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FACILITATING COMPULSORY LICENSING UNDER TRIPS IN RESPONSE TO THE AIDS CRISIS IN DEVELOPING COUNTRIES

Hans Henrik Lidgard and Jeffery Atik¹

Abstract

The AIDS crisis in the developing world has become a priority for international collaboration. The challenge is to find a balance between the acknowledged need to protect large investments expended in developing new medicines and the goal of providing essential medicines to poor countries. Patent protection must prevent undue infringement yet at the same time allow solutions to humanitarian needs. Is compulsory licensing a way out? TRIPS originally restricted compulsory manufacturing licenses to the country experiencing a public health emergency – which was of little utility to countries lacking manufacturing capacity. The Doha agreement effectively permits twinned compulsory licensing – a distribution and use license in countries experiencing a public health emergency and a manufacturing-for-export license in countries possessing appropriate manufacturing capacity. These changes make possible, at least in principle, a greater source of supply of generic pharmaceuticals for use in those least developed countries confronting the AIDS crisis. It is still early to evaluate the results from the Doha agreement, but it appears that the agreed measures may entice ordinary market forces to start making contributions to an improving situation.

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1. DISASTROUS PROJECTIONS

The development of new antiretroviral treatments and other HIV-related therapies have made HIV/AIDS a more manageable disease in advanced countries. The situation in the developing world is markedly different. According to UNAIDS, in 2003 more than 25 million people in Sub-Saharan Africa were living with HIV, an estimated 3 million people were newly infected and more than 2 million people had died of AIDS. Botswana and Swaziland have the highest prevalence, with more than 35% of their population infected.²

Despite various efforts, access to medicines remains low. In 2000 the yearly price for a triple therapy for one patient was approximately 12,000 USD. Competition has reduced the price to some 300 USD. Still, this price is exorbitant for major population groups in developing countries and only an estimated 7% of the infected have access to relevant medicines.³ The disastrous projection has been that five to six million people in low- and middle-income countries will die of AIDS during 2004 and 2005 if they do not have access to medicines.

Many initiatives have been taken under the UN⁴ and WHO⁵ regimes to improve the situation. Responses have been based on overriding human rights considerations,⁶ but approaches involving a more hands-on trade

² UNAID, Fact sheet, AIDS epidemic in sub-Saharan Africa, www.unaids.org.

³ UNAID, Fact sheet, Access to HIV Treatment and Cure, www.unaids.org.

⁴ The 57th Session of the United Nations Commission on Human Rights adopted on April 2001 Resolution 2001/33 on Access to Medication in the Context of Pandemics such as HIV/AIDS. The Resolution recognizes access to medicines as an essential human right. States should (a) refrain limiting equal access; (b) adopt legislation to safeguard access; (c) facilitate access in other countries; and (d) ensure the right of everyone to the enjoyment of the highest attainable standard of physical and mental health.

⁵ The 54th World Health Assembly in May 2001 approved the resolution on “Scaling Up the Response to HIV/AIDS” and “WHO Medicines Strategy”. Drugs should be made available at lower prices and states should cooperate to strengthen pharmaceutical policies, and expand access to drugs.

⁶ Cann, W.A., On the relationship between intellectual property rights and the need of less-developed countries for access to pharmaceuticals: Creating a legal duty to supply under a theory of progressive global constitutionalism, *University of Pennsylvania Journal of International Economic Law* 2004:755-944. Cann provides a well designed presentation of the human rights perspective on the HIV/AIDS pandemics and outlines obligations of comity based on international law on all nations to find solutions, which go far beyond the obligations established by the TRIPS agreement.

facilitation character have dominated the discussion. WTO members have been addressing trade in counterfeit medicines and opening possibilities for parallel trade. Governments and non-governmental organizations are actively and side by side providing relief under general development programs. In spite of all the good intentions, significant problems remain. A real solution requires the involvement of all actors concerned.

This article approaches the recent developments under the TRIPS Agreement, focusing on the compulsory licensing authority provided under TRIPS Article 31 and the extent by which this mechanism can contribute to addressing the HIV/AIDS problem in developing countries.⁷

2. TRIPS – A BALANCING ACT

The 1994 WTO Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) effectively extends the intellectual property right (IPR) obligations under the Paris, Berne and Rome Conventions to the entire WTO community. The Most Favoured Nation and the National Treatment requirements contained in these conventions are cornerstones in TRIPS and the agreement also provides basic substantive principles on the protection and enforcement of IPR.

TRIPS has a bifocal objective. The preamble recognizes the protection of intellectual property as a prime objective. At the same time, and as a form of compensation for introducing stricter IPR standards, developing countries should be allowed - with the support of the industrialized world - to create a sound and viable technological base.⁸ According to TRIPS Article 7, IPR

⁷ Other significant matters which affect the availability of medicines, such as parallel trade issues, counterfeit goods problems, trade diversion aspects, and pharmaceutical data protection, are not included in this brief paper. It is likely that efforts in the developed world should, apart from creating access to essential medicines in developing countries, be focused on avoiding counterfeit trade and trade diversion of products intended for developing countries. There are good reasons to believe that the principle of exhaustion should be carefully extended between developed countries based on bilateral or multilateral agreements, but that it should not cover developing countries in order to secure price differentiation between the developed and the developing world.

⁸ See the developing country group's position paper submitted to the TRIPS Council on 19 June 2001, IP/C/W/296: "Our commitment to the TRIPS Agreement stems from our expectation that the protection and enforcement of intellectual property rights, in accordance with the objectives of the Agreement (Article 7)," ... "should contribute to the promotion of technological innovation and to the transfer and dissemination of technology, to the mutual advantage of producers and users of technological knowledge and in a manner conducive to social and economic welfare, and to a balance of rights and obligations".

protection should contribute to the promotion of technological innovation and to the transfer and dissemination of technology. Both producers and users should benefit and IPR protection should be employed in a manner conducive to social and economic welfare, and to a balance of rights and obligations.⁹

To underscore the social welfare perspective, WTO Members may according to TRIPS Article 8 adopt measures necessary to protect public health and nutrition, and to promote the public interest in sectors of vital importance to their socio-economic and technological development. They can also act to prevent the abuse of intellectual property rights or practices, which unreasonably restrain trade or adversely affect the international transfer of technology.

In spite of these general statements, which at the same time encourages innovation and protects health, the overriding problem is that poor economies in developing countries leave little or no capacity to provide their citizens with the required means to reach the “highest attainable standard of physical and mental health” in terms of the International Covenant on Economic, Social and Cultural Rights.¹⁰ They certainly do not have the capacity to consume high priced western products. The innovating western industry has been reluctant to price differentiate in favour of the poor, as sales of patented products in developing countries have negligible impact on global sales and profits of large multinational companies. The problem has often been expressed as a tug-of-war between on the one hand the essential needs in the developing world and the wish to promote and encourage innovation.¹¹ A general view seems to be that TRIPS has consolidated the economic power and monopoly privileges of the developed nations and their pharmaceutical industry.¹²

The record so far shows that the introduction of IPR rules in the developing world has been a slow process. This protracted development is further aggravated by the fact that the transfer of technology from developed to developing countries has not really expanded. The less happy result is

⁹ The importance of TRIPS Article 7 is underlined by Bagchi, A., *Compulsory licensing and the duty of good faith*, *Stanford Law Review* 2003:1529, p. 1542.

¹⁰ ICECR, December 16, 1966, 993 U.N.T.S. 4, 5, article 12.1.

¹¹ Outterson, K., *Pharmaceutical arbitrage: Balancing access and innovation in international prescription drug markets*, *Yale Journal of Health Policy, Law and Ethics* 2005:193, p. 223.

¹² Baker, K., *Arthritic flexibilities for accessing medicines: Analysis of WTO action regarding paragraph 6 of the Doha Declaration on the TRIPS Agreement and public health*, *Indiana International and Comparative Law Review* 2004:613, p. 621.

demonstrated by the joint failure to address the HIV/AIDS crises in the developing world.

3. COMPULSORY LICENSING

Even if the TRIPS Agreement has not yet to any major extent contributed to solutions to health problems by securing the voluntary transfer of technology,¹³ it does contain mechanisms that could be used to force a development.¹⁴ TRIPS Article 30 arguably opens the possibility for WTO Members to issue compulsory licences without infringing rights of the patent holder on condition that the exception is limited, not in unreasonable conflict with normal use and that the legitimate interests of the patent holder and third parties are taken into account.

The mechanism in TRIPS Article 30 has much of a “fair use” ring to it,¹⁵ but its vagueness is disturbing. The treaty language does not give any guidance to the meaning of the different concepts it contains. Should compulsory licensing be regarded as a “limited exception” or is it rather in conflict with the “normal exploitation” of the patent right? What “legitimate interests” do the patentee and third parties have? Does the stipulation in itself provide a ground for compulsory licensing or must it be read together with TRIPS Article 31?

The interpretation of these notions is developing within the WTO’s Dispute Settlement Body. With respect to “legitimate interests,” the EU/Canada pharmaceutical case¹⁶ opted for a broad norm providing for those economic, social and political considerations, which are relevant in the HIV/AIDS context.¹⁷ An argument could be made that Article 30 provides all the elements for producing pharmaceuticals in one country and consuming them in another under compulsory licenses in emergency

¹³ WTO members are providing annual reports on advances in transferring technology, but the overall result is not too encouraging.

¹⁴ See Schug, M.K., Promoting access to HIV/AIDS pharmaceuticals in Sub-Saharan Africa within the framework of international intellectual property law, *Law and Inequality* 2001:229.

¹⁵ Baker, [FN12], p.670 refers to TRIPS Article 30 as a principle of proportionality “such that if public health interests of third parties are substantial, then a more significant limitation on patent rights is permissible.

¹⁶ WTO Panel Report on EU/Canada – Patent Protection of Pharmaceutical Products, WT/DS 114/R, March 17 2000, www.docsonline.wto.org.

¹⁷ Cann, [FN6], p. 814.

situations.¹⁸ However, the specific provisions of TRIPS Article 31 – which assuredly address the conditions under which a compulsory license may issue – might suggest that independent authority for compulsory licenses under less strict terms may not be found in TRIPS Article 30.

Under TRIPS Article 31, a WTO Member may in its domestic law provide for compulsory licensing in situations of national or extreme emergencies or in cases of public non-commercial use. Procedural safeguards require that the measure is used for essential products and that prior negotiations with the rights-holder have failed to obtain a reasonable result.¹⁹ TRIPS waives the requirement of prior negotiation in emergency cases or when the subject matter of the patent is required for public non-commercial use. The scope and the duration of the license shall be limited to the purpose for which it was authorized.

Importantly, TRIPS Article 31(f) adds that any use of a compulsory license shall be predominantly for the supply of the domestic market of the member state authorizing such use. Article 31(f) had been read to prohibit the manufacture of generics in third countries for export to those countries experiencing the public health crisis. Thus, countries lacking indigenous pharmaceutical manufacturing capacity could not effectively access medicines in compliance with TRIPS Article 31.

The scheme provided in TRIPS Article 31 is also flawed with a number of unclear notions, which have created tensions regarding when and how compulsory licensing may be applied. For example, it is unclear:

- when a situation of national emergency may be invoked
- how much efforts must be employed to reach a voluntary agreement with the patent holder before a failure has been established
- what royalty compensation must be awarded to the rights holder

¹⁸ Abbott, F.M., The TRIPS Agreement, Access to Medicines and the WTO Doha Ministerial Conference, Occasional Paper 7, September 8, 2001, Quaker United Nations Office – Geneva, <http://www.geneva.quino.info/pdf/OP7%20Abbott1.pdf>.

¹⁹ TRIPS starts from the assumption that the importing country shall first approach the rights-holder. Only if an agreement cannot be reached on commercially reasonable terms may the importer approach others. Barbosa, S.A., Implementation of the Doha Declaration: Its impact on American pharmaceuticals, Rutgers Law Journal 2004:205, 258 suggests that there are reasons to allow the rights-holder a second bite at the apple. Once the importer has tentatively agreed with a third party, the rights-holder could be offered a right to supply on the same terms and conditions offered by the third party. It would not only be fair to the rights-holder, but it may also be in the interest of the buyer to have access to an approved product, which is produced according to established high safety standards, rather than a product that is merely less expensive.

- whether least developed countries with no production capacity may rely on importation

Under TRIPS, the resolution of many of these uncertainties is in the hands of the importing country. As long as it follows the TRIPS procedure, the importing country can make the final determination itself.²⁰

In reviewing the TRIPS system as it applies to compulsory licensing, it must also be emphasized that the general security exemption in TRIPS Article 73 may have an impact, as it allows a WTO Member wide discretion to take any action it considers necessary in time of war or other emergency. This provision relieves a party from virtually all of its substantial obligations under TRIPS.²¹

4. DIVERGING INTERPRETATIONS

In most civil law jurisdictions, legislation providing for compulsory licensing has been enacted to protect the public interest, but in reality the possibility has rarely been put to practice. Judging from cases referred to the European Court of Justice, it appears that resort to compulsory licensing has primarily been employed in common law Great Britain, where national courts have referred cases on the conflict between compulsory licensing under national law and European requirements on the free movement of goods.²²

The United States has no specific provision for compulsory licenses in its patent law. However, competition law (antitrust law in U.S. parlance) remedies include solutions which closely resemble compulsory licensing.²³

²⁰ On the other hand, the Chairperson's statement to the August 30 Agreement [FN51 below] makes clear that "any Member may bring any matter related to the interpretation or implementation of the Decision ... to the TRIPS Council for expeditious review with a view to take appropriate action." This statement may reduce the control of the importing state. Barbosa, [FN19], p. 249 argues that a special WTO committee should be set up to oversee the proposed action in order to establish that the proposed activity is optimal and that no equally good generic alternatives exists.

²¹ Cann, [FN6], p. 822-832 argues convincingly that the security exception applies in times of HIV/AIDS emergency.

²² European Court of Justice, case 19/84, *Pharmon v Hoechst*, 9 July 1985, [1985] ECR 2281; Case 434/85, *Allen & Hanburys Ltd v Generics (UK) Ltd*, 3 March 1988, [1988] ECR 1245; Case C-30/90, *EC Commission v Great Britain*, 18 February 1992, [1992] I-ECR 777; and Case C-191/90, *Generics and Harris Pharmaceuticals v SK&F*, 27 October 1992, [1992] ECR I-5335.

²³ From August 1941 to January 1959 there were 107 judgments in which patent rights were restricted under U.S. antitrust laws. The use of "compulsory licenses" has continued.

The use of the essential facility doctrine and patent misuse practice appear to lead to a larger amount of de facto “compulsory licensing” in the United States than in civil law Europe.²⁴ Several proposals to introduce a compulsory licensing regime have been made, but have been defeated.²⁵ This fact has not prevented the country from finding internal solutions in emergency situations.²⁶ At the same time, the United States has over the years been resistant to other countries declaring an emergency that would support the issuance of a compulsory license.

Even if the multinational pharmaceutical industry has limited commercial interest in developing-world markets, it has a strong interest in what happens to a patented product in those markets. Neglecting developing-world markets may mean that the product ends up being provided by aggressive generic producers, which may use the compulsory license to initiate activities in developing countries in preparation for eventual launch in lucrative western markets (upon expiry of the relevant patents) and then harming the commercial welfare of the innovating industry.

U.S. government and industry have carefully monitored the handling of compulsory licensing in developing countries and have objected to activities not in compliance with the TRIPS Agreement. The aggressive reaction provoked by South Africa’s introduction of the 1997 Medicines and Related Substances Control Amendment Act²⁷ amply demonstrates the ambivalent U.S. attitude. The U.S. Government threatened South Africa with trade sanctions and large US pharmaceutical producers introduced complaints in South African courts claiming that this legislation did not contain TRIPS safeguards for the protection of the patent holder. Considering the marginal importance of the market for larger pharmaceutical companies, the wisdom of these and similar actions could well have been queried. Both the U.S. government and the pharmaceutical companies were forced to withdraw

Scherer, F.M., Pricing, profits, and technological progress in the pharmaceutical industry, *The Journal of Economic Perspectives* 1993:97, p.106.

²⁴ Relying on a “stretched” interpretation of U.S. antitrust principles, Baker, [FN12], pp. 664-667 and 678-683, argues that these theories could well be employed as a compulsory licensing rationale under TRIPS Article 31(k).

²⁵ Valach, A., Protecting the rights of patent holders and addressing public health issues in developing countries, *Chicago-Kent Journal of Intellectual Property* 2005:156, p. 181.

²⁶ Mullin, T.F., Aids Anthrax, and Compulsory Licensing: Has the United States learned anything? A comment on recent decisions on the international intellectual property rights of pharmaceutical patents, *Journal of International and Comparative Law* 2002:185, p. 212.

²⁷ Medicines and Related Substances Control Amendment Act 90 of 1997, referring back to the Medicines and Related Substances Control Act 101 (S.Afr.) of 1965.

their actions in view of public pressure.²⁸

Brazil is another example of a conflict between the United States and a developing country. Brazil has been successful in promoting a nation-wide HIV-program by combining public health initiatives with a tough stance on access to pharmaceuticals.²⁹ The Brazilian government promoted production of generic, non-patented pharmaceuticals in Brazil. For products patented in Brazil it initiated negotiations with foreign producers to secure access at low prices under the threat that it would otherwise grant compulsory licenses to local manufacturers.³⁰ The Brazilian hard-line position, which held that compulsory licences could be granted when products were not locally produced, was challenged by the U.S. Government, which in 2001 requested the WTO Dispute Resolution Panel to investigate the matter.³¹ Again, public pressure forced the United States to withdraw the request against an undertaking from Brazil to inform U.S. officials before invoking the local manufacturing requirement as a base for compulsory licensing.³²

Developments within the United States were a contributing factor to the withdrawal of U.S. claims against Brazil. Even though compulsory licensing is not a part of U.S. patent law, the U.S. Government has not hesitated to put pressure on foreign pharmaceutical manufacturers in case of need. Only a couple of months after the withdrawal of the Brazilian case from the WTO Panel, the United States experienced an “anthrax scare” where a bio-terrorist attack forced the government to consider issuing a compulsory license for the production of Ciproflaxin, a patented pharmaceutical produced by

²⁸ Walker, M.B., Assessing the barriers to universal antiretroviral treatment access for HIV/AIDS in South Africa, *Duke Journal of Comparative and International Law*, 2004:193, p. 212.

²⁹ Outtersson, [FN11], p. 224.

³⁰ Ferrone, J.D., Compulsory licensing during public health crises: Bioterrorism’s mark on global pharmaceutical patent protection, *Suffolk Transnational Law Review* 2003:385, pp. 395 ff and 403 ff.

³¹ In spite of a U.S. White House Executive Order (13155 of May 20, 2000 regarding access to HIV/AIDS pharmaceuticals and medical technologies) to promote access to medicines in developing countries, the United States has taken action against Brazil under the WTO dispute settlement system (WT/DS 199/3 of January 2001) claiming that the requirement of local manufacture in Brazilian patent law is contrary to TRIPs. Brazil objected and asserted that similar requirements could be found in U.S. patent law. The matter was settled in July 2001 (WT/DS 199/4) without any major undertakings from Brazil.

³² Valach, [FN25], p. 168.

Bayer.³³ Under the threat of compulsory licensing, Bayer agreed to supply the antibiotic to the United States at reduced prices.³⁴

In contrast to the United States, the European Union has taken a more flexible approach to finding solutions.³⁵ The European Union regards compulsory licensing as one option to address the global HIV/AIDS pandemic.³⁶ The Union and its member states have not been involved in legal disputes (at the WTO level or within national fora) with developing countries concerning the compulsory licensing of pharmaceutical, nor have they counteracted different developing country initiatives to secure relief, but rather have generally tried to promote compromise solutions within international organizations.

5. DOHA CALLS FOR AN EXPEDITIOUS SOLUTION

There can be little doubt that least developed and developing countries most affected by epidemic diseases are in an emergency situation under TRIPS Article 31 and that they are fully entitled to use the system of compulsory licensing.³⁷ That is, however, not sufficient to permit the supply

³³ Ferrone, [FN30], p. 403 ff.

³⁴ Hughes, J., & Gerberding, J., Emerging infectious diseases. Anthrax Bioterrorism: Lessons learned and future directions, <http://www.cdc.gov/ncidod/EID/vol8no10/02-0466.htm>.

³⁵ EU seeks to break deadlock for WTO access to medicines deal, EU News Release, January 9, 2003 proposing a multilateral solution which is workable, sustainable and legally secure, based both on the Doha mandate and on the chair's compromise text of December 16, 2002. The EU approach aimed at absolute clarity that the deal covers the widest possible list of major infectious diseases. But it would not be a restrictive list. EU would also refrain from challenging any Member which would want to export medicines according to the terms and modalities set out in the draft decision of December 16, 2002.

³⁶ In September 2000 the European Commission adopted a Communication on a new policy framework entitled: "Accelerated action targeted at major communicable diseases within the context of poverty reduction" (COM (2000) 585). In 2001, the Communication was followed by a Programme for accelerated action on HIV/AIDS, malaria and tuberculosis in the context of poverty reduction, COM (2001) 96 http://www.cc.cec:8082/comm/development/sector/social/health_en.htm). The EU position was further developed in a WTO position paper submitted to the TRIPS Council on 12 June 2001, IP/C/W/280 (01-2903).

³⁷ See the EU position paper, [FN36], § 12: "The view of the EC and their member States is that the absence of any explicit reference to public health in Article 31 does not prevent WTO Members from invoking public health concerns. Article 7 ('Objectives')

of needed pharmaceuticals. A real problem is that most such countries lack the know-how, education and technology to produce the essential medicines required.³⁸ In addition, national infrastructures are oftentimes insufficient to distribute medicines to larger groups of the population, even when they have access to the essential drugs. Transfer of know-how and technology from the industrialized world is required, but such development is long-term and the needs are imminent.

The shortcomings of TRIPS were obvious and in 2001 at the Ministerial Conference meeting in Doha,³⁹ WTO Members recognized the gravity of the health problems affecting many developing and least developed countries. The Doha Declaration affirmed that the TRIPS Agreement “can and should be interpreted in a manner supportive of WTO members’ right to protect public health and, in particular to promote access to medicines for all.” WTO Members could freely grant compulsory licenses and decide on the grounds therefore. In order to provide relief for countries with no production capacity in the pharmaceutical sector, Paragraph 6 of the Doha Declaration instructed the Council for TRIPS to find an expeditious solution before the end of 2002.⁴⁰

refers to 'social and economic welfare' as an objective of the Agreement while Article 8 ('Principles') allows Members to take measures necessary to protect public health, provided such measures are consistent with the provisions of the Agreement. Although Articles 7 and 8 were not drafted as general exception clauses, they are important for interpreting other provisions of the Agreement, including where measures are taken by Members to meet health objectives.”

³⁸ A different stance is presented in the Developing country group’s position paper, [FN8], where they place the protection and enforcement of IPRs in the context of the interests of society and advocate the development of domestic production when economically feasible to availability at affordable prices. Local manufacturing also insulates the price against currency devaluations and supports development of local expertise. In case of failure, members should be allowed to ensure transfer and dissemination of technology. Article 8.2 TRIPS prevents abuse of IPR or resort to practices which unreasonably restrain trade or adversely affect the international transfer of technology. Excessively high prices beyond reasonable margins of profit prevent access to medications and, likewise, refusal to offer products in sufficient amounts constitutes abusive behaviour. In such situations, patent rights are exercised in a way that conflicts with public health policies and developing countries should be allowed to take action.

³⁹ World Trade Organization, Ministerial Conference Fourth Session Doha, 9 - 14 November 2001, Declaration on the TRIPS Agreement and Public Health, Adopted on 14 November 2001, WT/MIN(01)/DEC/2, 20 November 2001 (01-5860), available at www.wto.org.

⁴⁰ A subsequent WHO/WTO report concluded that this “landmark” declaration “demonstrates that a rules-based trading system is compatible with public health interests. The careful and systematic attention which WTO Members afforded to finetuning the balance that needs to be found in the intellectual property system is indicative of the prominence accorded to public health on the international trade agenda.” WTO Agreement & Public Health: A joint study by the WHO and the WTO secretariat, 2002.

In spite of the clear language of the Doha Declaration,⁴¹ finding a solution to securing access to medicines turned out to be a difficult task.⁴² Countries were acting in their own self-interest either because they felt essential values were at stake (as with the United States⁴³) or because they saw opportunities for domestic industry to expand into new fields (India and Brazil).⁴⁴ The U.S. position was to limit the types of products that would be available for compulsory licensing to medicines to combat epidemic diseases and to reduce the number of countries that would be eligible as both importers and exporters of these products.⁴⁵ The European Union advanced a compromise solution.⁴⁶ The deadline of December 2002 passed without any agreement.⁴⁷

It was not until August 30, 2003 that the TRIPS Council was finally able to reach a decision⁴⁸ (“the August 30 Agreement”) shortly before the upcoming Cancún Ministerial Conference.⁴⁹

The August 30 Agreement is somewhat of a compromise. The agreement itself only refers to pharmaceutical products needed to address a public

⁴¹ The Doha Declaration is an interpretative statement by the organization. It does not amend or change the TRIPS Agreement, but still serves as a persuasive authority.

⁴² Lidgard, H.H., *Internationell handel med patentskyddade läkemedel*, Nordisk Immaterialrätt (NIR) 2004:1.

⁴³ In an undated memorandum from the EU Commission, Trade and Development entitled *Developing countries and access to medicines. How did we get here?*, available at www.EU.Europa.org, the Commission clearly points its finger at the United States, Australia, Canada, Japan and Switzerland suggesting that “their unambitious draft underscores their reluctance to do anything substantial and serious at this stage.”

⁴⁴ Brazil offers compromise to break TRIPs/medicines deadlock in WTO, BNA International Trade Reporter 20:8, 20 February 2003.

⁴⁵ Second Communication from the United States to TRIPS Council, concerning Paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health, 9 July 2002, IP/C/W/358.

⁴⁶ See the EU position paper, [FN36], at § 13, which indicated another possible interpretation allowing a Member to issue a compulsory licence to a manufacturer in another country, provided the government of that other country recognized the licence and the goods manufactured were exported to the country granting the licence. EU made the reservation “that it is far from certain whether such a 'permissive' reading of the Agreement would stand scrutiny by a panel or the Appellate Body.”

⁴⁷ See e.g. Trade Commissioner Lamy’s address to the association of Pharmaceutical Industry Managers on 21 March 2003 on International Trade in Drugs: its role in equitable development, available on http://europa.eu.int/comm/archives/commission_1999_2004/lamy/speeches_articles/spla162_en.htm.

⁴⁸ Decision of the WTO titled Implementation of paragraph 6 of the Doha Declaration on the TRIPS Agreement and public health, WT/L/540.

⁴⁹ World Trade Organization, Ministerial Conference Fifth Session Cancún, 10 – 13 September 2003, www.WTO.org.

health problem with a reference to the Doha Declaration.⁵⁰ The statement of the chairperson,⁵¹ which is attached to the decision, adds that the decision should be used in good faith to protect public health and should not be an instrument to pursue industrial or commercial policy objectives. It applies not only to formulated pharmaceuticals produced and supplied under the system, but also to active ingredients and to finished products produced using such active ingredients. The right to use compulsory licensing is not limited to least developed countries, but can be invoked by others as well. The difference is that an emergency situation is presumed in the least developed countries, whereas others have to show that such problems are at hand.

The chairperson statement further clarifies that a number of WTO Members will not avail themselves of the opportunity to import products under compulsory licensing or will only do it in emergency situations. As the statement is appended to the decision, it carries at best interpretive weight - the question remains how much.⁵²

Under the August 30 Agreement, the requirement of domestic production in TRIPS Article 31(f) is waived on the following conditions:

- The importing country must make an application to WTO
- The compulsory license granted in the exporting country shall also be notified to WTO and be limited to the amount necessary to meet the needs of the importing country
- Products shall furthermore be distinguishable through specific labelling and marking and information must be published on the internet⁵³

Accordingly, a combined reading of TRIPS Article 31 and the August 30 Agreement requires that a number of steps be carried out before a compulsory license can be granted. First, negotiations for a voluntary license on commercially reasonable terms must have failed. Only then can

⁵⁰ The August 30 Agreement, §1, definitions.

⁵¹ The General Council Chairperson's statement, 30 August 2003, www.WTO.org.

⁵² Nolff, M., Paragraph 6 of the Declaration on the TRIPS Agreement and public health and the Decision of the WTO regarding implementation: An "expeditious solution?", *Journal of the Patent and Trademark Office Society*, 2004:291, p 300, especially [FN22].

⁵³ In attachment to the statement made by the chair a "best practices guideline" for distinguishing products is initiated. The suggestive list also refers to the practice of prohibiting re-exportation. See the General Council's Chairperson's statement, 30 August 2003, available at www.WTO.org. The statement is regarded as an integral part of the Agreement and it specifies that the Agreement must not be an instrument to pursue industrial or commercial policy objectives and that several developed countries have opted out of benefiting from the Agreement as importers.

an application for a compulsory license be introduced to the WTO. In its application, the importing country must demonstrate an emergency situation and its own inability to produce the product locally. The potential exporter must also seek a voluntary license and needs an approval from its own national government. Royalties must be established and a distinguishable product produced and approved. These procedure must be repeated for each export transaction. Each step does not in itself present an insurmountable hurdle – but cumulatively they constitute a real obstacle.⁵⁴

The interests of the rights holder shall be secured in the process. In line with the general requirements for compulsory licensing provided in TRIPS Article 30, the rights-holder shall receive adequate compensation, but only from the country of exportation. In addition, it is expected that the importing country shall take reasonable measures to prevent trade diversion of the products and that other WTO Members shall take measures to prevent importation of such products. A special problem, which is not addressed by TRIPS or in the August 30 Agreement, is how developing countries can secure access to confidential data supplied by the rights holder to national regulatory authorities.⁵⁵

6. THE AFTERMATH OF AUGUST 30

To some extent the August 30 Agreement held advanced countries at gun point. Time was of essence in order to dispose of the controversy prior to the impending General Council meeting in Cancún. The United States had in the end to make concessions on a number of the requirements it had introduced during the negotiations.

⁵⁴ Valach, [FN25], p. 168.

⁵⁵ The protection of confidential data covers unfair commercial use of such data and prevents a third party from using test results undertaken by another company for an independent submission for marketing approval. Without this information, it is likely that production under compulsory licensing may encounter new problems. See the EU position paper, [FN36], at § 16: The EC and their Member States consider, though, that Article 39.3 neither obliges Members to have marketing approval procedures, nor does it prescribe what those procedures should be. The provision should certainly not be interpreted in such a way as to weaken or nullify Members' rights under other articles of the Agreement, such as the 'fast track' procedure in case of emergency foreseen under Article 31(b), which is a recognition of the need, in certain circumstances, for compulsory licences to be given immediate effect. EU suggested in an Issue Paper for a Round Table on access to medicines, 28 April 2003, that the regulatory burden should be alleviated for tiered priced products as time was of essence. See also Developing Country Group's Position Paper, [FN8], point 40.

Immediately after the August 30 Agreement was signed, non-governmental organizations expressed fears that it would not serve its purposes. Pressure from developed nations would make compulsory licensing unfeasible. The fact that activities could not be for commercial ends would deprive potential generic manufacturers in developing countries of the incentive to take action and above all, the agreement introduced a far too complicated process.⁵⁶ The NGO's favoured an authoritative interpretation of TRIPS Article 30, which could have been achieved by a simple vote at the General Council.⁵⁷

Individual states have thereafter declared that they intend to amend national patent laws in order to facilitate production by compulsory licensees for subsequent exportation.⁵⁸ Canada took steps in this direction in November 2003, when a proposed amendment to the Canadian Patent Law was introduced. Compulsory licensing would be granted to Canadian generic manufacturers to produce and export patented products to least developed countries lacking production capacity.⁵⁹ The initial proposal contained a march-in-right for the patent holder and was limited to products for certain epidemic diseases. In May 2004 these limitations were deleted from the final version.

The EU has undertaken a series of measures to facilitate export of pharmaceuticals⁶⁰ and is carefully observing to assure that products intended for export to developing countries at low prices may not be reintroduced on the European market.⁶¹

⁵⁶ Barbosa, [FN19], p. 215.

⁵⁷ Parrish, R., Does waiver of patent restrictions clear way for generics in poor countries? *Health Lawyer* 2004:12, p.14.

⁵⁸ UK intends to introduce such legislation. See Bentley, L., & Sherman, B., *Intellectual Property Law*, (2nd ed.) Oxford 2004, p. 561. Canada, Norway and Switzerland have announced similar intentions according to Minutes of the Meeting of 18 November 2003 with the Council for Trade-Related Aspects of Intellectual Property Rights, www.WTO.org.

⁵⁹ An Act to amend the Patent Act and the Food and Drug Act, Bill C-56, 51-52 available at www.parl.gc.ca.

⁶⁰ A proposal for a regulation to implement the August 30 Agreement has been adopted by the Commission on 29 October 2004, COM(2004) 737 aiming to allow WTO Members a simplified procedure to grant compulsory licences for the production and sale of patented pharmaceutical products intended for export to third countries with insufficient or no manufacturing capacity in the pharmaceutical sector.

⁶¹ Council Regulation (EC) No 953/2003 of 26 May 2003 to avoid trade diversion into the European Union of certain key medicines, OJ 2003 L135/5. On its face the EU legislation was in line with the European position on regional exhaustion of intellectual property rights and in conformity with the parallel development in the World Trade Organization. Even if the protection is granted to original manufacturers, the aim is to add

U.S. interests have focused on generous financial aid and on a variety of private initiatives.⁶² Through negotiations with affected regions and with pharmaceutical companies, a foundation initiated by former U.S. president Bill Clinton has been able to arrange supplies for the most infected areas. The Clinton Foundation is collaborating with the Global Fund, the World Bank, the UN Children Fund and private sector companies. The Foundation now claims that antiviral drugs will be provided at a price of 140 USD per patient per year, which is substantially less than the cheapest commercially available drug.⁶³ The developing countries will order under procurement regimes and are responsible for payment and distribution, but the Foundation guarantees payment in relation to the manufacturer.⁶⁴

A more controversial U.S. approach has been the entry of a number of bilateral and regional trade agreements that contain so-called "TRIPS plus" provisions which impose stricter IPR standards in order to reduce the negative impact of WTO developments.⁶⁵

The August 30 Agreement entered into immediate effect as a binding instrument, but it was foreseen that a revision of the TRIPS Agreement should take place within a six month period. The matter was not addressed during the unsuccessful Cancún discussions⁶⁶, which was probably just as well, but rather was left for the attention of the TRIPS Council.

Amending TRIPS in line with the August 30 Agreement has proved more complicated than anticipated. The TRIPS Council has encountered problems both with the substance and the technical form, and delays have been

another dimension to the efforts to provide essential medicines to combat AIDS/HIV and other epidemic diseases in the poorest countries. By preventing re-importation of low priced products from developing countries, the hope is that the medicine will stay in the country of destination and serve those in desperate need. If this goal is achieved, pharmaceutical manufacturers should be more willing to supply at low cost and the need for compulsory licensing should diminish.

⁶² Fayerman, J.J., The spirit of TRIPS and the importation of medicines made under compulsory license after the August 2003 TRIPS Council agreement, *Northwestern Journal of International Law and Business* 2004:257. The author favours voluntary programs and suggests that compulsory licensing is in conflict with the spirit of TRIPS.

⁶³ Baker, [FN12], p. 615. Baker discusses possible ramifications of Global Fund involvement pp. 688–699. The prime source of supply of drugs will be four Indian manufacturers and Aspen Pharmacare Holdings of South Africa, *Wall Street Journal*, 23 October 2003.

⁶⁴ UNAID, Fact sheet, Access to HIV Treatment and Cure, www.unaids.org.

⁶⁵ The United States has negotiated so-called "TRIPS plus" provisions in both bilateral and regional trade agreements. Recent examples include the bilateral agreements with Australia, Chile and Vietnam and the August 2, 2005 Central American Free Trade Agreement (available at www.ustr.gov).

⁶⁶ See the *Economist*, Cancún's charming outcome, September 20, 2003 p. 13.

announced. On June 16, 2004 the chairman reported that positions had not evolved and that work continued with the aim of having a proposal for the meeting in March 2005.⁶⁷

Considering that any amendment of TRIPS requires a complicated procedure, including ratification by all WTO Members, it could very well be that no revision is ever effected. Such a failure is of limited importance, as the August 30 Agreement remains valid and binding even in the absence of a future revision of TRIPS. Unfortunately, the legal situation is muddled. The August 30 Agreement should be interpreted in the context of the objectives and principles of the TRIPS Agreement and against the ambiguous chairperson statement. It contains a number of unclear and controversial notions,⁶⁸ which should probably be of prime concern for the United States. The overriding experience so far is that public pressure relying on overall humanitarian grounds out-weights the economic pressure mounted by American interests. It is against this background that the increased U.S. bilateral and regional activities must be evaluated.

7. CONCLUSIONS

There is a growing understanding in the international community that the HIV/AIDS pandemic affecting the least developed and the developing nations is an international concern that must be addressed through international collaboration. The UN has recognized that the crises may pose a risk to stability and security.⁶⁹ Responding to this international obligation means employing all available means under international law to achieve the highest available standard of health in the countries affected.

It is still premature to evaluate the consequences of the August 30 Agreement. By March 2004 no application for compulsory licensing had been received by WTO.⁷⁰

Is compulsory licensing an “expeditious solution” to the AIDS/HIV problems as required by the Doha Declaration? It could be argued that it is

⁶⁷ Baer, A.B., Price controls through the back door: the parallel importation of pharmaceuticals, *Journal of Intellectual Property Law* 2001:109, p. 134.

⁶⁸ Mercurio, B.C., TRIPS, patents, and access to life-savings drugs in the developing world, *Marquette Intellectual Property Law Review* 2004:211, p. 237.

⁶⁹ Resolution 1308, U.N. SCOR, 55th Sess. 4132 mtg, Doc S/Res 1308 (2008).

⁷⁰ See Minutes of the Meeting of November 18, 2003, which expressly states that no application had been received as of March 8, 2004 with the Council for Trade-Related Aspects of Intellectual Property Rights, www.WTO.org.

not the lack of local production that presents the true obstacle. Most essential medicines are not protected by patents in developing countries. Generic production is open to anyone interested and if the product is patented elsewhere in the world, that patent in reality serves as a recipe for manufacturing by a generic producer.⁷¹ Even if the right to access patented products is secured at low costs, bringing it to the patient is not an easy process. Poverty, corruption and lack of health-care infrastructure have been cited as equally important reasons that access cannot be secured.⁷²

Still, providing access to medicines is one important step in the chain of events required to provide an “expeditious solution”. Providing generous and uncomplicated rules on compulsory licensing may therefore be a first important step. Permitting generic producers in third countries to manufacture pharmaceuticals for use in countries facing health emergencies but which lack productive capacity is a useful and likely necessary step, though not a sufficient one, towards resolving the AIDS crisis

If generic producers from different parts of the world are making inroads in the developing world, the question is: What will be the counter-reaction of the innovative pharmaceutical industry? On the one hand, sales of patented pharmaceuticals in developing countries have almost no impact on sales or profits of the innovative industry. Fears that developed markets will be overrun by product destined for least developed markets are greatly exaggerated. Such markets could be licensed away at no charge without affecting their innovative capacity. If it is not replacing a commercial market it cannot be considered as doing any harm and the pharmaceutical industry is likely to remain inactive.

On the other hand, if the industry remains inactive, it risks losing out on future markets in developing countries and may also in due time see the effects spill over to the developed world.⁷³ Neglecting the market may mean that the product ends up being supplied by aggressive generic producers, who are using a compulsory license to start up activities that will eventually contribute to a launch in developed markets. This simple logic will force the

⁷¹ Attaran, A., and Gillespie-White, L., Do patents for antiretroviral drugs constrain access to AIDS treatment in Africa? *The Journal of the American Medical Association* 2001:1886-1892 where the authors determine that HIV/AIDS medicines are rarely patented in developing countries and they conclude that patents are not a major barrier to access to medicines.

⁷² Barbosa, [FN19], p. 248.

⁷³ Compare Bagchi, [FN9], p. 1546 where he predicts that drug companies will act rationally.

pharmaceutical industry to take action and to positively contribute to finding solutions.

Therefore, compulsory licensing continues to be a meaningful threat in inducing the innovative industry to drastically lower prices. A condition is that effective trade diversion rules are put in place by the developed world. The threat of compulsory licensing is not only a tool to lower prices, but also a long-term vehicle to introduce generic production and competition. These factors will make the pharmaceutical industry more interested in participating in building a technological base in developing countries.