor countries. The existing situation is, instead, characterized by a pronounced market failure, in which less than ten per cent of all pharmaceutical R&D is directed toward infectious diseases making up ninety percent of the global disease burden, and primarily affecting developing countries.

Given this market failure, the best immediate hope in this regard is the growing success of the Public-Private Partnerships that have been formed to address these diseases. As recently reported, there are now over 60 ongoing research projects sponsored by PPPs, and six or seven new drug registrations are expected in the next five years.¹⁴⁷ However, in many cases private foundations provide the bulk of PPP funding, and contributions from governments (including the EU and its member states) remain lower than might be hoped.¹⁴⁸

¹⁴⁶ See generally Tracy R. Lewis, Jerome H. Reichman, & Anthony D. So, *The Case for Public Funding and Public Oversight of Clinical Trials*, ECONOMISTS' VOICE, www.bepress.com/ev (January 2007)

¹⁴⁷ See London School of Economics & Wellcome Trust, *The New Landscape of Neglected Disease Drug Development* (8 September 2005).

¹⁴⁸ See, e.g., Nicoletta Denticò, *DNDi's antimalarial: a new public good for neglected patients*, presented at Public Health, Innovation and Intellectual Property Rights: EU Input to the Global Debate, organized by the European Commission Health and Consumer Protection Directorate-General, Apr. 2, 2007. This is not intended to discount the importance of contributions made so far to DNDi by, *inter alia*, the British and Dutch governments.

Here patents may constitute a barrier to entry unless they are pooled for these purposes, which should be encouraged. Similarly, universities in OECD countries should be encouraged to ensure that government-funded research results are made available to poor countries under humanitarian licenses. Above all, funds are needed from the European Union sufficient to ensure that Public-Private Partnership sponsored research continues at a proper pace.

4. Strengthening the Global Scientific Foundation

The existing market failures make it especially important for the public sector to fund research on relevant diseases and, to this end, governments should seek to strengthen the scientific and technical foundations in the affected countries. Here, funds are needed to support local research capacities, especially at universities, and to promote long-term benefits of cooperation with universities in EU countries, that could strengthen the scientific and technical base in participating poor countries over time. Institutions such as UNESCO, Third World Academies, and the U.S. National Academies could assist in this regard, with funds from the European Union.

Thinking boldly, one might establish a well-funded, peer-reviewed grant making body, modeled on the National Institutes of Health (NIH) in the U.S., which would support medical research in and for developing country diseases. This approach might appeal to young scientists in developing countries and provide them with opportunities and outlets for innovative proposals that do not otherwise exist at the present time.

IV. Conclusions and Recommendations

A. Action on the Protocol of Amendment

The European Parliament must decide whether to ratify the pending Amendment, reject it, or postpone action with a view to seeking further improvements in its legal machinery. In theory, postponing action on Amendment Article 31*bis* would afford an opportunity to obtain more streamlined procedures, free of the cumbersome requirements discussed earlier. On this view, a renegotiated solution could not be worse than the pending Amendment, so there is little to lose in trying.

No one can predict future events with certainty, and we assess the prospects for renegotiation hesitantly. Nonetheless, being charged with considering recommendations, we respectfully express our skepticism about the necessarily benign scenario suggested above. The political uproar triggered by the recent spate of compulsory licensing, coupled with the overwhelming pressures exerted on behalf of higher intellectual property standards at the multilateral, bilateral and regional levels by USTR and now the EC itself, cause us concern that the odds against a successful renegotiation are high. While the most likely result may be an impasse, there is also the prospect of a normative solution that embodies further restrictions like those narrowly avoided in the past (such as scope of diseases and eligible importing country limitations) and that would be noticeably worse than the procedures embodied in Article 31*bis*. Given that we believe Article

31*bis* can be made functional through a combination of political will, good lawyering, financial support for appropriate implementation efforts and collective action, including at the regional level as described above, we are concerned that the risks attendant upon a renegotiation may outweigh the likely benefits.

Perhaps the biggest risk is that, if the pending Amendment in Article 31*bis* is not given timely ratification, its failure would make the Paragraph 6 solution dependent on continuation of the existing waiver. The vitality of that continuation should not be taken for granted, however, given the political contentiousness currently surrounding the use of compulsory licenses under existing laws. The waiver is legally constructed to continue in effect notwithstanding the absence of its transition into an amendment, but powerful states and lobbies may eventually undermine confidence in the waiver through aggressive forms of persuasion. The process might be thrown back upon the mandate to negotiate some solution as initially set out in paragraph 6 of the Doha Declaration, with unforeseeable results.

Nevertheless, the EP could decide to postpone assent to ratification of the Amendment while seeking to negotiate a suitable program of action with the Commission and Council that would color the EU's future outlook and conduct relevant to implementing the Amendment. For example, once the Commission and Council accepted to pro-actively support the IGWG process, refrain from negotiating TRIPS-plus provisions affecting public health in the EPAs and other bilateral agreements with developing countries, discussed the use of Article 30 by the member states as an alternative approach to authorizing exports (*see* below), and took into account some of the proposals that the Committee on International Trade put forward in regard to the implementing regulation, the EP might conclude that the package negotiated with Commission and Council was a significant improvement over the status quo, even if the text of the Amendment remained unchanged. However, care must be taken with the message conveyed by the EP, and the timing of its decisions, so that the fundamental force of the Decision and Amendment are not undermined.

The European Parliament should, accordingly, weigh its decision to ratify or postpone with care. If ratification seems advisable, then the Parliament should throw its weight into implementation, both by exercising oversight of the Commission's own activities in this regard and by supporting, through funding and other measures, efforts like those undertaken by the German Development Agency, UNCTAD, DFID and other IGOs and NGOs. Specific recommendations in this regard are summarized below. It should also press the Commission to avoid hindering the goals of the Amendment either directly or indirectly through offsetting provisions of the EPAs.

B. Alternative Arrangements under the Exceptions Clause of Article 30

The bulk of this report has focused on the solutions to the problem of inadequate manufacturing capacity embodied in the Decision of August 30, which in turn was carried over into the proposed Amendment in the form Article 31*bis*. Both the waiver currently in force under the Decision of August 30 and the permanent Amendment set out

in Article 31*bis* take existing Article 31(f)'s restriction on exports under a compulsory license as their starting point, and then proceed to adopt various other regulatory measures to obviate that problem.

During the negotiations, however, many stakeholders argued that WTO Members seeking to assist poor countries through exports of needed medicines could accomplish the same goal by proceeding under Article 30 of the TRIPS Agreements, which authorizes exceptions to the patentees' exclusive rights that are consistent with a three step test drawn from copyright law under the Berne Convention. Article 30 says, in essence, that governments may decide to override the rights that patent holders ordinarily are given to exclude others from the market when the exceptions to those rights are appropriately limited, and would not unreasonably interfere with them, taking into account the public interest. The basic premise of the contemplated Article 30 approach was that no damage would be inflicted on the patentees' domestic market in supplier countries because the products to be manufactured would be exported to needy countries under compulsory licenses issued (if needed) in those countries. Hence, with no appreciable harm to the patentees' market at home, it was argued that the patentee had no cause to complain, even if such an exception was not previously sanctioned by state practice.

Indeed, there is some legislative history suggesting that the European Parliament was interested in this approach at one time. However, the U.S. government adamantly opposed this approach, and was joined by the Commission and Council. A further legal obstacle was created by the WTO panel decision in the *Canadian Generic Products* case, in which the panel took a restrictive view of Article 30's three step test.¹⁴⁹

That decision has been criticized on both technical and policy grounds, and the fact that it was taken before the Doha Declaration on TRIPS and Public Health may in any case limit its precedential authority. The Declaration admonishes states to allow use of the TRIPS flexibilities for public health purposes, and it makes access to essential medicines a common overriding goal of WTO Members, indirectly supported by the principles laid out in Article 8.1. It seems questionable, therefore, that a Member proceeding under Article 30 to aid a state by exporting supplies of medicines to address public health needs could be successfully challenged on legal grounds before a WTO dispute settlement panel today, unless the panel were to view Article 31*bis* as an exclusive remedy, which its express provisions deny.

The problem with resort to Article 30 then is mainly political in nature, given that a legislative solution has been codified in the waiver and pending Amendment, and the U.S. continues to oppose other solutions. However, even if the European Parliament were to decide to ratify and accept the pending Amendment, nothing prevents it from also endorsing use of Article 30 by the EU and/or its member states.

On this approach, enabling legislation at the Community level, while perhaps desirable, would not necessarily be required. The European Parliament is already on record as

¹⁴⁹ See Christopher Garrison, *Exceptions to Patent Rights in Developing Countries* ICTSD/UNCTAD Issue Paper No. 17 (2006).

having expressed interest in this solution. The Council and Parliament might adopt a joint policy statement to the effect that EU member states are free to proceed by the Article 30 route under their domestic patent laws, and recommend that the Commission refrain from taking action to interfere with such proceedings. Clearly, such action by the Council would lend considerable stature and credibility to this approach at the international level.

This alternative, favored by some influential NGOs, is not without corresponding risks. For example, industry pressures at the member state level might inhibit some governments from proceeding under Article 30, despite such an enabling policy statement, and state practice could vary considerably throughout the EU. But the continued availability of Article 31*bis* would attenuate these risks.

If state practice coalesced around exports of pharmaceuticals to assist countries requiring medicines that issued a single compulsory license at home, under Article 30, the simplicity and efficiency of this solution would become apparent. Worldwide acquiescence might follow as a matter of course if the benefits on the ground and the lack of corresponding problems were empirically verifiable.

C. Countervailing Pressures to Ratchet Up Intellectual Property Standards

Whether the flexibilities built into the TRIPS Agreement, including those embodied in the Amendment, will withstand assault from the multinational purveyors of knowledge goods that are driving the WIPO SPLT negotiations and the bilateral and regional FTAs and EPAs remains to be seen. The SPLT negotiations could reduce flexibilities across the board for all countries, while the bilaterals and FTAs have significantly cut back on the ability of national governments to provide public goods that involve intellectual property inputs. The Commission's decision to follow a more aggressive intellectual property strategy in the EPAs being negotiated with the APC countries is particularly worrisome in this regard.

Some observers, including one of the authors of this report, have gone on record to urge "a moratorium on further intellectual property standard setting exercises," in order to give the incipient transnational system of innovation, triggered by TRIPS, time to breathe and grow.¹⁵⁰ In vetting the proposed Amendment, the European Parliament should carefully monitor these additional pressures on developing countries and use its intermediary role to restrain the Commission from unilaterally worsening the public health situation in poor countries by these and other means. It should demand that the Commission support full implementation of TRIPS flexibilities as recognized in the Doha Declaration to promote access to medicines for all.

D. Other Recommendations

For reasons of space, we list other recommendations that follow logically from the matters discussed in this report.

¹⁵⁰ Maskus & Reichman, *supra* note 1.

- Direct the Commission to support the work of IGWG at the WHO and to maintain a position that does not sacrifice the public health interests of developing countries to special interest lobbying.
- Encourage the pharmaceutical companies to pursue pricing alternatives involving a high volume, low margin approach, which could produce a win-win situation and might reduce pressure to invoke compulsory licenses.
- Encourage the EU and the member states to support transfer of technology to LDCs, and local production of pharmaceuticals in all developing countries, especially LDCs, in keeping with the objectives of Article 66.2 and the example that the German government, with its partners, has been setting in this regard.
- Encourage the EU and its member states to provide concrete financial support for pharmaceutical-related transfer of technology and capacity building for developing countries.
- Discourage the EU from pursuing higher intellectual property standards affecting pharmaceuticals in multilateral, bilateral, and regional forums, and especially from introducing new and controversial disciplines into EPAs, such as nonoriginal database protection, which damages science and has been strongly criticized inside the EU.
- Press the EU to avoid using regulatory data as an excuse for new restrictions on TRIPS flexibilities and support studies of how clinical trial data might be better regulated as a global public good.
- Encourage the EU to support recognition of disclosures of origin of patents on products deriving from traditional knowledge and/or genetic resources found in developing countries, with a view to promoting the sharing of benefits and technology derived from those sources by native populations in those countries.
- Encourage the Commission to lower the political rhetoric surrounding use of the TRIPS flexibilities; to remind other powers of their duties to avoid unilateral action in trade disputes under the DSU and WTO Agreement; and to support efforts by any adversely affected countries to defend themselves against unilateral acts before WTO dispute settlement panels.
- Support funding for R&D on poverty-related, tropical and neglected diseases across a broad spectrum of venues, including PPPs and other possible funding ventures, and to support research institutes willing to cooperate with public health initiatives dedicated to these efforts.