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Access To Medicines, Paragraph 6 Of The Doha Declaration On Public Health, And Developing Countries In International Treaty Negotiations

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**ACCESS TO MEDICINES, PARAGRAPH 6 OF
THE DOHA DECLARATION ON PUBLIC
HEALTH, AND DEVELOPING COUNTRIES IN
INTERNATIONAL TREATY NEGOTIATIONS**

*Daya Shanker**

ABSTRACT

Paragraph 6 of the Doha Declaration on Public Health, dealing with access to medicines for countries lacking the manufacturing capacity for them, became an important issue because its solution on 30th August 2003 on the basis of the Note of the Chairman of the TRIPS Council was perceived as changing the basic features of the TRIPS Agreement. This was the subject of much debate, and a number of proposals from different countries were submitted either individually or collectively. However, the proposals from developing countries did not find their way into Paragraph 6, and the problem of developing countries not being able to make their voices heard in international negotiations is the focus of this article. By discussing the circumstances of the Paragraph Solution and the ways in which the interests of the developed countries were prioritised over the interests of developing countries, this article attempts to find ways in which the negotiating process may be made more transparent in future so as to accommodate all interests more fairly.

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I. INTRODUCTION

Access to medicines for underdeveloped countries has always been a crucial issue, and it became especially controversial after the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS)¹ was finalised in 1995. The controversy has acquired particular significance in the wake of the HIV/AIDS pandemic, particularly given its prevalence in many parts of the world which are not in a position to manufacture the required drugs to treat the disease.² The issue of access to medicines for such nations came to the fore during the Doha Ministerial Meet, where the developing countries present moved a resolution for an authoritative interpretation of Article 30 of the TRIPS Agreement for the purpose of clarification so as to avoid unnecessary litigation in situations where countries permit manufacture and export of drugs to countries which lack the requisite capacity, especially to those countries which were in the grip of the HIV/AIDS pandemic. However, this simple and TRIPS-compatible approach was not accepted, and a strict regulatory regime was imposed through various means, the failure of which becomes evident when one finds that no medicines at all have been exported since August 30, 2003 under this solution.³ In fact, countries such as Canada have even tried to undermine it through first permitting the patent-holder to take over export after the completion of the negotiation between the country in need and the third-party supplier, and then limiting the scope of diseases, another bone of contention.⁴

An issue of crucial importance to the lack of access to medicines for developing countries is thus their marginalisation in international treaty negotiations, which is evident from the introduction of industrial and other monopolies as a part of the

¹ Agreement on Trade-Related Aspects of Intellectual Property Rights, Apr. 15, 1994, Marrakesh Agreement Establishing the World Trade Organisation, Annex 1C, Legal Instruments—Results of the Uruguay Round vol. 31 (1994), 33 I.L.M. 81 (1994) [hereinafter TRIPS Agreement].

² WTO Secretariat, *Available Information on Manufacturing Capacity for Medicines*, IP/C/W/345 (May 24, 2002), <http://www.wto.org/tw/SmartKMS/fileviewer?id=33236>.

³ According to certain WHO officials, no country has yet issued a demand for compulsory licences as authorised by the paragraph 6 solution of August 30, 2003. It has also been reported that the complexity of the Solution, along with the pressure on the needy countries not to take advantage of it, are the factors responsible for its non-use. UNI, Poor Nations Fail to Import HIV Generics, *available at* <http://www.union-network.org/uniafrican.nsf/574a89c88160dd42c125682c0046d1c8/55c62506e7488140c1256e510040819f?OpenDocument>.

⁴ See Bill C-56, An Act to Amend the Patent Act and the Food and Drugs Act, S.C. 2004, c. 23, *available at* <http://www.aidslaw.ca/Maincontent/issues/cts/patent-amend/BillC-9passed40504.pdf>.

WTO through TRIPS,⁵ restrictive interpretations of the flexibility of this Agreement⁶ and its rewriting on August 30, 2003⁷ in the form of the solution of Paragraph 6 of the Doha Declaration on Public Health,⁸ which added exports as one of the patenting rights in the TRIPS Agreement. The solution has drastically curtailed the possibilities of access to drugs being given to countries which lack the manufacturing capacity for them.⁹ This inability of developing countries to participate effectively in international treaty negotiations is reflected in a number of proposals from developing countries requesting developed countries, primarily the USA, not to resort to threats and

⁵ See generally Frederick M. Abbott, *Protecting First World Assets in the Third World: Intellectual Property Negotiations in the GATT Multilateral Framework*, 22 VAND. J. TRANSNAT'L L. 689 (1989) (discussing two relevant documents: General Agreement on Tariffs and Trade: Decisions on Negotiating Structure and Plans for the Uruguay Round, 26 I.L.M. 850 (1987), and General Agreement on Tariffs and Trade: Decisions Adopted at the Mid-Term Review of the Uruguay Round, 28 I.L.M. 1025 (1989)).

⁶ WTO Dispute Panel Report on Canada – Patent Protection of Pharmaceutical Products, WT/DS114/R (Mar. 17, 2000), available at http://www.wto.org/english/tratop_e/dispu_e/7428d.pdf [hereinafter Canada Patent Protection].

⁷ WTO, Decision of 30 August 2003, Implementation of Paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health, WT/L/540 (30.8.2003), available at http://www.wto.org/english/tratop_e/implem_para6_e.htm. [hereinafter Decision of August 30, 2003]. See also The General Council Chairperson's Statement, Aug. 8, 2003, available at http://www.wto.org/english/news_e/TRIPS_stat_28aug03_e.htm [hereinafter the Chairperson's Statement].

⁸ Declaration on the TRIPS Agreement and Public Health, WT/MIN(01)/Dec/2 [hereinafter Doha Declaration], available at http://www.wto.org/english/thewto_e/minist_e/mindecl_TRIPS_e.pdf (Nov. 14, 2001).

⁹ The inability of WTO Members to use the Decision of August 30, 2003 to access requisite medicines becomes evident in the new proposal from the African Group submitted to the TRIPS Council. The African Group has argued that the Chairman's Statement does not provide any legal value and should be removed completely from the Decision of August 30, 2003. They also argued that the conditions imposed through the Decision of August 30, 2003 are neither practical nor required and that article 31 conditions are sufficient to cover any question of quantity of medicines to be produced and its diversion to wrong countries. However, the amendment protocol arrived at on December 6, 2005 does not appear to take into account any of the concerns raised by the African countries. WTO, The TRIPS Agreement and Public Health, Communication from Rwanda on Behalf of the African Group (IP/C/W/2005 dated Apr. 6, 2005) and Legal Arguments to Support the African Group Proposal on the Implementation of Paragraph 11 of the 30th August Decision, Communication from Rwanda on behalf of the African Group (IP/C/W/440 dated Mar. 1, 2005); Proposal for a Decision on an Amendment to the TRIPS Agreement, Implementation of paragraph 11 of the General Council Decision of 30th August 2003 on the Implementation of Paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health: Proposal for a Decision on an Amendment to the TRIPS Agreement, IP/C/41 dated Dec. 6, 2005).

sanctions in international transactions.¹⁰ The problem has been discussed by a number of scholars with widely differing viewpoints, sometimes influenced by their own nationalities.¹¹ While Gathii tries to explain it as the use of structural power by developed countries,¹² Drahos is more inclined to attribute the limitation of developing countries to participate effectively in international negotiations to their inability to form a coherent group.¹³

This article concentrates on the Paragraph 6 Solution of the Doha Declaration on Public Health and the position of developing countries in international negotiations in the context of the effects of the HIV pandemic. In the course of this article, I will touch upon a number of factors relevant to this issue, such as the concept of enablement, the relevance of Articles 30 and 31 of the TRIPS Agreement in relation to export of the patented products, the legality of the Paragraph 6 Solution, and the issue of repression, exclusion and disorganisation of the developing countries at international negotiations. I will also attempt to analyse the actual process of domination, and thus arrive at possible ways to improve international negotiations involving developing countries.

II. THE HIV PANDEMIC AND ITS SOCIO-ECONOMIC CONSEQUENCES

The extent of the problem caused by diseases like AIDS can be gauged from some of the reports providing the relevant data. The UNAIDS Report says that there have been 20 million deaths from AIDS in the twenty years since the first diagnosis of AIDS in 1981, with young people in the age group of 15-24 accounting for nearly half

¹⁰ TRIPS: Proposal-Draft Ministerial Declaration: Proposal from a Group of Developing Countries, IP/C/W/312 dated Oct. 4, 2001, addressed to General Council and Council for Trade-Related Aspects of Intellectual Property Rights: Proposals 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, [hereinafter Developing Countries' Proposal, Oct. 4, 2001] available at http://www.wto.org/english/tratop_e/TRIPS_e/mindecdraft_w312_e.htm, 10.

¹¹ See generally James T. Gathii, *The Structured Power of Strong Pharmaceutical Patent Protection in US Foreign Policy*, 7 J. GENDER, RACE & JUST. 267 (2003); Peter Drahos, *When the Weak Bargain with the Strong: Negotiations in the WTO*, 8 INT'L NEGOTIATION 79 (2003); A. Samuel Oddi, *TRIPS – Natural Rights and a “Polite Form of Economic Imperialism,”* 29 VAND. J. TRANSNAT'L L. 415 (1996).

¹² See Gathii, *supra* note 11.

¹³ See Drahos, *supra* note 11.

of all new infections worldwide, and almost 38 million people are living with AIDS.¹⁴ Sub-Saharan Africa accounts for 25 million of these 38 million – approximately 68% of world's AIDS sufferers – whereas it is home to only 10% of the world's population, although there is a diversity across the African continent in the levels and trends of HIV infection.¹⁵ Among Asian countries, China, Indonesia and Vietnam account for another 7.4 million HIV sufferers, followed by India with nearly 5 million infected people.¹⁶ The AIDS/HIV pandemic has reversed the gradual growth in life expectancy in sub-Saharan Africa.¹⁷ According to the WHO, nearly 6 million people are expected to die because of this disease in the near future if they do not receive treatment—a staggering number by any account.¹⁸ According to the WHO's estimates, only 400,000 people were able to receive treatment by the end of 2003.¹⁹ Out of this 400,000, access to medicines for HIV in the African region is the lowest with only an estimated 100,000 people receiving treatment, a coverage of just 2%.²⁰

The World Health Report paints a bleak picture of the economic and social consequences of the HIV/AIDS pandemic.²¹ The economic effect of such devastation is already visible; even the economy of Nigeria, a relatively prosperous country with petroleum wealth, is shrinking rather than expanding,²² and Prof. Clive Bell and others, on the basis of significant importance given to human capital and transmission

¹⁴ UNAIDS, REPORT ON THE GLOBAL AIDS EPIDEMIC 3, *available at* http://www.unaids.org/bangkok2004/GAR2004_html?GAR2004_oo_en.htm. With the margin of error provided, the figure could be anything between 34.6 million and 42.3 million.

¹⁵ *See id.*

¹⁶ *See id.*

¹⁷ WORLD HEALTH ORGANISATION, WORLD HEALTH REPORT, 2004 at 2 (2004), *available at* <http://www.who.int/whr/2004> [hereinafter WORLD HEALTH REPORT, 2004]. *See also* UNITED NATIONS, WORLD POPULATION PROSPECTS: THE 2002 REVISION (2003) (noting that the life expectancy in sub-Saharan region reached a high of 49.2 years during the late 1980s and projecting it to drop to just under 46 years in the period 2004-2005).

¹⁸ *See* WORLD HEALTH ORGANISATION, UNPRECEDENTED OPPORTUNITY TO FIGHT HIV/AIDS AND CHANGE THE COURSE OF HISTORY (2004), *available at* <http://www.who.int/mediacentre/releases/2004/pr33/en/print.html>.

¹⁹ *See id.*

²⁰ *See* WORLD HEALTH REPORT, 2004.

²¹ *See id.* at 8. *See also* Simon Dixon et al., *The Impact of HIV and AIDS on Africa's Economic Development*, 324 BRIT. MED. J. 232 (2002); Economic Commission for Africa, *Africa: The Socio-Economic Impact of HIV/AIDS*, *available at* http://www.ace.msu.edu/agecon/fs2/adult_death/SOCIO_ECO_IMPACT.pdf; Botswana Institute for Development Policy Analysis, *Impacts of HIV/AIDS on Poverty and Income Inequality in Botswana*, *available at* <http://www.iaen.org/coonferences/durbansym/papers/31Green.pdf>.

²² *See* Constance Ndubuisi-Enyali, Nigerian Economy to Shrink by 20% due to HIV/AIDS, at the 4th National Conference on HIV AIDS in Africa (May 7, 2004) *available at* <http://www.Nigeria-aids.org/msgRead.cfm?ID=2901>.

mechanism across generations, have argued that the long-run economic costs of AIDS are going to be devastating for South Africa.²³ By affecting young people, AIDS reduces family and national resources and exacerbates economic inequality. Economic welfare is therefore necessarily dependent on the health of the population.²⁴ In the context of the Asia-Pacific region, the impact of HIV/AIDS on households and businesses is expected to be disastrous, not only because the death and incapacitation of workers

²³ See generally CLIVE BELL ET AL., THE LONG-RUN ECONOMIC COSTS OF AIDS: THEORY AND AN APPLICATION TO SOUTH AFRICA 5 (2003), available at http://econ.worldbank.org/files/30343_wps3152.pdf; C. Arndt & J. D. Lewis, *The Macro Implications of HIV/AIDS in South Africa: A Preliminary Assessment*, 68 SOUTH AFRICA J. ECO. 856, 887 (2000); R. Dorrington et al., *The Current State and Future Projections of the HIV/AIDS Epidemic in South Africa*, 57 SOUTH AFRICAN DENTAL J. 408, 409 (2002); and R. Dorrington et al., *Some Impacts of HIV/AIDS on Adult Mortality in South Africa*, 15 (Supp 2) SOUTH AFRICAN J. CLINICAL NUTRITION S3 (2002); South African Institute of Race Relations, *The Economic Impact of HIV/AIDS*, available at <http://www.sairr.org.za>; John S. Nabila et al., *A Preliminary Review of the Economic Impact of AIDS on Firms and Business in Ghana* available at <http://www.policyproject.com/pubs/country-reports/GHeconimp.pdf> (Oct. 1, 2000); UNAIDS, THE SOCIAL AND ECONOMIC IMPACTS OF HIV/AIDS IN POOR COUNTRIES: A REVIEW OF STUDIES AND LESSONS (T. Barnett et al., eds., 2000); M. BECHARA & O. WEEKS, *AIDS: AN ECONOMIC CATASTROPHE?* (2000); L. BOLLINGER & J. STOVER, THE ECONOMIC IMPACT OF AIDS, (1999) (Bollinger and Stover have done systematic analysis of the economic impact on a number of African countries) available at <http://www.policyproject.com/pubs/SEImpact/angola.pdf>; M. Butler et al., *The Socioeconomic Impact of HIV/AIDS in the Dominican Republic, 1991-2005*, at the 13th International AIDS Conference, Durban (2000); ING Barings, *Economic Impacts of AIDS in South Africa: A Dark Cloud on the Horizon*, (ING Barings, Johannesburg), 2000; P. Wehrwein, *The Economic Impact of AIDS in Africa*, HARV. AIDS REV., Fall Winter 1999, at 4 available at http://www.aids.harvard.edu/news_publications/har/fall_win_1999-4.html; Edoardo Gaffeo, *The Economics of HIV/AIDS: A Survey*, 21 DEV. POL. REV. 27 (2003) (The extent of the negative effect of AIDS varies between the studies as the forecastings depend significantly on the assumptions but even the most optimistic assumptions such as those in the ING Barings' study confirm a significant negative impact of HIV pandemic on the countries concerned particularly those in Africa).

²⁴ See D. Bloom & D. Canning, *Health and the Wealth of Nations*, 287 SCIENCE 1207 (2000). Also see D. Bloom & D. Canning, *The Effect of Health on Economic Growth: Theory and Evidence*, NBER Working Paper No. 8357 available at <http://www.nber.org/papers/w8357.pdf>; D. Bloom & D. Canning, *Health as Human Capital and its Impact on Economic performance*, 28 GENEVA PAPERS 304, 315 (2003); WHO, REPORT OF THE COMMISSION ON MACROECONOMICS AND HEALTH (2002) available at http://www.who.int/gb/ebwha/pdf_files/WHA55/ea555.pdf. (the WHO Report on Macroeconomics and Health headed by Jeffrey Sachs estimated that in Sub-Saharan Africa, the loss due to HIV/AIDS is more than 12% of GNP annually and that in malaria-free regions, the growth is more by 1% compared to malaria-ridden regions); WHO CMH, *Macroeconomics and Health: Investing in Health for Economic Development*, available at <http://www.cid.harvard.edu/cidcmh/CMHReport.PDF>.

III. TRIPS AND THE PARAGRAPH 6 SOLUTION

A. History of the TRIPS Agreement

The Paris Convention²⁸ and the Berne Convention²⁹ dealing with the patenting monopoly and copyright protection were controlled by the Bureaux Internationaux Réunis pour la Protection de la Propriété Intellectuelle (BIRPI).³⁰ The original treaties provided for little more than national treatment among signatory countries, and a major part of the present developing world was not involved at all. The USA accepted the Berne Convention only in 1989, more than 100 years after it entered into force.³¹ From 1971 to 1986, the USA mostly entered into bilateral agreements with developing countries introducing higher levels of industrial property monopoly.³² Some of the provisions of the General Agreement on Tariffs and Trade (GATT)³³ also had intellectual property implications, namely Article IX(6) and Article XX(d). While Article IX(6) dealt with the issues of trademarks and geographical indications, Article XX(d) permitted contracting parties to “adopt or enforce measures necessary to secure compliance with laws or regulations which are not inconsistent with the provisions

²⁸ Paris Convention for the Protection of Industrial Property, Mar. 20, 1883, as revised at Stockholm on July 14, 1967, 21 UST. 1630, 828 U.N.T.S. 305 [hereinafter Paris Convention].

²⁹ Berne Convention for the Protection of Literary and Artistic Works, Sept. 9, 1886, as revised at Paris on July 24, 1971, 25 UST. 1341, 828 U.N.T.S. 221 [hereinafter Berne Convention].

³⁰ World Intellectual Property Organisation, *The First Twenty five Years of the World Intellectual Property Organisation*, from 1967 to 1992 at 31-40 (1992).

³¹ See Orrin G. Hatch, *Better Late than Never: Implementation of the 1886 Berne Convention*, 22 CORNELL INT'L L. J. 171, 180-81 (1989).

³² Bilateral agreements the USA entered into with Nicaragua and Sri Lanka are some of the examples. Agreement on the Protection and Enforcement of Intellectual Property Rights, Sept 20, 1991, US- Sri Lanka *available at* <http://www.cptech.org/ip/health/c/agreements/srilanka-1991-ip.html>.

Agreement Concerning Protection of Intellectual Property Rights, 1998, US–Nicar. *available at* <http://www.cptech.org/ip/health/c/agreements/nicargua-1998-ip.html>. Abbott, *supra* note 5, at 711 n 71 (Abbott has described a number of bilateral strategies the USA resorted to, to achieve enhanced intellectual property protection).

³³ General Agreement on Tariffs and Trade, Oct. 30, 1947, 24 UST. 146, 55 U.N.T.S. 194 [hereinafter GATT]. This agreement was supposed to be the part of the Havana Treaty establishing the International Trade Organisation (the ITO) but US Congress did not permit the USA to accede to this treaty. It was replaced in 1995 by the GATT 1994.

of this Agreement, including those relating to the protection of patents, trademarks, copyrights and prevention of deceptive practices.”³⁴

At the Uruguay Round Negotiations, TRIPS was introduced without much clarity as to its *raison d'être*, as the Ministerial Declaration at Punta del Este only stated the need to “...clarify provisions and elaborate as appropriate new rules and disciplines” with an aim to “...develop a multilateral frame work of principles, rules and disciplines dealing with international trade in counterfeit goods, taking into account work already undertaken in GATT.”³⁵ However, in 1990, the EC,³⁶ the USA,³⁷ Japan,³⁸ and Switzerland³⁹ tabled exceptionally far-reaching proposals on similar lines to the GATT Negotiating Group dealing with intellectual property. These proposals contained detailed rules on the application of intellectual property, including its interpretations before national courts, and the draft legal texts also contained proposals for the application of the dispute-settlement system which was to be

³⁴ Article XX(d) of GATT 1947 as incorporated in GATT 1994 reads as follows:

“Subject to the requirement that such measures are not applied in a manner which would constitute a means of arbitrary or unjustifiable discrimination between countries where the same conditions prevail, or a disguised restriction on international trade, nothing in this Agreement shall be construed to prevent the adoption of enforcement by any contracting party of measures:

(d) necessary to secure compliance with laws or regulations which are not inconsistent with provisions of this Agreement, including those relating to customs enforcement, the enforcement of monopolies operated under paragraph 4 of Article II and Article XVII, the protection of patents, trademarks and copyrights, and the prevention of deceptive practices.”

³⁵ General Agreement on Tariffs and Trade (GATT) Punta Del Este Declaration, (Sept. 20, 1986) *available at* http://www.sice.oad.org/trae/Punta_e.asp. *See also* Ministerial Declaration of the Thirty-Eight Session at Ministerial Level, Nov. 29, 1982, GATT B.I.S.D. (29th Supp.) 19 (1983) (this had discussed the issue of counterfeit goods); DANIEL GERVAIS, *THE TRIPS AGREEMENT: DRAFTING HISTORY AND ANALYSIS*, 11 (1998).

³⁶ GATT. Draft Agreement on the TRIPS, Communication from the EC., GATT Doc. No. MTN.GNG/NG11/W/68, Mar. 29, 1990, *available at* http://www.wto.org/english/tratop_e/TRIPS_e/ur_rft.exe.

³⁷ GATT. Draft Agreement on the TRIPS, Communication from the United States, GATT Doc. No. MTN.GNG/NG11/W/70, May 11, 1990 *available at* http://www.wto.org/english/tratop_e/TRIPS_e/ur_rft.exe.

³⁸ GATT. Draft Agreement on the TRIPS, *Communication from Japan*, GATT Doc. No. MTN.GNG/NG11/W/74 dated May 15, 1990, *available at* http://www.wto.org/english/tratop_e/TRIPS_e/ur_rft.exe.

³⁹ GATT. Draft Agreement on the TRIPS, *Communication from Switzerland*, GATT Doc. No. MTN.GNG/NG11/W/73 dated May 14, 1990, *available at* http://www.wto.org/english/tratop_e/TRIPS_e/ur_rft.exe.

established at the end of the Uruguay Round. Developing countries also managed to submit their draft legal texts,⁴⁰ which were bundled together with the other draft legal texts by Lars Anell, then Chairman of the TRIPS negotiating group.⁴¹ However, practically all the proposals from developing countries were removed by Arthur Dunkel, the then Director-General of the GATT and the Chairman of the Trade Negotiating Committee, in collusion with Lars Anell.⁴² Braithwaite and Drahos have discussed the role of mechanisms, principles and actors in the developments leading to the TRIPS Agreement and observed that it was mainly coercion by the USA and a very close cooperation between the USA, the EC and major Western firms which led to the successful introduction of the TRIPS Agreement in the Uruguay Round.⁴³ The TRIPS Agreement did not stabilise even after the establishment of the WTO,

⁴⁰ GATT. Communication from Argentina, Brazil, Chile, China, Colombia, Cuba, Egypt, India, Nigeria, Peru, Tanzania and Uruguay, GATT Doc. No. MTN.GNG/NG11/W/71 May 14 1990 available at http://www.wto.org/english/tratop_e/TRIPS_e/ur_rft.exe.

⁴¹ GATT, *Chairman's Report to the GNG: Negotiating Group on Trade-Related Aspects of Intellectual Property Rights, including Trade in Counterfeit Goods*, Doc. No. MTN.GNG/NG11/W/76 July 23 1990.

⁴² The Draft Final Act Embodying the Results of the Uruguay Round of Multilateral Trade Negotiations, GATT doc. No. MTN.TNC/W/35/Rev.1 Dec. 3, 1990. This still contained developing countries' points. See Daya Shanker, *The Vienna Convention on the Law of Treaties, the Dispute Settlement System of the WTO and the Doha Declaration in the TRIPS Agreement*, 36 J. WORLD TRADE 721, 758. See also Paul Champs & Ameer Attaran, *Patent Rights and Local Working Under the WTO TRIPS Agreement: An Analysis of the US-Brazil Patent Dispute*, 27 YALE J. INT'L L. 365, 378-379. See JOHN BRAITHWAITE & PETER DRAHOS, GLOBAL BUSINESS REGULATION (2000) ("The considerable power of the Director General is symbiotically linked to the power of the US and EC. One senior US Trade Official pointed out, for example, in the later stages of the Uruguay Round the Director General (Sutherland) 'conspiring with us' made it almost impossible to change texts.").

⁴³ See JOHN BRAITHWAITE & PETER DRAHOS, GLOBAL BUSINESS REGULATION, 73 (2000); See DUNCAN N. MATTHEWS, GLOBALISING INTELLECTUAL PROPERTY RIGHTS: THE TRIPS AGREEMENT (2002); S.K. SELL, POWER AND IDEAS: THE NORTH-SOUTH POLITICS OF INTELLECTUAL PROPERTY AND ANTITRUST 138 (1998); M. P. RYAN, KNOWLEDGE DIPLOMACY: GLOBAL COMPETITION AND THE POLITICS OF INTELLECTUAL PROPERTY, 100 (1998); R. Weissmann, *A Long Strange TRIPS: The Pharmaceutical Industry Drive to Harmonise Global Intellectual Property Rules, and the Remaining WTO Legal Alternatives Available to Third World Countries*, 17 U. PA. J. INT'L ECO. L. 1069, 1084 (1996).

with constantly-changing interpretations of its provisions by the USA⁴⁴ or the EC, and conveniently-generated disputes such as *Canada Patent Protection*.⁴⁵

B. The Paragraph 6 Solution of August 30, 2003

The Paragraph 6 Solution of August 30, 2003 has its genesis in a proposal submitted by developing countries requesting an authoritative interpretation of Article 30 of the TRIPS Agreement to permit manufacture and export of patented medicines by third parties to countries lacking the capacity to manufacture such products.⁴⁶ No decision was taken on this proposal, as it was postponed under paragraph 6 of the Doha Declaration on Public Health. Subsequently, the developing countries' proposal of a solution to this problem based on Article 30 of TRIPS was totally removed by the TRIPS Council Chairman, Eduardo Perez Motta, and an Article 31-centric solution based on a combination of the US and EC proposals was adopted on August 30, 2003 by the General Council, which was not rightfully authorised to take such a decision.

⁴⁴ See Daya Shanker, *Brazil, the Pharmaceutical Industry and the WTO*, 5 J. WORLD INTELL. PROP. 51 (2002). Daya Shanker has discussed the complaint filed by the United States against Brazil against the presence of the local working requirements in the Brazilian Patent Act. Argentina also appears to have been coerced into changing its compulsory licensing provisions amending the use of competition policy to deal with the abuses of the TRIPS Agreement. See also Daya Shanker, *Argentina-US Mutually Agreed Solution, Economic Crisis in Argentina and Failure of the WTO Dispute Settlement System* 44 IDEA 565 (2004).

⁴⁵ *Canada Patent Protection*, *supra* note 6, is a unique dispute where both parties tried to remove local working from the patent acts of Members of the WTO by insisting that Article 27.1 of the TRIPS Agreement would be applicable to Articles 31 and 30 exceptions. The irony of the dispute becomes clear when one recognises that the German Supreme Court on the basis of the Community Patent Convention had decided that the experimental use exemption would be applicable to the generation of data to be submitted to the regulatory authorities in *Klinische I* and *Klinische II*. This aspect has been discussed in Daya Shanker, *Experimental Use Exceptions and Australian Patent Act: Submission to Advisory Council on Intellectual Property*, available at <http://www.acip.gov.au/expusesubs.htm>. See also BRAITHWAITE & DRAHOS, *supra* note 42, at 87, and Duncan Matthews, *Trade Related Aspects of Intellectual Property Rights: Will the Uruguay Round Consensus Hold?* CSGR Working Paper NO. 99/02, 20 (2002) available at http://papers.ssrn.com/sol3/papers.cfm?abstract_id=319545/.

⁴⁶ TRIPS, Council Discussion on Access to Medicines – Developing Country Group's Paper, IP/C/W/296, June 20, 2001, (submitted by a group of developing countries to the TRIPS Council, for the special discussion on intellectual property and Access to Medicines, TRIPS and Public Health: Submission by the Africa group, Barbados, Bolivia, Brazil, Dominican Republic, Ecuador, Honduras, India, Indonesia, Jamaica, Pakistan, Paraguay, Philippines, Peru, Sri Lanka, Thailand and Venezuela.).

The result is that it has now become virtually impossible for needy countries to access the requisite medicines.⁴⁷

In the Paragraph 6 Solution, the General Council has waived the obligations set out in paragraphs (f) and (h) of Article 31 of the TRIPS Agreement with respect to pharmaceutical products, prescribing specific conditions for exporting and importing countries. The exporting country can export such drugs only when it has made a notification to the Council for TRIPS:

- a. specifying the names and expected quantities of the product(s) needed;
- b. confirming that the importing Member does not have the manufacturing capacity or has insufficient manufacturing capacities in the pharmaceutical sector for the product(s), and;
- c. confirming that a compulsory licence has been issued in its territory under Article 31 of the TRIPS Agreement.

The compulsory licence by the exporting Member, apart from the conditions mentioned in Article 31, must contain additional conditions that only the amount necessary to meet the needs of the eligible importing Member(s) may be manufactured under the licence, and the entirety of this production must be exported to the Member(s) which has notified its needs to the Council for TRIPS. The products

⁴⁷ Marrakesh Agreement Establishing the World Trade Organisation (Apr. 15, 1994), Annex 1C1867 U.N.T.S. 154, 33 I.L.M. 1144 (1994) *available at* http://www.wto.org/english/docs_e/legal_e/04-wto_e.htm [hereinafter WTO Agreement]. Art. IV(2) states “There shall be a General Council composed of representatives of all the Members, which shall meet as appropriate. In the intervals between meetings of the Ministerial Conference, its functions shall be conducted by the General Council. The General Council shall also carry out the functions assigned to it by this Agreement...”.

Art. IV(1) of the Marrakesh Agreement deals with the authority of the Ministerial Conference. It says “... [T]he Ministerial Conference shall carry out the functions of the WTO and take actions necessary to this effect. The Ministerial Conference shall have the authority to take decisions on all matters under any of the Multilateral Trade Agreements, if so requested by a Member, in accordance with the specific requirements for decision making in this Agreement and in the relevant Multilateral Trade Agreement.”

Art. IX(3) of the Marrakesh Agreement states “In exceptional circumstances, the Ministerial Conference may decide to waive an obligation imposed on a Member of this Agreement or any of the Multilateral Trade Agreements, provided that any such decision shall be taken by three fourths of the members unless otherwise provided for in this paragraph.”

Art. IX(4) of the Marrakesh Agreement discusses the procedures the Ministerial Conference has to follow while granting a waiver and that such waiver is to be reviewed by the Ministerial Conference within one year to verify the existence of such exceptional circumstances.

produced under the licence must be clearly identified as being produced under the system set out in this Decision through specific labelling or marking. Suppliers should distinguish such products through special packaging and/or special colourings or shaping of the products themselves, provided that such distinction is feasible and does not have a significant impact on price. It must be clarified here that the supplier is not the patent holder, as there would not be any need to issue a compulsory licence for export purposes in such cases. A similar provision, i.e., that the patented products should be clearly identified, has been added in the EC for export of medicines by the patent holders to poor developing countries to prevent any diversion of such products.⁴⁸

All of the above would have to be done specifically under the guidance of the TRIPS Council, which would have to be informed of “the name and address of the licensee, the product(s) for which the license has been granted, the quantity(ies) for which it has been granted, the country(ies) the product(s) is (are) to be supplied to and the duration of the licence.” Paragraph 3 of the Paragraph 6 Solution, which deals with remuneration, says that the supplier from the exporting countries (generic manufacturers) must pay remuneration to the patent holder whereas the receiver is waived from such payment. As we will see later on, none of the above provisions formed a part of any developing country’s proposal, nor are they TRIPS-compatible. There is no requirement of payment of remuneration in the importing member countries if the goods are not manufactured in those countries by the patent-holder, in violation of ‘local working’ requirements. Such compulsory licensing would be covered by Article 5A(2) of the Paris Convention, which does not provide for any remuneration for abuse of the patent. Similarly, if the manufacture and export of the patented product does not affect the commercial interest of the patent-holder in the territory of the patent (i.e. the geographic area of the country), the question of any payment of remuneration to the patent holder does not arise.⁴⁹

The marginalisation of developing countries was consolidated by the General Council Chairperson’s Statement accompanying the Decision of August 30, 2003 sharing the “...understandings of Members regarding the Decision to be taken and the way in which it would be interpreted and implemented” and “to provide comfort

⁴⁸ EC, *Trade and Development: Access to Medicines*, available at http://europa.eu.int/comm/trade/csc/med08qa_en.htm (“q.4. Is there any link between this regulation and the Trade related Aspects of Intellectual Property Rights (TRIPS) discussions on enabling developing countries to use of compulsory licences to manufacture the drugs they need? In principle, no. The discussion on compulsory licensing at the WTO TRIPS Council is a separate exercise. However, in practice it’s clear that if poorer countries get the medicines they need under tiered pricing arrangement, they won’t need to use compulsory licences.”).

⁴⁹ See Daya Shanker, *The Paragraph 6 Solution of the Doha Public Health Declaration and Export Under the TRIPS Agreement*, 7 J. WORLD INTELL. PROP. 365 (2004).

to those who feared that the decision might be abused and undermine patent protection.”⁵⁰ The Chairman’s statement attached the “Best Practices” guidelines apparently prepared by the pharmaceutical multinationals for members to follow. It also provided the names of the members who opted out of using the system as importers.⁵¹ The vacuity of the above solution becomes clear when one realises that not one country has been able to avail of the intended benefit under the Decision of August 30, 2003. In fact, Canada, while trying to amend its patent legislation to permit manufacture and export of patented products, insisted on giving the option to the patent-holder to take over the export of the products after the completion of negotiations between generic manufacturers and the importing countries.⁵²

C. The Paragraph 6 Solution of the Doha Declaration

The Doha Declaration on the TRIPS Agreement and Public Health⁵³ was essentially an outcome of developing countries’ proposals to affirm the concept of the basic international customary law in international treaty interpretations to ensure availability of medicines to their citizens because of the distortion introduced by the WTO Panel Report in Canada Patent Protection saying that the objectives and purpose are not to be taken into account while interpreting provisions of TRIPS.⁵⁴ However,

⁵⁰ The Chairperson’s Statement, *supra* note 7. See African Group’s recent proposals, *supra* note 9, where they have questioned the legality of the Chairman’s Statement and why it was linked at all in the August 30, 2003 Decision. It is still a controversy whether the Chairman’s Statement would form part of December 6, 2005 Amendment.

⁵¹ These countries are Australia, Austria, Belgium, Canada, Denmark, Finland, France, Germany, Greece, Iceland, Ireland, Italy, Japan, Luxembourg, Netherlands, New Zealand, Norway, Portugal, Spain, Sweden, Switzerland, the United Kingdom and the United States of America.

⁵² However, in an editorial in Canadian Medical Association Journal, the editor discussed the limitation of the Canadian legislation. See Editorial, *Patently necessary: improving global access to essential medicines*, 169 CANADIAN MEDICAL ASSOCIATION JOURNAL 1257, (December 9, 2003) available at <http://www.cmaj.ca/cgi/content/full/169/12/1257?etoc>.

⁵³ Doha Declaration, *supra* note 8.

⁵⁴ Developing countries submitted two proposals to the Council for Trade Related Aspects of Intellectual Property Rights. The first one was submitted on 20th June 2001 (IP/C/W/296) followed by the second one which was submitted on 4th October 2001 (IP/C/W/312). Both the proposals contained paragraphs related to interpretations of the provisions of the TRIPS Agreement, flexibility in issuing compulsory licensing and use of Article 30 to export medicines to countries not having sufficient capacity to manufacture required medicines. In Canada Patent Protection, the Panel led by Professor Robert Hudec agreed with the EC’s argument that the objectives and purpose mentioned in Articles 7 and 8 of the TRIPS Agreement are not relevant in interpretation of other provisions such as Articles 30 and 31 of the TRIPS Agreement which led to a narrowing of flexibility present in the TRIPS Agreement.

Paragraph 10 of the Draft Ministerial Declaration from a group of developing countries⁵⁵, which states that each member shall refrain from imposing sanctions or threatening to impose sanctions against developing countries which avail themselves of policy options to promote and protect public health, suggests that the present economic and power structure have deteriorated considerably against developing countries.⁵⁶ This proposal was not accepted in the Doha Declaration on Public Health. The only thing that developing countries gained at Doha was an affirmation that, when applying the customary rule of interpretation to the provisions of the TRIPS Agreement, it should be done in the light of the object and purpose of the TRIPS Agreement,⁵⁷ a fundamental tenet in international treaty interpretation as mentioned in Article 31 of the Vienna Convention and in various decisions of the Appellate Body.⁵⁸ This was necessary because the Panel Report in *Canada Patent Protection*⁵⁹ had accepted the argument of irrelevance of the object and purpose in interpretations of the provisions of the TRIPS Agreement.⁶⁰ However, as stated earlier, the most important issue affecting the majority of the world's population was the matter of access to medicines in countries without manufacturing capacity or with insufficient manufacturing capacity, because such countries have to depend on other countries for the supply of medicines at accessible prices. The developing countries requested in their October 4, 2001 proposal that a compulsory licence issued by a member to supply medicines should be allowed to be given effect by another member under Article 30 of TRIPS (general exceptions).⁶¹

⁵⁵ TRIPS: Proposal-Draft Ministerial Declaration, *supra* note 10.

⁵⁶ *Id.* 10.

⁵⁷ TRIPS: Council Discussion on Access to Medicines, *supra* note 46, 17. "Each provision of the TRIPS Agreement should be read in light of the objectives and principles set forth in Articles 7 and 8. Such an interpretation finds support in the Vienna Convention on the Law of Treaties (concluded in Vienna in 23 May 1969), which established, in Article 31, that '[a] treaty shall be interpreted in good faith in accordance with the ordinary meaning to be given to the terms of the treaty in their context and in the light of its object and purpose...'", available at, http://www.wto.org/english/tra_top_e/TRIPS_e/mindecdraft.htm. The Doha Declaration in paragraph 5(a) says "[I]n applying the customary rules of interpretations of public international law, each provision of the TRIPS Agreement shall be read in the light of the object and purpose of the Agreement as expressed, in particular, in its objectives and principles."

⁵⁸ See Shanker, *supra* note 44.

⁵⁹ See *Canada Patent Protection*, *supra* note 6, 7.92.

⁶⁰ See *id.* ("... to the extent that prohibition of discrimination does limit the ability to target certain products in dealing with certain important national policies referred to in Articles 7 and 8.1, the fact may well constitute a deliberate limitation rather than a frustration of purpose"). Also see Shanker, *supra* note 42, at 738-39 and 742.

⁶¹ See Developing Countries' Proposal Oct. 4, 2001, *supra* note 10.

The most crucial outcome of the Doha Declaration – that TRIPS should be interpreted and implemented in a manner supportive of WTO members’ “right to protect public health, and in particular, to promote access to the medicines for all”⁶² – was not actually agreed to in the Decision of August 30, 2003. While recognising that a “WTO Member with insufficient or no manufacturing capacities in the pharmaceutical sector could face difficulties in making effective use of compulsory licensing under the TRIPS Agreement”,⁶³ the developed countries, particularly the USA, did not agree to the proposal regarding Article 30 as mentioned in paragraphs 5 and 9 of the Draft Declaration.⁶⁴ However, under paragraph 6 of the Doha Declaration, the Council for TRIPS was instructed to find an expeditious solution to this problem and to report to the General Council before the end of 2002.⁶⁵

D. Non-Local Working and Compulsory Licensing

The concept of non-local working is applied to a situation where a patent-holder, after obtaining the patent, does not start manufacturing the patented goods in the territory of the patent. Although, on the basis of Article 27.1 of the TRIPS Agreement, the USA has tried to push the interpretation that working a patent can be accomplished by importing the said patented product, this interpretation runs contrary to Article 5(A) of the Paris Convention, which deals with the issue of compulsory licences and forfeiture of patents.

The major issue raised by incapacity or insufficient capacity to manufacture the patented product is that, after obtaining a patenting monopoly, a patent-holder would not start manufacture of the patented product in the territory of the patent. The resulting non-manufacturing or non-local working is regarded as an abuse of the patenting monopoly under Article 5(A) of the Paris Convention⁶⁶ as incorporated in TRIPS in Article 2.1, and permits such countries to issue compulsory licensing to third parties to manufacture or import such patented products without payment of any remuneration. There is no provision for remuneration under Article 5(A) of the

⁶² Doha Declaration, *supra* note 8, 4.

⁶³ *Id.* 6.

⁶⁴ See Doha Declaration on the TRIPS Agreement and Public Health: Second Communication from the United States, IP/C/W/358, July 9, 2002, 6 [hereinafter ‘US Second Communication’].

⁶⁵ Doha Declaration, 6 states “[W]e recognise that WTO members with insufficient or no manufacturing capacities in the pharmaceutical sector could face difficulties in making effective use of compulsory licensing under the TRIPS Agreement. We instruct the Council for TRIPS to find an expeditious solution to this problem and to report to the general council.”

⁶⁶ See Paris Convention, *supra* note 28.

Paris Convention in cases where a compulsory licence is granted to third parties such as generic manufacturers because the patent-holder did not start manufacturing the patented product. The issue of compulsory licences for public order or public policy or other reasons is covered by other provisions of the TRIPS Agreement.⁶⁷ It is clear that Articles 30 and 31 deal with different situations, and not with the abuse of a patent through non-local working or insufficient working. This interpretation has been followed by the House of Lords in *Parke Davis v. Comptroller of Patents*⁶⁸ and by the German Supreme Court in *Zwangslizenz*.⁶⁹

The requirement of local working of the patent cannot be satisfied by importing the patented product. This has been clarified by Bodenhausen, former Director of the World Intellectual Property Organisation (WIPO), and by a large number of judicial decisions.⁷⁰ Article 27.1 would not be applicable in the case of compulsory licences issued for non-local working, as Article 2.2 of the TRIPS Agreement

⁶⁷ See generally Daya Shanker, *India, the Pharmaceutical Industry and the Validity of TRIPS*, 5 J. WORLD INTELL. PROP. 315 (2002); See also Paul Champs and Ameer Attaran, *Patent Rights and Local Working Under the WTO TRIPS Agreement: An Analysis of the US-Brazil Patent Dispute*, 27 YALE J. INT'L L. 365, 378-379; E. Richard Gold and David K. Lam, *Balancing Trade in Patents-Public Non-Commercial Use and Compulsory Licensing*, 6 J. WORLD INTELL. PROP. 5 (2003). A number of judgements have clarified the point that the abuse under Art. 5(A) is limited to local working and insufficient working and would not be covered by provisions of compulsory licensing under public policy such as for food or medicines issued under public policy. See *Parke Davis v. Comptroller-General of Patents* [1971] RPC 425, [1970] FSR 443 and *Zwangslizenz*, GRUR 1996, 190. Other relevant judgments are *Fette's Patent* [1961] RPC 396; *Re Cohmor Holdings*, Chancery Division (Patents Court), (Transcript Martin Walsh Cherer), Jan 27, 1997. Ss. 48, 49 and 50 of the un-amended UK Patent Act 1977 were intended to reduce the 'abuse of monopoly' by the patent holder. S. 50(1)(a) of the un-amended UK Patent Act 1977 stated "...that an invention which can be worked on a commercial scale in the United Kingdom and which should in the public interest be so worked shall be worked here without undue delay and the fullest extent that is reasonably practicable."

Section 48(3) of the UK Patent Act till it was partially modified by The Patents and Trademarks (World Trade Organisation) Regulations, 1999, provides for the issue of compulsory licences. It said "Where the patented invention is capable of being commercially worked in the United Kingdom, that it is not being so worked to the fullest extent that it is reasonably practicable; Where the patented invention is a product, that a demand for the product in the United Kingdom... is being met to a substantial extent by importation; Where the patented invention is capable of being commercially worked in the United Kingdom, that it is being prevented or hindered from being so worked."

⁶⁸ See *Parke Davis v. Comptroller-General of Patents* [1971] RPC 425, [1970] FSR 443.

⁶⁹ *Zwangslizenz*, GRUR 1996, 190 [Supreme Court](G.D.R.).

⁷⁰ See G.H.C. BODENHAUSEN, GUIDE TO THE APPLICATION OF THE PARIS CONVENTION FOR THE PROTECTION OF INDUSTRIAL PROPERTY, (BIRPI, World Intellectual Property Organisation, Geneva, 1968).

specifically prohibits any derogation from the provisions of the Paris Convention by any provision of the TRIPS Agreement and it is a general principle of interpretation that a general provision cannot be applied to a specific stipulation.⁷¹ In the case of compulsory licensing for non-local working or insufficient working, there is no provision for any remuneration, which explains the exceptional hostility of the USA against local working, as revealed in its complaints against Brazil,⁷² which forced Brazil to enter into a Mutually Agreed Solution for prior consultation with the United States.⁷³ The local working provision is present in patent acts of practically all developing countries including that of India. However, the threatening language used by the United States Trade Representative (USTR), implying that countries which issue compulsory licensing for non-local working would be aggressively pursued, have been sufficient to deter developing countries from resorting to such compulsory licenses.

E. Enablement and Voidability of the Patent

The incapacity of a country to manufacture a patented product has a corresponding issue of non-enablement. The concept of enablement while granting a patent requires a clear and precise description of the patent and the manner of making and using such patent for the patent to be valid. A patent is a limited monopoly given to the innovator of the product on the express condition that he or she would provide detailed and accurate information, using which a person familiar with the Art would be able to replicate the product. If, because of the lack of technical qualifications and other resources, it is not possible to duplicate the patented product, then the purpose of granting a monopoly to promote social welfare through dissemination of information would be defeated. The enablement of a patent is one of the most important obligations of a patent-holder, wherein the temporary monopoly is granted on the grounds that the patent can be enabled in the territory of the patent.⁷⁴ Two

⁷¹ See Daya Shanker, *Brazil, the Pharmaceutical Industry and the WTO*, 5 J. WORLD INTELL. PROP. 51, 62-64.

⁷² See *id.*

⁷³ See World Trade Organisation, *Brazil-Measures Affecting Patent Protection*, Notification of Mutually Agreed Solution, WT/DS199/4, G/L/454, IP/D/23/Add.1, July 19, 2001.

⁷⁴ 93 F2d 94 (1937, CA III), *cert. den.* 304 US 570 (1938), 82 L Ed 1535, 58 S Ct 1039, *reh den* (1938) 304 US 590, 82 L Ed 1549, 58 S Ct 1054.

In *National Carbon v. Western Shade Cloth Co.* 304 US 570 (1938), the Court observed "Specifications of patent including description and claims constituted contract between public and patentee under which public, through government, agreed that in consideration of inventor's disclosure and grant of right to use same after his monopoly expired, he should have been protected in his exclusive use during life of patent; the object was to place patent fully within knowledge of public and defined actual creation which public had undertaken to protect."

important considerations should thus be kept in mind during the patent grant process: firstly, that the description of the patent should be so clear and precise that it is possible for one in the art to replicate the patent, and, secondly, that in a situation where the patent cannot be replicated because of lack of suitably qualified personnel and infrastructure in the territory of the patent, granting of the patenting monopoly should not arise. Enablement cannot be uniform across all countries and will differ depending on each country's human resources and industrial capacity. Where a patent cannot be enabled it would be void, as interpreted in a number of judicial decisions in the USA and UK.⁷⁵ The US Supreme Court and other courts observed that, when foreign patent specifications do not sufficiently describe essentials of the invention so that a person skilled in the art cannot put it into practice, such prior art cannot invalidate the patent.⁷⁶ The specifications should be so clear that undue experimentation is not required by one skilled in the art to which it appertains to enable him to compound and use it.⁷⁷ Sections 5(2)(b), 14.3 and 72.1(c) in the UK Patent Act, Article 83 of the European Patent Convention (EPC), Article 5 in the Patent Cooperation Treaty (PCT)

⁷⁵ Recent decisions dealing with enablement in the US are *Hazeltine Research v. Dage Electric Co.*, 271 F.2d 218, 220 (7th Cir. 1959); *Plant Genetic Systems v. Dekalb Genetics*, 271 F.2d 218 (Fed. Cir. 2003); *Genentech v. Novo Nordisk* 108 F. 3d 1361, 1365 (Fed. Cir. 1997) (quoting *In re: Wright*, 999 F.2d 1557, 1561 (Fed. Cir. 1993)); *Biotechnology General v. Genentech*, 267 F. 3d 1325 (Fed. Cir. 2001); *Process Control Corporation v. Hydroclaim* 190 F. 3d 1350 (Fed. Cir. 1999); *University of Rochester v. G.D. Searle*, 249 F. Supp. 2d 216 (W.D.N.Y. 2003) *aff'd* 358 F.3d 916, 928 (Fed. Cir. 2004) (The Federal Circuit reiterated its observation in *Union Oil Co. v. Atlantic Richfield Co.*, 208 F. 3d 989 (Fed. Cir. 2000) that ordinarily skilled artisans would have been able to identify any compound based on its vague functional description as "a non-steroidal compound that selectively inhibits activity of the PGHS-2 gene product."); *Johns Hopkins University v. CellPro*, 152 F. 3d 1342, 1360 (Fed. Cir. 1998); *Durel Corporation v. Osram Sylvania*, 256 F.3d 1298, 1306-1307 (Fed.Cir. 2001); *Enzo Biochem v. Calgene* 188 F.3d 1362, 1369 (Fed. Cir. 1999), 52 USP.Q.(BNA) at 1134; *In re: Vaek*, 947 F. 2d 488, 495-96 (Fed. Cir. 1991); *In re: Fisher*, 57 C.C.P.A. 1099 (C.C.P.A. 1970) (The Federal Circuit reiterated the factors to be taken into consideration while determining enablement. These are: (1) the quantity of experimentation necessary, (2) the amount of direction or guidance presented, (3) the presence or absence of working examples, (4) the nature of the invention, (5) the state of the prior art, (6) the relative skill of those in the art, (7) the predictability or unpredictability of the art, and (8) the breadth of the claims.).

⁷⁶ *Cawood Patent* 94 US 695 (1877), 24 L Ed 238; *Carson v. American Smelting & Refining Co.* 4 F2d 463 (1925, CA9 Washington), cert den 269 US 555 (1925), 70 L Ed 441, 57 S Ct 18; *Wisconsin Alumni Research Foundation v. George A. Breon & Co.* (1936, CAB Mo) 85 F2d 166, cert den 299 US 598 (1936), 81 L Ed 441, 57 S Ct 191; *Le Roy v Tatham* 55 US 156 (1853), 14 How 156, 14 L Ed 367.

⁷⁷ *Wood v. Underhill* 46 US 1 (1846), 5 How 1, 12 L Ed 223; *Expanded Metal Co. v. Bradford* 214 US 366 (1909), 53 L Ed 1034, 29 S Ct 652; *United States Industrial Chemical Co. v. Theroz Co.* (1928, CA4 Md) 25 F2d 387, cert. den (1928) 278 US 608, 73 L Ed 534, 49 S Ct 12

and section 27(3) of the Canadian Patent Act have similar enablement provisions.⁷⁸ The concept of enablement can be clearly understood by an analysis of various judicial decisions dealing with § 112 in the US Patent Act.

In *Johns Hopkins*, the Federal Circuit discussed the District Court's observation that "testimony at trial established that a person skilled in the art of making monoclonal antibodies must have a bachelor's degree in the appropriate scientific field and must have made a monoclonal antibody at least once with approval."⁷⁹ The reasoning used was that the requirements for enablement were based on the notion that the purpose of granting a patent is to grant a limited monopoly to encourage the further progress of science and art and thus, if a particular product could not be manufactured by a lack of description, wherewithal, equipment, or personnel, it would not be patentable as the whole purpose of patenting it would be defeated. In a developing country, therefore, enablement of a patent of high complexity would be harder than in a technologically advanced country such as the USA. The description of a patent leading to enablement in such situation would be different and, in those countries where the products cannot be manufactured or replicated, patenting rights for such products cannot be granted. The importing of a patented product would not satisfy enablement criteria for granting a patent.⁸⁰ In the UK, the disclosure has been regarded as that of the highest degree of good faith for being granted a monopoly and it is required to be clear, precise, honest and open.⁸¹ In *Biogen v. Medeva*,⁸² the

⁷⁸ S. 14. 3 of the UK Patent Act says that "[t]he specification of an application shall disclose the invention in a manner which is clear enough and complete enough for the invention to be performed by a person skilled in the art." S. 72(1) of the UK Patent Act provides that the absence of enabling disclosure as one of the grounds for the revocation of patent, the paragraph (c) of which states the treason for revocation of a patent when "the specification of the patent does not disclose the invention clearly enough and completely enough for it to be performed by a person skilled in the art."

The Canadian Patent Act 27(3) requires the inventor to set forth clearly the steps required to make the "composition of matter, in such full, clear, concise and exact terms as to enable any person skilled in the art or science to which it pertains, or with which it is most closely connected, to make it."

⁷⁹ See *Johns Hopkins University v. CellPro*, 152 F.3d 1342, 1360 (Fed. Cir. 1998).

⁸⁰ 35 USC. § 112 of the US Patent Act provides that "[t]he specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same, and shall set forth the best mode contemplated by the inventor of carrying out his invention."

⁸¹ *British Ore Concentration Syndicate Ltd. v. Minerals Separation Ltd.*, 27 R.P.C. 47 (1907); *Cincinnati Grinders (Inc.) v. BSA Tools Ltd.*, 48 R.P.C. 33 (1931); *Biogen v. Medeva* [1997] R.P.C. 1.

⁸² *Biogen v. Medeva* [1997] R.P.C. 1.

question of enablement was discussed by the House of Lords, which held that for the purposes of Sections 14(3) and 72(1)(c), the disclosure must be sufficient to enable the whole width of the invention to be performed. Where the specifications are regarded as addressed to a group of persons with different capabilities, such group of persons is assumed to cooperate for the purpose in view.⁸³ In *Mentor Corporation v. Hollister Inc.*, the Court observed that the hypothetical addressee had to be prepared to display a reasonable degree of skill and common knowledge of art in making trials and to correct obvious errors.⁸⁴

Hence, the TRIPS Agreement covers the issue of exports to countries with no capacity or insufficient capacity to manufacture completely and does not need any addition or subtraction as suggested by the EC, the USA, Japan, Canada and Switzerland for this purpose. The incapacity to manufacture a patented product brings out the relationship between enablement and local working. The concept of local working thus continues to be present in the Paris Convention and has been incorporated into TRIPS.

IV. THE POSITION OF ARTICLES 30 AND 31 OF TRIPS IN THE PARAGRAPH 6 SOLUTION

A. Paragraph 6 at Doha and Proposals from WTO Members

As mentioned earlier, the developing countries' proposal at Doha for an authoritative interpretation of Article 30 of TRIPS regarding the manufacture and export of required medicines to needy countries was not finalised, and participants were pushing for either alternative proposals or non-proposals at the negotiations. The TRIPS Council received a number of proposals about Paragraph 6 of the Doha Declaration. By June 2002 the proposals were compiled together in document IP/C/W/363 dated 11th July 2002.⁸⁵

1. Proposal from the European Community

The EC first asserted that current WTO legislation did not cater to situations in which a nation which issues a compulsory license does not have the capacity to

⁸³ *Valensi v. British Radio Corporation* [1973] R.P.C. 377; *Osram Lamp Works v. Pope's Electric Lamp Co. Ltd.* 34 R.P.C. 369, 391 (1917).

⁸⁴ *Mentor Corporation v. Hollister Inc.* [1973] RPC 7.

⁸⁵ World Trade Organisation, Proposals on Paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health: Thematic Compilation, IP/C/W/363 dated 11 July 2002 [hereinafter Thematic Compilation].

manufacture the said product.⁸⁶ The two options suggested by the EC to deal with such situations were:

- a. an amendment to Article 31(f) so that the medicines can be produced elsewhere under compulsory licenses and exported to the country in need; or
- b. an interpretation of Article 30 of the TRIPS Agreement to allow medicines to be produced elsewhere for export to the country in need.

The EC also introduced the issues of diversion of the medicines manufactured for export to needy countries to other countries and transparency in such transactions “in order to allow other Members to be informed if a Member makes use of this mechanism”.⁸⁷

However, the most significant part of the EC’s proposal concerned the use of Article 30 to manufacture and export medicines to needy WTO members. The EC without reservation proposed: “WTO members could adopt a declaration stating that a WTO Member may, in accordance with Article 30 of the TRIPS Agreement, provide that the manufacture, on its territory, of a patented product, without the authorisation of the right holder, is lawful when it is meant to supply another country which has granted a compulsory licence for the import and sale of the product concerned in its territory in order to deal with a serious public health problem.”⁸⁸ The EC reiterated its Article 30 solution in the subsequent document also.⁸⁹

⁸⁶ *EU Tables Proposals on Access to Medicines for Developing Countries with No Drug Production*, Press Release, Brussels, (Mar. 5, 2002), available at http://europa.eu.int/comm/trade/csc/pr_050302.htm and Concept Paper Relating to Paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health: Communication from the European Community and its Member States, IP/C/W/339, Council for Trade Related Aspects of Intellectual Property Rights, WTO (Mar. 4, 2002) [hereinafter EC’s Concept Paper]. Subsequently on 20th June 2002, the EC submitted another Communication (IP/C/W/352) adding two more solutions based on the US Communication. These additional potential solutions were

- a. a dispute settlement moratorium with regard to the non-respect of the restriction under a compulsory licence, and
- b. a waiver with regard to Article 31(f).

⁸⁷ *See id.*, EC’s Concept Paper 16, 20.

⁸⁸ *See id.* at 24.

⁸⁹ World Trade Organisation, Paragraph 6 of the Doha Declaration of the TRIPS Agreement and Public Health (Communication from the European Communities and their member States to the TRIPS Council), IP/C/W/352 dated 20th June 2002, WTO [hereinafter EC’s Para 6 Proposal].

2. Proposals from the United States

The US proposal was in line with that of the Pharmaceutical Research and Manufacturers Association (PhRMA), a lobby group of the US pharmaceutical industry, when it stated in paragraph 7 of its Second Communication: “A TRIPS-based solution can also only be expected to be effective where Members have, or are provided, the resources necessary to procure pharmaceuticals under the terms of a TRIPS-consistent compulsory license, which includes the provision of adequate remuneration to the patent holder.”⁹⁰

In paragraph 8 of the US Second Communication, the question of import from other countries was introduced. While the USA stated the obvious by saying that there was nothing to prevent import under compulsory licenses from other countries, it also stated that “a compulsory license would also need to be issued in that country before medicines could be exported.”⁹¹ There is, in fact, no provision either in Article 28 or any other article of TRIPS to support this.⁹²

The right to exclude exports has never been granted to the patent-holder either by the TRIPS Agreement or through national patent acts. Except in Section 2567 of the PVPA⁹³ and § 271(f) of the US Patent Act,⁹⁴ a patenting monopoly has never been extended to export.⁹⁵ The patenting monopoly on “making” and “offering for sale”

⁹⁰ See US Second Communication, *supra* note 66, at 7.

⁹¹ See *id.* at 8.

⁹² See generally Daya Shanker, *Para 6 Solution of the Doha Declaration, Article 30 of TRIPS and Non-Prohibition of Exports under the TRIPS Agreement*, Working Paper, University of Wollongong, published in SSRN Working Paper Series, available at <http://ssrn.com/abstract=377160>.

⁹³ See The Plant Variety Protection Act (1970) (PVPA) where the patenting monopoly has specifically been extended to export and from 35 USC. § 271(f). The PVPA reads as follows: “Except as otherwise provided in this subchapter, it shall be an infringement of the rights of the owner of a novel variety to perform without authority, any of the following acts in the United States, or in commerce which can be regulated by Congress or affecting such commerce, prior to expiration of the right to plant variety protection but after either the issue of the certificate or the distribution of a novel plant variety with the notice under section 2567 of this title:

“(1) sell the novel variety, or offer it or expose it for sale, deliver it, ship it, consign it, exchange it, or solicit an offer to buy it, or any other transfer of title or possession of it;

“(2) import the novel variety into, or export it from, the United States;

⁹⁴ 35 USC. § 271(f) (1994).

⁹⁵ 35 USC. § 271(f) was introduced in the US Patent Act, 12 years after the judgement of the US Supreme Court in *Deepsouth Packing* to overrule its observation that patenting monopoly did not extend to the individual constituents of the assembled machine of invention.

would not affect export of the patented product or process, given the decisions of the US,⁹⁶ Canadian,⁹⁷ UK⁹⁸ and Japanese courts.⁹⁹ National patent acts generally only exclude those types of “making” which affect the commercial exploitation of the patent in the territory of the patent. In a number of judicial decisions in the USA¹⁰⁰ and in the WTO Panel decision in *Canada Patent Protection*,¹⁰¹ it was confirmed that the making of a patented product even in an unlimited amount would not violate the patenting provision if such making does not lead to the commercial exploitation of

⁹⁶ See *Sawin v. Guild*, 1 Robb, Pat. Case 47, Fed. Cas. No. 12391, 21 F. Cas. 554 (Cir. Ct D. Mass. 1813); *Bonsack Machine v. Underwood* 73 F. 206 (Cir. Ct. E. D. N. Car. 1896); *Brown v. Duchesne* 60 US 183 (1856); *Dugan v. Lear Avia, Inc.* 55 F. Supp. 223, 229 (S.D.N.Y. 1944) affirmed 156 F.2d 29 (2d Cir. 1946); *Roche Products Inc. v. Bolar Pharmaceuticals* 572 F. Supp. 255, 258 (E.D.N.Y. 1983), rev. *Roche Products v. Bolar Pharmaceuticals* 733 F.2d 858 (Fed. Cir. 1084) which in turn was reversed by US Congress by introducing § 271(e) in the US Patent Act; *Aakro Agate v. Master Marble Co. v. Master Marble Co.* 18 F. Supp. 305 (N.D.W. Va. 1937); *Kaz Manufacturing Co. v. Chesebrough-Pond's Inc.*, 211 F. Supp. 815 (S.D.N.Y. 1962), *aff'd* 317 F. 2d 679 (2d Circuit, 1963); *Quality Tubing v. Precision Tube Holdings* 75 F. Supp. 2d 613, 623 (S. D. Tex. 1999); *Rotec Industries v. Mitsubishi* 215 F. 3d 1251 (Fed. Cir. 2000); *Cybotronics v. Golden Source Elecs.* 130 F. Supp. 2d 1152, 1167-73 (C.DE. Cal. 2001), WL 327826.

⁹⁷ *Microchem v. SmithKline & French*, [1972] S.C.R. 506.

⁹⁸ *Frearsaono v. Loe*, (1878), 9 Ch. D. 48.

⁹⁹ See *Ono Pharmaceuticals Co. v. Kyoto Pharmaceutical Industries*, Case No. 1998 (ju) 153 (Apr. 16, 1999) (decided by the Supreme Court of Japan).

¹⁰⁰ See *Intermedics v. Ventritex*, 775 F. Supp. 1269, 1280 (N. D. Cal. 1991), *aff'd*, 991 F. 2d 808 (Fed. Cir. 1993) (non-presidential decision) (“We infer that the phrase ‘reasonably related’ (to development information for the FDA) as used in § 271(e)(1) reflects Congress’s acknowledgement that it will not always be clear to parties setting out to seek FDA approval for their new product exactly which kinds of information, and in what quantities, it will make to win that agency’s approval.” The question of quantity was discussed in the context that the defendant had manufactured several hundred Cadences); In *Amgen v. Hoechst Marion Roussel*, 3 F. Supp. 2d 104, 108 (D. Mass. 1998) *aff'd* by *Amgen v. Hoechst Marion Roussel* 314 F. 3d 1313 (Fed. Cir. 2003)) the court discussed the question of commercial production of patented products by a generic manufacturer before the expiry of the patent. The argument was based on Amgen’s assertion that Hoechst had planned a total of five batches of commercial scale production of GA-EPO as required by the Japanese and the European regulatory agencies and had produced at least three commercial scale productions apart from batch 07. The court in *Amgen* observed that Hoechst was protected by § 271(e)(1) if the production of three batches of GA-EPO was objectively likely to generate useful information, even if the results were discarded for reasons unrelated to FDA approval. The court specifically observed that retention of the GA-EPO manufactured is not an activity that could constitute infringement under § 271(a) as was observed in *Telectronics (Telectronics Pacing Sys., Inc. v. Ventritex Inc.)*, 982 F. 2d 1520, 1523-24, 25 USPQ2D 1196, 1199 (Fed. Cir. 1992).

¹⁰¹ See *Canada Patent Protection*, *supra* note 6, 7.45.

the patent in the territory of the patent. The assertion of the USA that a compulsory licence would also need to be issued in that country for the export of medicines to be possible is, thus, not based on any valid legal interpretation.

In paragraph 12 of its Second Communication,¹⁰² the USA insisted on identification of the countries not having manufacturing capacity or insufficient capacity on the basis of certain criteria followed by its proposal to limit the countries willing to export only to the members of developing and least developed countries.¹⁰³ The proposal pertaining to transfer of technology under Article 31(f) by the group of African countries was probably discussed in this context.¹⁰⁴ The USA introduced the concept of “transparency” in part V, paragraph 20 of its Second Communication requiring developing countries and least developed countries to inform the TRIPS Council of actions taken under the proposed mechanism where Article 31(f) is used to export the patented product to fulfil the requirement of other countries, which will apparently ensure that goods reach the needy countries under the policing of the TRIPS Council.

The most disturbing statement in the United States’ proposal pertains to Article 30 of the TRIPS Agreement, wherein the USA insisted that the use of Article 30 to export a patented product would unreasonably conflict with normal exploitation of the patent and prejudice the legitimate interests of the patent owner.¹⁰⁵ The US argument appears to be specious, considering that the US permitted manufacturing of the patented product in unlimited quantities for regulatory approval purposes under the *Bolar* exception embodied in the US in the Hatch-Waxman Act, which was confirmed as compatible with Article 30 exceptions in *Canada Patent Protection*.¹⁰⁶ The reasoning behind this assertion from the USA appears to be based on a discussion of Article 30 by Abbott.¹⁰⁷ The US compounded its position by the inclusion of a one-time waiver along the lines of the *Bolar* exception, in line with PhRMA’s suggestions

¹⁰² See US Second Communication, *supra* note 66, 12.

¹⁰³ See *id.*, 15.

¹⁰⁴ WTO, Proposal on Paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health: Joint Communication from the African Group in the WTO, IP/C/W/351 (June 24, 2002) received from the Permanent Mission of Kenya on behalf of the African Group in the WTO [hereinafter African Proposal] at 6(e).

¹⁰⁵ See US Second Communication, *supra* note 66, 6.

¹⁰⁶ See *Canada-Patent Protection*, *supra* note 6.

¹⁰⁷ See Frederick M. Abbott, *WTO TRIPS Agreement and Its Implications for Access to Medicines in Developing Countries*, Report commissioned by the CIPR as a background paper, Study Paper 2a, Commission on Intellectual Property Rights (Feb. 14, 2002) available at http://www.iprcommission.org/papers/pdfs/study_papers/sp2a_abbott_study.pdf.

as enumerated by Amir Attaran.¹⁰⁸ The USA also questioned the legality of the authoritative interpretation of a WTO provision provided under Article IX (2) of the Marrakesh Agreement,¹⁰⁹ despite the fact that this assertion goes against the United States' own argument in the *Alcoholic Beverages* case¹¹⁰ and against the decision of the Appellate Body¹¹¹ (discussed in detail later in this chapter). The USA is not only trying to undermine the flexibility inherent in the TRIPS Agreement as partly retrieved by developing countries in the Doha Declaration on Public Health, but also undermines the Ministerial Conference which has been empowered in terms of Article IX: 1 of the Marrakesh Declaration, to authoritatively interpret the provisions of these agreements.

The USA's assertion does not appear to have legal support, as both the phrases "unreasonably conflict with the normal exploitation of a patent" and "unreasonably prejudice the legitimate interests of the patent owner" mentioned in Article 30 of TRIPS are to be interpreted in terms of the direct economic and commercial effect on the patent in the territory of the patent. When the patented products are exported out of the patented areas, they are not affecting the interests of the patent-holder reasonably or unreasonably at all in the territory of that patent. Even without Article 30, the US Supreme Court has delivered verdicts such as *Deepsouth Packing v. Laitram Corporation*¹¹² to the effect that patented products exported under knocked-down conditions do not violate the US Patent Act and that the patent holder does not have the right to prohibit the export of the patented product.¹¹³

¹⁰⁸ See Amir Attaran, *Paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health: Options for TRIPS Council*, Working paper No. 87, Center for International Development, Harvard University (2002) at 8 available at <http://www2.cid.harvard.edu/cidwp/087.pdf>. This paper was subsequently published in *Fordham Intellectual Property, Media and Entertainment Law Journal* (Amir Attaran, *The Doha Declaration on the TRIPS Agreement and Public Health, Access to Pharmaceuticals, and Options Under WTO Law*, 12 FORDHAM INTELL. PROP. MEDIA & ENT. L. J. 869 (2002)) (Attaran suggested a concept of non-justiciability which would exempt the manufacture and export of generic versions of patented pharmaceuticals when these are intended for countries lacking pharmaceutical manufacturing capacity.) Amir Attaran's relations with the Harvard University was a little controversial when it was found out that his salary during his stay in the Harvard University was paid by an outside organisation, the Africa Fights Malaria, essentially financed by a group of mining firms in South Africa interested in playing down the extent of AIDS/HIV impacts.

¹⁰⁹ See US Second Communication, *supra* note 66, 29.

¹¹⁰ WTO Report of the Appellate Body, *Japan Taxes on Alcoholic Beverages*, WT/DS58/AB/R, WT/DS10/AB/R, WT/DS11/AB/R (4th October, 1996) adopted 8th November 1999 [hereinafter *Japan Taxes*].

¹¹¹ *Id.*

¹¹² 406 US 518, 532 (1972).

¹¹³ See Daya Shanker, *supra* note 42, 764-767.

3. Proposals from Developing Countries and the UAE

The proposal from the developing countries was essentially a continuation of their proposal in the Draft Declaration dated October 4, 2001¹¹⁴ and maintained that the use of Article 30 should “recognise the right of WTO members to authorise third parties to make, sell and export patented public health-related products without the consent of the patent holder to address public health needs in another country.”¹¹⁵ Using Articles 7 and 8 of the TRIPS Agreement, the developing countries discussed two aspects of the issues raised by the insufficiency or incapacity of certain members of the WTO to manufacture: the first was regarding “local working”,¹¹⁶ which was a continuation of their argument put forth in June 2001,¹¹⁷ and the second was the authoritative interpretation of Article 30 as set out above.¹¹⁸ There are two aspects to the developing countries argument. The first aspect appears to be based on the presumption that the patent rights granted cover the export of the patented products to territories outside that of the patent, while the second aspect suggests that it is the responsibility of the countries exporting and importing the patented products to establish appropriate safeguards. In paragraphs 9 and 11 of their document, the developing countries elaborated on the use of Article 30 of the TRIPS Agreement and why it would not “unreasonably conflict with the normal exploitation of the patent or unreasonably prejudice the legitimate interests of the patent owner.”¹¹⁹ The United

¹¹⁴ TRIPS: Council Discussion on Access to Medicines, *supra* note 46.

¹¹⁵ See Paragraph 6 of the Ministerial Declaration on the TRIPS Agreement and Public Health received from the Permanent Mission of Brazil, on behalf of the delegation of Bolivia, Brazil, Cuba, China, Dominican Republic, Ecuador, India, Pakistan, Peru, Sri Lanka, Thailand and Venezuela, IP/C/W/355 (June 24, 2002), TRIPS Council [hereinafter Communication from Developing Countries].

¹¹⁶ *Id.* at 3 “The development of local manufacturing capacities for public health-related products, whenever economically feasible, is critical to ensuring the development of sustainable health policies and access to affordable medicines, particularly in developing countries”.

¹¹⁷ WTO, TRIPS and Public health – Submission by the African Group, Barbados, Bolivia, Brazil, Cuba, Dominican Republic, Ecuador, Honduras, India, Indonesia, Jamaica, Pakistan, Paraguay, Philippines, Peru, Sri Lanka, Thailand and Venezuela, document IP/C/W/296 (June 20, 2001) at 20, *available at* http://www.wto.org/english/tratop_e/TRIPS_e/paper_develop_w296_e.htm

¹¹⁸ See *id.* at 20.

¹¹⁹ Communication from Developing Countries, *supra* note 119, 9;

Similarly 11 of the Communication from Developing Countries says

“Clearly, nothing in the letter and spirit of Article 30 of TRIPS prevents members from authorising local producers to make, sell and export public health –related products, without the consent of the patent holder, to address health needs in other countries with insufficient or no manufacturing capacities, as a limited exception under this provision. In light of the

Arab Emirates suggested an interpretation of Article 30 of TRIPS to “engage, sell and export patented public health related products without the consent of the patent holder to address public health needs in another country” and further suggested that the interpretation should not “prejudice other exceptions to the exclusive rights initially available to the members under Article 30 of the TRIPS Agreement.”¹²⁰ While discussing a possible Article 31(f) solution, the developing countries proposed that Article 31(f) should be eliminated altogether.

4. Proposal from the African Group

Perhaps due to their free trade negotiations with the USA, the African countries preferred to file their own proposal separate from the other developing countries.¹²¹ Their proposal was concerned predominantly with the Common Market approach of the African Nations, which they expanded in the paragraph 6(d) of their proposal. This paragraph says:

*Members, in respect of licences issued to address practices that restrain trade, other abusive practices, and insufficiency of supplies of pharmaceutical products, may recognise or give effect to the licences at a regional level where a domestic market is part and parcel of a regional market for instance under a free trade area or a custom union or the interim arrangements.*¹²²

However, in paragraph 3(5) of this document, the African group recognised the limitation of the Article 31(f) solution and suggested that it should be deleted or a clear authoritative interpretation adopted.¹²³ It also insisted on flexibility in the

mandate to find expeditious solutions to the problem recognised in Paragraph 6, an authoritative interpretation of Article 30 confirming this legal solution would be an important step to ensure legal certainty of all WTO Members. Moreover, in light of paragraph 4 of the Ministerial Declaration on the TRIPAS Agreement and Public Health [Doha Declaration], Article 30 of TRIPS ‘should be interpreted and implemented in a manner supportive of WTO member’s right to protect public health and, in particular, to promote access to medicines for all.’”

¹²⁰ See WTO, Paragraph 6 of the Doha Declaration of the TRIPS Agreement and Public health, Communication from the United Arab Emirates, IP/C/W/354 (June 24, 2002), 20-21.

¹²¹ African Proposal, *supra* note 108.

¹²² See *id.* at 6(d).

¹²³ *Id.* at 3(e) “These limitations show how paragraph (f) of Article 31 may be far out of line with the needs of members in the face of the international and national health crises upon us. The paragraph needs to be deleted, or a clear exception introduced, or an authoritative interpretation adopted, bearing in mind the said time frame within which an expeditious solution should be adopted.”

grounds for issuing of compulsory licenses.¹²⁴ The approach of the African group seems to have been to use the opportunity to push for the industrialisation of Africa, which is supported by their subsequent statement in paragraph 6(e) asking for adoption of measures to build a sound technological base in the developing countries of Africa so as to facilitate the domestic production of pharmaceutical products to meet public health needs.¹²⁵

The most important point raised by the African group was the reiteration of a “comprehensive moratorium on disputes against any Member that takes measures to address the international and national health concerns in countries with insufficient or no manufacturing capacity.”¹²⁶ Another observation from the African group pertains to the tendency seen in some bilateral and multilateral arrangements between developed and developing countries, wherein developing countries have been asked not only to give up not only the flexibility due to them under the TRIPS Agreement but also to raise their levels of patenting monopoly.¹²⁷ Such arrangements have been made in the FTAA (Free Trade Agreement of America) treaty signed between the USA and Chile and are part of the free trade agreements being negotiated between the USA and the African countries such as South Africa, Lesotho, Botswana, Namibia and Swaziland, which are members of the South African Customs Union (SACU).¹²⁸ The African group suggested that members “should avoid the fragmentation of the multilateral regime on intellectual property rights provided by the TRIPS Agreement, and should respect and ensure the use to the full flexibility in the TRIPS agreement.”¹²⁹ Overall, the proposal from the African group was essentially complementary to the proposals from the developing countries and the UAE without diluting them, and additionally incorporates an important point on the transfer of technology.

5. The TRIPS Council and Thematic Compilation

On the basis of these proposals, the TRIPS Council prepared a thematic compilation by the middle of July 2002.¹³⁰ Coincidentally, Document MTN.GNG/

¹²⁴ *Id.* at 3(f) “As the declaration points out, for instance, members have the right to determine the grounds on which to issue compulsory licences and such grounds are not set out in the TRIPS Agreement. This flexibility needs to be protected against attempt to restrictively define the scope of the freedom of members to determine grounds for compulsory licences.”

¹²⁵ *Id.* at 6(I), 5.

¹²⁶ *Id.* at 6(g).

¹²⁷ *See, e.g.*, Agreement Between the United States of America and the Hashemite Kingdom of Jordan on the Establishment of a Free Trade Area, *available at* <http://www.ustr.gov/regions/eumed/middleast/USJordanFTA.shtml>.

¹²⁸ USTR, The letter sent by Ambassador Robert B. Zoellick to Sen. Byrd on or about 4th November, 2002, www.ustr.gov.

¹²⁹ African Proposal, *supra* note 108, at 5.

¹³⁰ Thematic Compilation, *supra* note 89.

NG11/W/76 dated July 23, 1990 was prepared in similar circumstances during the TRIPS negotiations, where then-Chairman Anell put the proposals from different countries together and similarly divided it in a number of sections depending upon the origin of the proposals. Subsequently, each and every proposal from developing countries was removed or circumscribed. The TRIPS Council divided the proposals in its thematic compilation in two sections: one which included the elements suggesting facilitation of exports to members with insufficient manufacturing capacities (including proposals from the USA, the EC and developing countries) and one which included proposals mainly from the African group, which discussed the issues of technology transfer and establishment of manufacturing capacity along with the expansion of a unified market.

All this indicated the shape of things to come. The USA suggested the waiver of conditions in Article 31 of TRIPS as if the Article 30 solution did not exist, and made the unethical observation that an authoritative interpretation would lead to more litigation. The EC gave the Article 30 solution a chance to be adopted, but recommended a thick web of conditions to block the so-called diversion of patented products without providing any evidence of diversion.¹³¹ Outterson has discussed the question of diversion in detail and he concludes that the question of diversion to developed countries has never been an issue, since, throughout the period when medicines and chemicals were exempted from patenting in developing countries, there was no diversion of such medicines and chemicals to developed countries. Outterson also points out that parallel trade – where the patented goods, once sold, are supposed to go out of the control of the patent-holder under the first sale exhaustion regime and can be freely imported and exported – did not lead to price convergence, as is evident from the price divergence in the EC. The scare of diversion was created by the monopolistic industries essentially to segregate the international market into different segments to gain maximum revenue, without making any effort to provide access to medicines to developing countries.

Another intriguing development at this stage was the African group's choice to separate itself from the other developing countries. There was a commonality of purpose between the USA and the African group proposals regarding the need for technology transfer and the extension of compulsory licensing to the regional geographical area instead of confining it to a single country. The break-up of the

¹³¹ See Kevin Outterson, *Pharmaceutical Arbitrage: Balancing Access and Innovation in International Prescription Drug Markets*, 5 YALE J. HEALTH POL'Y, L. & ETHICS 193 (2004) (discussing the scare of diversion of such medicines generated by the pharmaceutical industry by giving example of the Dowelhurst case (Glaxo Group Ltd v. Dowelhurst Ltd [2004] All E.R. (D) 126 (Mar) where the goods claimed to have been diverted to Europe by Glaxo never left the EC.).

developing country group also perhaps emboldened Edouardo Motta, the Chairman of the TRIPS Council, resulting in the removal of the Article 30 solution completely from his note. It perhaps further resulted in the prime proposal being a combination of the American proposal of the waiver of the conditions of Article 31 solution and the thick web of conditions recommended in the EC's proposal, which in effect incorporated exports as one of the patenting rights in Article 28 of the TRIPS Agreement.

B. Paragraph 6 and the Introduction of Regulatory Provisions

The introduction of a series of regulatory provisions in the area of exports of patented products for the ostensible reason of providing transparency does not appear to be convincing, as provisions dealing with the exports of the patented products were clearly present in the TRIPS Agreement under Articles 31 and 30¹³² and there was a clear observation by the Panel in *Canada Patent Protection* that any question of diversion of the patented product is the responsibility of the patent holder and not that of national governments.¹³³ Articles 31(f) and 31(k) do not have a corresponding free import provision in the territories where a patent is in force, and the only way a patented product can get through in these territories is through trade diversion. Article 31 implies that non-predominant parts of such manufactured goods can be disposed of, and there is no account-maintenance system whereby the TRIPS Council is informed of details such as the amount manufactured. Based on Article 31(k) of the TRIPS Agreement, a large number of countries, including the UK and India, have incorporated provisions in their patent laws saying that patented products manufactured under Article 31(k) can be freely exported.

There is no provision in the TRIPS Agreement for putting into place an elaborate control structure. From the developments so far, the purpose of constructing such a

¹³² There are two provisions in Article 31 of TRIPS dealing with the manufacture and exports of such manufactured products under compulsory licensing. These are:

1. Article 31(f), which the General Council attempted to amend although not empowered to do so as per Article IX of the Marrakesh Agreement and which says:

any such use [of the products manufactured under Article 31 of TRIPS] shall be predominantly for the supply of the domestic market of the Member authorising such use; and

2. Article 31(k) which says:

Members are not obliged to apply the conditions set forth in sub-paragraph (b) and (f) where such use is permitted to remedy a practice determined after judicial or administrative process to be anti-competitive.

¹³³ *Canada Patent Protection*, *supra* note 6, at 7.46.

structure appears to be not only to frighten manufacturers or the countries concerned but subsequently to extend it throughout all compulsory licensing systems. Chairman Motta's note and its confirmation as an authoritative interpretation by the General Council of the WTO on August 30, 2003¹³⁴ is a rewriting of the TRIPS Agreement and, given the developments so far, it is evidently highly skewed towards the wishes of the USA and the EC. There is nothing new in the export of patented products produced under compulsory licensing, and there appears to be no requirement for such an elaborate structure, as the infringement action is the responsibility of the patent-holder through his private action.¹³⁵

The EC tried to justify the introduction of extensive regulations by Chairman Motta in the Decision of August 30, 2003 by insisting that the existing enforcement measures under the TRIPS Agreement mainly address the possibility of patent infringement and not that of trade diversion. According to the EC, the issue of diversion of a patented product is entirely different from that of the infringement of a patent and, whereas existing enforcement measures in the TRIPS Agreement deal with the latter, there are no provisions in the TRIPS Agreement to deal with the issue of the diversion of a patented product. In this context, as per the EC, the norms prescribed in the Decision of August 30, 2003 are for prohibiting trade diversion from their intended destination.¹³⁶ This is a unique argument, as the patent-holders have so much of control in the countries where they are producing the goods that no goods manufactured in developing countries where there has been no patenting have been exported to the developed countries so far.¹³⁷ This issue of diversion was exactly the argument raised by the EC in its dispute against Canada in *Canada Patent Protection*, to which the Panel did not agree on the ground that it is the responsibility of the private infringement action of the patent holder that the challenged conduct is inconsistent with the basic patent rights created by national laws, not that of the governments.¹³⁸

The elaborate formalisation of rules and regulations in the Decision of August 30, 2003 does not appear to have a legal basis either in the TRIPS Agreement or in the internal domestic law of these countries. What the EC could not gain from the

¹³⁴ See Decision of August 30, 2003, *supra* note 7.

¹³⁵ See *Canada Patent Protection*, *supra* note 6, at 7.46.

¹³⁶ Sustainable Trade: Access to Medicines-Main Elements of the Chair's 16 December 2002 draft compromise decision (Perez Motta text), Brussels (Jan. 9, 2003), available at http://europa.eu.int/comm/trade/csc/memo090103_en.htm.

¹³⁷ See Michael A. Friedman, Henk den Besten, Amir Attaran, *Out licensing: A Practical Approach for Improvement of Access to Medicines in Poor Countries*, 361 LANCET 341 (2003).

¹³⁸ See *Canada Patent Protection*, *supra* note 6, at 7.46.

Panel decision through the dispute mechanism in *Canada Patent Protection*, it gained through Paragraph 6 of the Doha Declaration negotiations. Changes were introduced in the Community Patent Convention to say that the import of a patented product would satisfy the local working requirement on the basis of the Panel's observation that Article 30 would be covered by Article 27.1's non-discrimination provision. This not only ignores other observations of the same Panel but also attempts to violate the decisions of the Panel in *Canada Patent Protection*, which is at least binding on both the EC and Canada. The attempt by the EC to distinguish between infringement and diversion after losing the issue of diversion of patented products in *Canada Patent Protection* suggests that there is little consistency in international treaty interpretations or negotiations over TRIPS.

C. Non-Discrimination under Article 30 and Paragraph 6 at Doha

Another important aspect of the proposals of the US and the EC is their argument that Article 30's authoritative interpretations to permit export would violate the non-discrimination provision of Article 27.1. This fails to understand the basis of the Panel's observation in *Canada Patent Protection*, which extended the applicability of non-discrimination provision in Article 27.1 to Article 30 of the TRIPS Agreement and was in fact based on the acknowledgement from Canada that Article 27.1 would be applicable to an exemption under Article 31 of the TRIPS Agreement.¹³⁹ The Panel observed that since Article 27.1 would be applicable to Article 31 of the TRIPS Agreement, it would also be applicable to Article 30 of TRIPS. If Article 27.1 is used to suggest that it would not be permissible under Article 30 of TRIPS, it cannot be permissible under Article 31 of TRIPS either, which effectively amounts to saying that there cannot be any solution at all. No international treaty can be interpreted in this manner. Moreover, the question of import of unauthorised patented products is covered by Article 41 of the TRIPS Agreement which explicitly says:

It is understood that this Part does not create any obligations to put in place a judicial system for the enforcement of intellectual property rights distinct from that for the enforcement of law in general, nor does it affect the capacity of members to enforce their law in general. Nothing in this Part creates any obligations with respect to the distribution of resources as between enforcement of intellectual property rights and the enforcement of law in general.

In other words, nations can resort to their own judicial system to block any diversion of unauthorised patented products.

¹³⁹ *Id.*

D. Exports Under Article 30 of TRIPS and the Limited Exception

Article 30 of the TRIPS Agreement is an exceptionally important provision in the TRIPS Agreement because it permits a degree of flexibility to reduce monopolistic negative externalities and to keep the social welfare purpose of the monopoly granted through patents on the right track. The Article states:

Members may 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 into account the legitimate interests of third parties.

One possible argument to eliminate an Article 30 solution to Paragraph 6 of the Doha Declaration is to say that manufacture of the patented products for the purpose of exports would not be covered under the limited exceptions permitted by Article 30 of TRIPS, although this argument was not made either by the EC or the USA. Another argument to exclude the Article 30 TRIPS solution could be to see whether the limited exception in Article 30 affects or prejudices the legitimate interest of the patent holder. The WTO Appellate Body has discussed the interpretation of the term 'exception' in *EC-Measures Containing Meat and Meat Products (Hormones)*,¹⁴⁰ in which it observed:

Merely categorising a treaty provision as an 'exception' does not by itself justify 'stricter' or narrower interpretation of that provision than would be warranted by examination of the ordinary meaning of the actual treaty words, viewed in context and in the light of the treaty's object and purpose, or, in other words, by applying the normal rules of treaty interpretations.¹⁴¹

In *Canada Patent Protection*, the Panel, led by Robert Hudec, interpreted the term "limited exception" in a very narrow sense, although in terms of the interpretation given by the Appellate Body, its interpretation is incorrect. Even accepting the restrictive interpretation of the term "limited exception" in *Canada Patent Protection* on the basis that the object and purpose of a treaty are irrelevant for treaty interpretation, the manufacture of patented medicine for approval by the regulatory authorities is regarded as within the exception of Article 30 as far as TRIPS is

¹⁴⁰ WTO, Report of the Appellate Body, *EC-Measures concerning Meat and Meat Products (hormones)*, WT/DS26/AB/R, WTO Doc. AB-1997-4, and WT/DS48/AB/R (Jan 16, 1998).

¹⁴¹ *Id.* at 104.

concerned. The manufacture to fulfil the tests requirement for regulatory approval permitted under the *Bolar* Exception in the USA,¹⁴² by the German Supreme Court in *Clinische I*¹⁴³ and *II*¹⁴⁴ and by the Japanese Supreme Court¹⁴⁵ in *Ono Pharmaceutical* is regarded as being within the exception permitted under Article 30. Although the Panel in *Canada Patent Protection* observed that additional benefits, such as monopoly for extended period of patents, are within the rights prescribed by Article 28.1 of the TRIPS Agreement without any legal support,¹⁴⁶ it found that manufacture to remove such extended market exclusivity would be covered by the 'limited exception' criteria mentioned in Article 30 of the TRIPS Agreement. What the Panel actually observed was:

*Even though regulatory approval processes may require substantial amounts for test production to demonstrate reliable manufacturing, the patent owner's rights themselves are not impaired any further by the size of such production runs, as long as they are solely for regulatory purposes and no commercial use is made of the resulting final products.*¹⁴⁷

The commercial use of the final products in the above observation of the Panel refers to the commercial use in the territory of the patent, not throughout the world. Once a compulsory licence is issued or where the patent cannot be granted for any reason, the export of the patented products would not be affected by the limitation placed by Article 28.1 and would be covered by Article 30 of TRIPS as it does not affect the patent owner's right as "no commercial use is made of resulting final products".

It must be understood that the term "normal exploitation of the patent" is legally valid only for the area for which the patent has been granted in view of the territoriality of the patent and not for the universal exploitation of the patent. If the patented products are exported out of the patented territory, it does not and cannot conflict

¹⁴² *Bolar* Exception, 35 USC. § 271(e) (1994).

¹⁴³ *Clinische Versuche I*, Federal Supreme Court of Germany [1997] RPC 623, LEXIS UK Patent Cases 32, BGH, 11th July 1995, GRUR 1996, 109 [Supreme Court] (F.R.G.).

¹⁴⁴ *Clinische Versuche II* [1998] RPC 423, LEXIS UK Patent Cases 32 [Supreme Court] (F.R.G.).

¹⁴⁵ *Ono Pharmaceutical Companies v. Kyoto Pharmaceutical Industries*, Case No. 1998 (ju) 153 (Apr. 16, 1999) (Decided by the Supreme Court of Japan).

¹⁴⁶ See *Canada Patent Protection*, *supra* note 6, at 7.35.

¹⁴⁷ See *id.* at 7.45.

with the “normal exploitation of the patent”¹⁴⁸ nor prejudice the legitimate interests of the patent owner in the territory of the patent. The European Parliament even gave “practical embodiment” to Article 30 exceptions to be used to provide access to such medicines.¹⁴⁹ The “limited exception” criteria is not affected by export under Article 30 of TRIPS to the region where either the patent-holder’s rights were suspended through issue of a compulsory licence, or the patent-holder has no interest because the products were not patented. The patent owner does not have access to the territory to which the goods are exported under compulsory licensing or non-granting of patents, and the patent owner does not have any legitimate commercial interests therein. This is how TRIPS stands, and this is how it was viewed by the EC in its concept paper.

¹⁴⁸ Daya Shanker, *supra* note 42, at 769. In *John Brown v. Duchesne*, 60 US 183, 195 (1886), the US Supreme Court has interpreted the patenting clause of the US Constitution and observed:

“The patent laws are authorised by that article in the Constitution which provides that Congress shall have power to promote the progress of science and useful arts, by securing for limited time to authors and inventors the exclusive right to their respective writings and discoveries. The power thus granted is domestic in its character, and necessarily confined within the limits of the United States. It confers no power on Congress to regulate commerce, or the vehicles of commerce, which belong to a foreign nation, and occasionally visit our ports in their commercial pursuits. That power and treaty-making power of the General Government are separate and distinct powers from the one of which we are now speaking, and are granted by separate and different clauses, and are in no degree connected with it. And when Congress are legislating to protect authors and inventors, their attention is necessarily attracted to the authority under which they are acting, and it ought not lightly to be presumed that they intended to go beyond it, and exercise another distinct power, conferred on them for a different purpose. Nor is there anything in the patent laws that should lead to a different conclusion. They are all manifestly intended to carry into execution this particular power. *They secure to the inventor a just remuneration from those who derive a profit or advantage, within the United States, from his genius and mental labors (emphasis added)*”.

¹⁴⁹ The European Parliament adopted proposals for an Article 30 solution during the first reading of the draft Directive to update Directive 2001/83/EC relating to medicinal products for human use. The amendment stated:

“Manufacturing shall be allowed if the medicinal product is intended for export to a third country that has issued a compulsory licence of that product, or where a patent is not in force and if there is a request to that effect from the competent public health authorities of that third country.” Available at <http://www3.europarl.eu.int/omk/omnsapir.so/calendar?APP=PDF&TYPE=PV2&FILE=p00210223EN.pdf&LANGUE=EN>. On 20th September 2002, the WHO in its submission to the TRIPS Council also suggested:

“Among the solutions being proposed, the limited exception under Article 30 is the most consistent with this public health principle. This solution will give WTO Members expeditious authorisation, as requested by the Doha Declaration, to permit third parties to make, sell and export medicines and other health technologies to address public health needs.” Available at <http://who.int/mediacentre/TRIPS/en/>.

E. The TRIPS Chairman's Note and Removal of the Article 30 Solution

By the middle of October 2002, the Chairman of the TRIPS Council, Edouardo Motta, put forward his proposal in the form of a note which omitted all the proposals of the developing countries pertaining to Article 30 of TRIPS from the "thematic compilations",¹⁵⁰ documents in which all the proposals from the various countries had been put together. This note was put before WTO Members on December 16, 2002 at the Sydney mini-Ministerial Meet but was not accepted. The attempt to remove the proposals of developing countries completely and to retain those from the USA regarding the amendment of Article 31(f) with extensive regulatory norms as proposed by the EC¹⁵¹ was similar to the developments which occurred during the finalisation of the TRIPS Agreement.¹⁵²

Daniel Gervais, a former staff member at WIPO and a regular consultant for the OECD, reproduced some of these developments in his book.¹⁵³ The arbitrated draft prepared by the GATT Secretariat, Chairman Anell and Director-General Arthur Dunkel was included as part of the Draft Final Act Embodying the Results of the Uruguay Round of Multilateral Trade Negotiations.¹⁵⁴ This Draft not only removed all the references to local working, but also practically all the proposals from developing countries compiled in MTN.GNG/NG11/W/76 dated 23rd July 1990 by Anell¹⁵⁵ and carried through the negotiations in the Brussels Draft Text.¹⁵⁶ These developments

¹⁵⁰ Thematic Compilation, *supra* note 89.

¹⁵¹ Chairman's Note dated 25. 10. 2002: Implementation of Paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health: Draft legal Language for General Council Decision. It was slightly modified in the form of addition of preamble in the draft circulated by the Chairman of the TRIPS Council on 16th December 2002 Job(02)/217. On 28th August 2003, the Council for TRIPS approved the draft Decision on "Implementation of Paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health" contained in document JOB(02)/217 and forwarded it along with the text of the statement contained in document JOB(03) /177 to be made by the Chairman of the General Council prior to the adoption of the Decision. On August 30 the General Council d adopted the Decision in the light of statement read out by its Chairman (WT/L/40).

¹⁵² See Daya Shanker, *supra* note 41, at 758.

¹⁵³ See DANIEL GERVAIS, THE TRIPS AGREEMENT: DRAFTING ANALYSIS AND NEGOTIATING HISTORY 167 (1998); the arbitrated draft (MTN.TNC/W/FA (Dec. 20, 1991) at Annex 10.

¹⁵⁴ See *id.* at 24.

¹⁵⁵ See *id.*

¹⁵⁶ Agreement on Trade Related Aspects of Intellectual Property, including trade in Counterfeit Goods in Draft Final Act Embodying the Results of the Uruguay Round of Multilateral Trade Negotiations, GATT doc. No. MTN.TNC/W/35/Rev.1, 3 December 1990, reproduced in part in GERVAIS, *supra* note 157, at 161.

suggest that the system of international negotiations has rarely been equitable, and that developing countries rarely have any genuine participation in international treaty negotiations as sovereign countries.

The current developments also appear to follow a predetermined script. All the proposals related to the Paragraph 6 solution of the Doha Declaration coming from different countries were put together by the TRIPS Council¹⁵⁷ and were discussed by WTO Members on July 18, 2002 (IP/C/M/36). The suggestions from developing countries were either removed or curtailed by Motta before he put the proposals in the Sydney mini-Ministerial Meet through his note, and even more stringent provisions were included than those in the US or the EC patent laws or their proposals.

F. The TRIPS Chairman's Note and the Article 31(f) Solution

The Chairman's Note presented at the Sydney mini-Ministerial Meet¹⁵⁸ and subsequently finalised on August 30, 2003 appears to follow only the proposals from developed countries. Most of the issues raised by developing countries have been either removed or circumscribed. It has also attempted to incorporate a series of regulations on the pretext of diversion and transparency as suggested by the EC and the USA.

The most disturbing aspect of the Chairman's note was that the proposals under Article 30 suggesting authoritative interpretations had been totally removed. The preamble, which was not drafted on November 19, 2002 but which had been included in the December 16 version of the Chairman's Note, says: "Noting that, in the light of the foregoing, exceptional circumstances exist justifying waivers from the obligations set out in paragraphs (f) and (h) of Article 31 of the TRIPS Agreement with respect to pharmaceutical products." It does not however, mention anything about the Article 30 solution, which was the most suitable and legal solution, and which did not need any amendment to the TRIPS Agreement. Without mentioning the names of countries, Motta's Note further says that "Most of the conditions have been in the context of an Article 31-based solution (whether through a waiver and/or an amendment) and therefore most of what follows relates to this scenario." It is not mentioned who gave the proposals on the basis of Article 31 of the TRIPS Agreement. Except for the USA

¹⁵⁷ Thematic Compilation, *supra* note 89.

¹⁵⁸ 16 December 2002 Draft, Implementation of Paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public health: Draft legal Language for General Council Decision dated 19th November 2002 followed by Implementation of paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health: Note from the Chairman, JOB(02)/217, Council of TRIPS (December 16, 2002) *available at* http://www.ictsd.org/ministerial/cancun/docs/TRIPS_para6_16-12-02.pdf.

and some of the smaller countries like Switzerland, no country proposed amendment of the Article 31 solution to the exclusion of other solutions. The EC made a proposal of either amending Article 31 or using Article 30 to cover the export to countries with no manufacturing capacity. A large number of countries demanded normal use of Article 30 to fulfil the requirement of access to medicines to countries without the capacity to manufacture the same, as permitted by the TRIPS Agreement. However, the introduction of an overtly restrictive amendment by the WTO General Council in its August 30, 2003 Decision under the pretext of providing easy access of medicines to needy countries essentially amounts to rewriting TRIPS.

Paragraph 2 of the Chairman's Note as incorporated in the Decision of August 30, 2003 proposed the inclusion of restrictive norms neither required by the TRIPS Agreement nor present in any of the existing patent laws of the Member nations. The Note also appears to cover the proposal from the African countries to extend the concept of domestic market to the regional blocks, but given the way it has been drafted and the way it has been subjected to a number of impractical conditions, the Note as incorporated in the Decision effectively nullified the African proposal.

Apart from its Communications,¹⁵⁹ the USA in its attempt to bring finality to Motta's Note sent another document to the TRIPS Council saying that the USA "...will not seek to enforce Article 31(f) of the TRIPS Agreement through the WTO dispute settlement procedure against a WTO member," provided that certain conditions mentioned in the Chairman's Note are followed.¹⁶⁰ The degree of similarity between the Chairman's Note and the conditions stated in the US Moratorium is remarkable.

G. Diversion of Patented Products and Imposition of New Regulations

The Chairman's Note as fully incorporated in the final Paragraph 6 Solution of August 30, 2003¹⁶¹ is based on Article 31 of the TRIPS Agreement and, by removing

¹⁵⁹ US Second Communication, *supra* note 66, at 29, which says "While each option suggested by Members has some merit, at this stage we believe an expeditious, workable, transparent, sustainable and legally certain solution may more likely be achieved through either a moratorium for dispute settlement or a waiver of the obligation in TRIPS Article 31(f). A moratorium or waiver of the obligation of TRIPS Article 31(f) may have several advantages over other options suggested by Members."

¹⁶⁰ Moratorium to Address needs of Developing and Least-Developed Countries with No or Insufficient Manufacturing Capacities in the Pharmaceutical Sector: Communication from the United States, IP/C/W/396 (Jan. 14th, 2003).

¹⁶¹ See Decision of August 30, 2003, *supra* note 7.

the Article 30 TRIPS solution completely, it indicates that developing countries do not have much of a voice in international negotiations and their presence is only to provide legitimacy to a treaty. The attempt to restrict the use of Article 30 to facilitate access to medicines was started by a number of scholars including Alan Sykes,¹⁶² Frederick Abbott¹⁶³ and Gillespie White.¹⁶⁴ Sykes stated that developing countries did not suggest "...that they may rely on Article 30 to deal with the pharmaceutical issue,"¹⁶⁵ yet the Draft Ministerial Declaration submitted by the developing countries in paragraphs 5 and 9 specifically demanded that "[u]nder Article 30 of the TRIPS Agreement, members may, among others, authorise the production and export of medicines by persons other than holders of patents on those medicines to address public health needs in importing members."¹⁶⁶ On the basis of a misunderstanding that a domestic patent act is applicable internationally, Abbott observed:

*The authorisation to make and export under certain conditions might unreasonably prejudice the interests of the patent holder. An authorisation to supply a high-income market might under some circumstances prejudice the interests of the patent holder. An authorisation regarding a low –income market might unreasonably prejudice the interests of the patent holder if the exports were systematically diverted to high-income markets, thereby undermining the commercial return on the patent.*¹⁶⁷

Gillespie White reiterated this position.¹⁶⁸

The artificial criteria suggested by Abbott of high- and low-income markets appear to ignore a large body of case law on patents as well as Article 30 of the TRIPS Agreement. To make and export under Article 30 to fulfil the obligations of Article 31 of another country does not prejudice the interests of the patent-holder in the country

¹⁶² See Alan O. Sykes, *TRIPS, Pharmaceuticals, Developing Countries, and the Doha "solution"*, CHI. J. INT'L. L. 47 (2002).

¹⁶³ See Abbott, *supra* note 111. Also see Frederick Abbott, *The Doha Declaration on the TRIPS Agreement and Public Health: Lighting a Dark Corner at the WTO*, 5 J. INT'L. ECON. L. 469, 499 (2002).

¹⁶⁴ See L. Gillespie-White, *What Did Doha Accomplish? Doha Declaration on Intellectual Property rights and Access to Medicines: What was really achieved?* (Nov. 19, 2001), available at <http://mail.iipi.org/db/views/detail.asp?itemID=21>.

¹⁶⁵ See Sykes, *supra* note 183, at 52.

¹⁶⁶ Developing Countries' Proposal, *supra* note 10, 5 and 9.

¹⁶⁷ See Abbott, *supra* note 111.

¹⁶⁸ See L. Gillespie White, *supra* note 168.

of manufacture. The patent-holder in the country of manufacture does not have any interest where there is no patent for the product or where a compulsory licence has been issued for any reason, from non-local working to emergency to the other situations mentioned in Articles 31 and 27.2 of the TRIPS Agreement. Dealing with the illegal diversion of such patented products to third countries is the responsibility of the patent-holder through private action against infringement. It has nothing to do with the exports under Article 30 of TRIPS to the country with no patenting right or a country that has suspended patent rights by issuing compulsory licences.

The likelihood of diversion of the patented products manufactured under compulsory licensing provisions to countries which have patents for the products has always been present. In the UK, the products produced under compulsory licensing are specifically permitted to be exported as an encouragement of export and this is regarded as being a part of the public policy.¹⁶⁹ Does Article 31 of TRIPS require that patented products under compulsory licensing should be of a different colour and size and have different labelling? Is there any requirement in Article 31 of the TRIPS Agreement to inform the WTO or TRIPS Council regarding manufacture and export of such patented products? The answer to both the above questions is no. The situation is no different in the case of the manufacture of patented products for export to fulfil the requirements of countries with no manufacturing capacity, and it does not require this elaborate and cumbersome procedure in the name of information-gathering and generating competition among the suppliers.

V. THE LEGALITY OF THE PARAGRAPH 6 SOLUTION

A. Authoritative Interpretations and Exports under Article 30

Paragraph 29 of the USA's Second Communication questioned the legal merit of an authoritative interpretation by the Ministerial Council of the WTO. The inconsistency of this argument becomes apparent when one examines the decision of the Appellate Body in *Japan Taxes on Alcoholic Beverages*,¹⁷⁰ in which the Appellate

¹⁶⁹ Penn Engineering and Manufacturing Corporation's Patent, [1973] R.P.C. 233. (Justice Graham J. in his observation stated "In my judgement, particularly at the present time, public interest does demand that exports from this country should be on as large scale as possible. At the same time it would not be right to deprive the inventor of such reasonable remuneration as he may be able to get from his own exploitation of his patent. ...If however the patentee is not manufacturing here and does not process foreign patents in countries in which there is not likely to be a market for export from this country, there seems very little, if any, reason to put restrictions on export in a compulsory licence to be granted.").

¹⁷⁰ *Japan Taxes*, *supra* note 110.

Body had accepted the USA's argument that a panel report does not have significance even as a subsequent practice and stated that authoritative interpretations are the sole prerogative of the Ministerial Conference and not of the Panel or the Appellate Body. As observed by the Appellate Body, the adopted Panel report is not even a "definitive interpretation" of the relevant provisions of GATT 1994.¹⁷¹ The reasoning given by the Appellate Body is: "There is a specific cause for this conclusion in the WTO Agreement. Article IX:2 of the WTO Agreement provides: 'The Ministerial Conference and the General Council shall have the exclusive authority to adopt interpretations of this Agreement and of the Multilateral Trade Agreements.'" Article IX:2 provides further that such decisions "shall be taken by a three-fourths majority of the members". The fact that such an "exclusive authority" in interpreting the treaty has been established so specifically in the WTO Agreement is reason enough to conclude that such authority does not exist by implications or by inadvertence elsewhere."¹⁷² Authoritative interpretations by the Ministerial Conference or the General Council of the WTO thus cannot be questioned by the Dispute Settlement Body.

The EC's attempt to consistently undermine Article 30 of TRIPS is evidenced by its argument of the societal neutrality of Article 30 in *Canada Patent Protection*, which was accepted by the Panel without any contextual support.¹⁷³ It was with great difficulty that the developing countries managed to introduce the requisite sensibility in treaty interpretation through the Doha Declaration by incorporating the fact that the TRIPS Agreement is to be interpreted in terms of societal values and not in terms of societal neutrality. By resorting to Article 31(f) solutions for Paragraph 6 in the Doha Declaration, however, the developed countries appear to have nullified the Doha Declaration.

B. Article 30 of TRIPS and Judicial Decisions

The USA's assertion in paragraph 31 of its Second Communication that "[i]nterpreting Article 30 to allow Members to amend their patent laws to permit compulsory licenses to be granted to authorise their manufacturers to produce and export patented pharmaceutical products to other countries"¹⁷⁴ is incorrect, not because there is no provision of issuing compulsory licensing under Article 30 of

¹⁷¹ See *id.*, at 12, "We do not believe that the contracting parties, in deciding to adopt a panel report intended that their decision would constitute a definitive interpretation of the relevant provisions of GATT 1947. Nor do we believe that this is contemplated under GATT 1994. There is a specific cause for this conclusion in the WTO Agreement."

¹⁷² *Id.*, at 12.

¹⁷³ See *Canada-Patent Protection*, *supra* note 6, at 4.30(a), indent 2.

¹⁷⁴ See US Second Communication, *supra* note 63, at 31.

TRIPS (if the conditions are satisfied, the patented products can be manufactured and sold without any case-by-case analysis as in Article 31) or because it was against Article 4bis of the Paris Convention, but because it is in disregard of its own patent laws as interpreted by the US Supreme Court and other courts in their judgments. The USA's fundamental problem with the Article 30 solution seems to be the non-payment of remuneration to the patent-holder, which limits multinational companies' litigation capacity. The developed countries have supported remuneration not because remuneration is important in itself, but because the question of remuneration would provide unlimited litigation opportunities, which could apparently be used to block any use of compulsory licensing.

The inconsistency in the US Second Communication regarding freedom to export the patented product is reflected in *Deepsouth Packing Co., Inc. v. Laitram Corporation*,¹⁷⁵ in which the US Supreme Court observed: "If Laitram has a right to suppress Deepsouth's export trade it must be derived from its patent grant, and thus from the patent statute. We find that 35 USC. 271, the provision of the patent laws on which Laitram relies, does not support its claim."¹⁷⁶ Justice Laddie also observed in the context of copyright, "If the devices (infringing) are to be sold in a country where manufacture of the unlicensed copies is not proscribed and therefore not objectionable, there is no compelling reason why the handling of them here should be proscribed."¹⁷⁷ Neither TRIPS nor internal patent laws explicitly or implicitly prohibit the export of patented products.¹⁷⁸ The non-applicability of the exporting monopoly to the export of patented products would remove the need for reliance on the exceptions permitted under the TRIPS Agreement, and there is no reason why the Article 31 provision should be resorted to for this purpose.

C. Article 30 of TRIPS and Extraterritoriality in US Patent Act

The US's First and Second Communications also appear to be attempts to introduce amendments to the internal patent law of the USA through international negotiations.¹⁷⁹ In 1994, using the TRIPS negotiations framework, through the Uruguay Round Agreements Act,¹⁸⁰ the US Patent Act was made far more restrictive than it was before by including the introduction of the terms "importing", and "offering

¹⁷⁵ *Deepsouth Packing Co., Inc. v. Laitram Corporation*, 406 US 518 (1972).

¹⁷⁶ *Id.* at 528.

¹⁷⁷ *Kabushiki Kaisha Sony Computer Entertainment v. Ball*, [2004] EWHC 1984 (Ch), 21.

¹⁷⁸ See Daya Shanker, *Paragraph 6 Solution of the Doha Declaration and Exports under the TRIPS Agreement*, 7 J. WORLD INTELL. PROP. 365 (2004).

¹⁷⁹ *Id.*

¹⁸⁰ Pub. L. No. 103-465, ss. 532, 533, 108 Stat. 4809, 4983-90 (1994).

for sale”, and extending the patenting period to twenty years.¹⁸¹ Barfield and Groombridge asserted that the importation amendment provides “full statutory backing for United States patent holders to block parallel imports”,¹⁸² which is rather an incongruous assumption.¹⁸³ This use of international negotiations to incorporate expansive restrictions in the patent laws of developing countries appears to be an extraterritorial expansion of the patent laws of developed countries. In spite of the introduction of clauses (f) and (g) in § 271, the extraterritoriality of the US Patent Act has so far been interpreted in a limited manner by US courts, and the US Supreme Court has held that the US Congress is not empowered by the US Constitution to extend its patenting act beyond its borders.¹⁸⁴

The term “normal exploitation” of a patent pertains to the commercial exploitation in the territory of the patent, and would not cover the situations where the patented products do not affect the commercial marketplace. By insisting that movement of the patented products outside the territory of the patent would affect the normal exploitation of the patent, the USA is suggesting that the effect of the patent extends outside the territory of the patent, a concept not permitted by the territoriality enshrined in the TRIPS Agreement through Article 4bis of the Paris Convention and

¹⁸¹ As amended by the Uruguay Round Amendment Act, Patent Act, § 154 (a) (1) says: “Every patent shall contain a short title of the invention and grant to the patentee, his heirs or assignees, the right to exclude others from making, using, offering for sale, or selling the invention throughout the United States or importing the invention into the United States, and, if the invention is a process, of the right to exclude others from using, offering for sale or selling throughout the United States, or importing into the United States, products made by that process, referring to the specifications of the particulars thereof. 35 USC. s. 154(a)(1). § 271(a), as amended, provide: [e]xcept as otherwise provided in this title whoever without authority makes, uses, offers to sell, or sells any patented invention, within the United States or imports into the United States any patented invention during the term of the patent therefore, infringes the patent 35 USC. § 271 (a).”

¹⁸² See Claude E. Barfield & Mark A. Groombridge, Parallel Trade in the Pharmaceutical Industry: Implications for Innovation, Consumer Welfare, and Health Policy, 10 FORDHAM INTELL. PROP., MEDIA AND ENT. L. J., 185 (1999) at 198.

¹⁸³ See generally Margareth Barrett, The United States’ Doctrine of Exhaustion: Parallel Imports of Patented Goods, 27 N. KENT. U. L. R. 911 (2000); Daya Shanker, *supra* note 41.

¹⁸⁴ Brown v. Duchesne 60 US 183, 195-196 (1856). “The patent laws are authorised by that article in the Constitution which provides that Congress shall have power to promote the progress of science and useful arts, by securing for limited time to authors and inventors the exclusive right to their respective writings and discoveries. The power thus granted is domestic in its character, and necessarily confined within the limits of the United States. It confers no power on Congress to regulate commerce, or the vehicles of commerce, which belong to a foreign nation, and occasionally visit our ports in their commercial pursuits.”

in the USA by its Constitution.¹⁸⁵ A number of decisions by the US Court of Appeals have also followed the principle of the territorial limits of the patents. For example, in *Trustees of Columbia University in the City of New York v. Roche Diagnostics*,¹⁸⁶ Columbia University tried to extend the effect of the US Patent Act's extraterritoriality by arguing that Roche was liable under § 271(a) because an American company owned the cell lines used by Roche in Germany, and because Roche imported serum-free EPO, a by-product of the Axel patents, into the USA. The argument was rejected as "suggesting that ownership status transcends geographical boundaries".¹⁸⁷

So far, § 271(f) of the US Patent Act has been strictly interpreted as applicable only to component parts.¹⁸⁸ § 271(b) appears to extend the US Patent Act to extraterritorial situations, such as inducement to direct infringement within the United States. Although the Federal Appeals Court in *Packard Co. v. Bausch & Lomb*¹⁸⁹ decided that such extraterritorial activity to encourage and advance the infringement should be accompanied with actual intent, circumstantial evidence was found to be sufficient to show such intent.¹⁹⁰ From the discussion in *Hauni Werke Koerber & Co. v. Molins*,¹⁹¹ it appears that the observation of the US Supreme Court in *Strassheim v. Daily*,¹⁹² a case dealing with two states within the USA, has been interpreted as permitting extraterritorial use of § 271(b) of the US Patent Act dealing with inducement to infringe. Although the Court did not decide the extraterritoriality of § 271(b) in *Hauni Werke Koerber* and its observation can thus at most be regarded as *obiter dicta*, the injunctive relief under § 283 of the US Patent Act has been interpreted as having extraterritorial implications.¹⁹³ It is worth noting here that the US Court of Appeals for the Federal Circuit declined to expand the territoriality of the US Patent Act in *Johns Hopkins University v. Cell Pro*¹⁹⁴ when it observed that "neither export

¹⁸⁵ *Id.*

¹⁸⁶ *Trustees of Columbia University in the City of New York v. Roche Diagnostics*, 150 F. Supp. 2d 191 (D. Mass. 2001).

¹⁸⁷ *Id.* at 203 n. 30.

¹⁸⁸ *Standard Havens Products, Inc. v. Gencor Indus., Inc.* 953 F.2d 1360, 1374 (Fed. Cir. 1991) (foreign sales of a machine which used a patented asphalt-making process did not implicate s. 271(f) because no components were involved); *Aerogroup International Inc. v. Marlboro Footworks* 955 F. Supp. 220, 231 (S.D.N.Y. 1997) (a design patent for a shoe sole had no component parts to assemble, and therefore beyond the scope of s. 271(f)).

¹⁸⁹ *Packard Co. v. Bausch & Lomb*, 909 F.2d 1464, 15 USP.Q.2d 1525 (Fed. Cir. 1990).

¹⁹⁰ *Water Technologies Corp. v. Calco. Ltd.* 850 F.d 660, 668 (Fed. Cir. 1988).

¹⁹¹ *Hauni Werke Koerber & Co. v. Molins* (1974 US District. Lexis 8152).

¹⁹² 221 US 280, 285 (1911).

¹⁹³ *Spindelfabrik Suessen-schurr v. Schubert and Salzer* 903 F.2d 1568 (Fed. Cir 1990).

¹⁹⁴ *Johns Hopkins University v. CellPro*, 152 F.3d 1342 (Fed. Cir. 1998).

from the United States nor use in a foreign country of a product covered by a United States patent constitutes infringement.”¹⁹⁵ Thus, apart from limiting the patenting monopoly to the territory concerned, the export of patented products from the USA itself does not violate the US Patent Act. Thus, PhRMA and the USTR appear to be attempting to influence domestic patent legislation by introducing the idea that export would violate patent protection under Articles 28 and 30 of the TRIPS Agreement, and by insisting on introducing a plethora of regulations apparently to control diversion (and thus infringement) through an amendment in TRIPS.

D. The Paragraph 6 Solution and Its Legitimacy

The Paragraph 6 Solution arrived at by the members of the WTO on August 30, 2003 raises a number of important legal questions. Throughout the negotiations, the EC spoke of the amendment of Article 31 as one of the solutions of the Paragraph 6 of the Doha Declaration. In fact, the USA questioned the whole concept of authoritative interpretation by the Ministerial Conference as being of dubious significance,¹⁹⁶ in spite of the fact that the WTO Appellate Body in *Japan Alcohol* had categorically stated that the Ministerial Conference’s authoritative interpretation is binding on every WTO Member, unlike a decision of either the Panel or the Appellate Body.¹⁹⁷ On August 30, 2003, eleven days before the Ministerial Conference was to open at Cancun, the General Council decided that the Article 31 solution prepared by the Chairman of the TRIPS Council was the most appropriate option.¹⁹⁸ This solution and the accompanying statement of the Chairman of the General Council prescribing procedures¹⁹⁹ not only waived the obligations set out in paragraphs (f) and (h) of Article 31 of the TRIPS Agreement as per the preamble of the Decision, but also prescribed detailed procedures regarding the manufacture, movement and sale of the goods manufactured or to be manufactured to fulfil the requirements of the countries which do not have sufficient manufacturing capacity for such drugs.

A simple reading of the Marrakesh Agreement makes it abundantly clear that neither the General Council nor the Chairman of the General Council is authorised to waive the conditions or amend the provisions of TRIPS by adding or subtracting any of the provisions. The question of either of these authorities introducing conditions does not arise in any situation. Article IX(2) permits both the Ministerial Conference and the General Council to authoritatively interpret the provisions of the WTO,

¹⁹⁵ *Johns Hopkins University v. CellPro*, 152 F.3d 1342, 1366 (Fed. Cir. 1998).

¹⁹⁶ US 2nd Communication, *supra* note 63.

¹⁹⁷ *Japan Taxes*, *supra* note 110 at 9.

¹⁹⁸ See Decision of Aug 30, 2003, *supra* note 7.

¹⁹⁹ See *Chairperson’s Statement*, *supra* note 7.

whereas paragraphs 1, 3 and 4 of Article IX permit only the Ministerial Conference to waive any of the provisions. Although Article IV(2) of the Marrakesh Agreement says that in “the intervals between meetings of the Ministerial Conference, its functions shall be conducted by the General Council”, this authorisation cannot be interpreted to extend to each and every provision of the Marrakesh Agreement containing a reference to the Ministerial Conference, nor is it a correct interpretation to allow the General Council to take over when a Ministerial Conference is only days away. Such an interpretation would render any reference to the Ministerial Conference in Article IX(2) superfluous. There is also no mention at all of powers being given to the Chairman of the General Council to introduce conditions in the decisions taken either by the Ministerial Conference or by the General Council. The authority to conduct routine functions of the Ministerial Conference given to the General Council cannot extend to the decision-making authority of the Ministerial Conference; and, even if the General Council takes such decisions, they have to be confirmed and ratified by the Ministerial Conference. In the August 30, 2003 Decision, the General Council has not only taken a decision it is not authorised to take, it has also eliminated the Ministerial Conference from further monitoring the waiver through Paragraph 8 of the Decision, which says:

*The Council for TRIPS shall review annually the functioning of the system set out in this Decision with a view to ensuring its effective operation and shall annually report on its operation to the General Council. This review shall be deemed to fulfil the review requirements of Article IX:4 of the WTO Agreement.*²⁰⁰

There is no mention at all in the Marrakesh Agreement of any means by which the Chairman of the General Council may be permitted to introduce conditions in the decisions taken either by the Ministerial Conference or by the General Council. The decision to waive the conditions of Articles 31(f) and 31(h) is not legally appropriate. The waiver of Article 31(h) does not apply with respect to countries which do not have manufacturing capacity or which have issued compulsory licensing under Article 5A of the Paris Convention for non-working or insufficient working of the patent. The waiver is, at best, applicable specifically to Article 31(f), which says that the

²⁰⁰ On 28th August 2003, the Council for TRIPS approved the Draft Decision on “Implementation of Paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health” contained in document JOB(02)/217 and forwarded it along with the text of the statement contained in document JOB(03) /177 to be made by the Chairman of the General Council prior to the adoption of the Decision. On August 30 the General Council adopted the Decision in the light of the statement read out by its Chairman (WT/L/40). The Chairperson’s Statement, *supra* note 7.

Also see the 30 August 2003 Decision, *supra* note 7, at 8.

patented products manufactured under Article 31 should be “predominantly” for domestic consumption. The term “predominantly” has been defined in various dictionaries as frequently or mostly.²⁰¹ The meaning of “predominantly”, used by Frederick Abbott to refer to more than fifty percent of production was thus not appropriate, as mentioned by Abbott himself.²⁰² The principle of effectiveness in interpretation of international treaty demands that the provisions of a treaty must

²⁰¹ Abbott selected a definition of the word “predominantly” on the basis of the New Shorter Oxford Dictionary which defined predominantly as “(1) Having supremacy or ascendancy over others, predominating. (2) Constituting the main or strongest element, prevailing. (3) Rising High over.” (at 2329) as a major part or majority and insisted the reading of the word “predominantly” as “more than fifty percent of the production by a compulsory licence [which] should be intended for supply of the domestic market of the Member granting the licence.” This particular meaning of the word predominant was most non-compatible with the context of the exemption under Article 31. Abbott himself mentioned that “The difficulty with this interpretation is that it potentially reduces the term “predominantly” to a nullity, for example, if there were 80 Members receiving supplies under compulsory licence, perhaps only two percent (2%) might need to be supplied to the market of the member granting the licence to maintain its predominance.” In international treaty negotiations such type of interpretations are not permitted. In *Indonesia Automobile* (WTO, Report of the Panel, *Indonesia Certain Measures Affecting the Automobile Industry*, WT/DS55/R, WT/DS55/R, WT/DS/59/R and WT/DS64/R, dated 2 July 1998) based on the Vienna Convention, the Panel observed “In this context we recall the principle of effective interpretation pursuant to which all provisions of a treaty (and in the WTO system all agreements) must be given meaning using the ordinary meaning of words” to avoid turning them into nullity.

The ordinary meaning of “predominantly” in *Oxford Advanced Learners Dictionary* is “mostly” or “mainly.” The dictionary meaning of the term “Predominant” in *Collier’s Dictionary* which is also published as *Webster’s New World Dictionary of American English*, Third College Editing (1994) means “1. having ascendancy, authority or dominating influence 2. to be dominant in amount , number, etc. 3, most frequent. Thus the normal meaning of predominantly can be read as mostly or mainly or frequently. The normal meaning given to the word predominantly does not prohibit export of the patented products manufactured under compulsory licensing. It just says such manufacture mainly should be for domestic consumption and does not stipulate that it is to be measured in quantity as suggested by Frederick Abbott.

Using the ordinary meaning of the word predominantly as mainly or mostly, there is no obligation that is to be waived and the waiver just becomes superfluous and has essentially been used to impose obligations where there have been no such obligations.

²⁰² See generally Frederick Abbott, *Compulsory Licensing for Public Health Needs: The TRIPS Agenda at the WHO after the Doha Declaration on Public Health*, Quaker United Nations Office- Geneva, Occasional Paper 9, February 2002, p. 26 available at <http://www.geneva.quino.info/pdf/OP9%20Abbott1.pdf>; Duncan Matthews, *WTO Decision on Implementation of Paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health: A Solution to the Access to Essential Medicines Problem?* 7 J. INT’L ECO. L., 73, 78 (2004).

have meaning to avoid them turning into a nullity.²⁰³ If the ordinary meaning of the word “predominantly” – mostly – is used, there can be no ban on manufacture and export under a compulsory licence issued under Article 31(f) of more than fifty percent as suggested by Abbott.

VI. INTERNATIONAL NEGOTIATIONS AND RELEVANCE OF DEVELOPING COUNTRIES

A. The Paragraph 6 Solution and Power as Exclusion

Negotiations regarding Paragraph 6 of the Doha Declaration show the presence of tendencies which suggest the use of primitive power in international negotiations as discussed by Prof. Robert Hudec.²⁰⁴ He observes that “international legal arrangements have relatively more in common with laws of primitive societies studied by anthropologists, in which litigation is still emerging as a rather tenuous alternative to dispute resolution by force.”²⁰⁵

The absence of meaningful participation by developing countries in the WTO negotiations, particularly TRIPS, has been discussed by a number of scholars. Gathii used Susan Strange’s definition of structural power as the ability to set “the rules of

²⁰³ WTO, Report of the Appellate Body, *United States – Standards for Reformulated and Conventional Gasoline*, WT/DS/9, adopted 20th may 1996, p. 23 Principle of Effectiveness-One of the important observations of the Appellate Body in *Alcoholic Beverages* is that of the principle of effectiveness (ut res valeat quam pereat) which was determined as a “fundamental tenet of treaty interpretation” flowing from the general rule of interpretation set out in Article 31 of the Vienna Convention. In *United States – Standards for Reformulated and Conventional Gasoline*, the Appellate Body observed that “one of the corollaries of the ‘general rule of interpretation’ in the Vienna Convention is that interpretation must give meaning and effect to all the terms of the treaty. An interpreter is not free to adopt a reading that would result in reducing whole classes or paragraphs of a treaty to redundancy or inutility”.

²⁰⁴ See Robert Hudec, “*Transcending the Ostensible*”: *Some Reflections on the Nature of Litigations Between Governments*, 72 MINN. L. R. 211, 212 (1987).

²⁰⁵ See also Meinhard Hilf, *Power, Rules and Principles – Which Orientation for WTO/GATT Law?*, J. INT’L. ECO. L. 111 (2001); Karin Mickelson, *Third World Voices in International Discourse*, 16 WIS. INT’L L. J., 353, 413 (1998). Mickelson says, “Third World writers are frequently characterised as having tremendous faith in the ability of law in general, and international law in particular, to institute social justice. Yet these writers are well aware of the ways in which law has been made to serve the interests of the powerful, and there is something quixotic in their attempts to transform what is perceived as an essentially oppressive discourse into a liberatory one.”

the game”²⁰⁶ to argue that, “[t]o the extent that patents are therefore a barrier to access antiretrovirals, the TRIPS Agreement is no more than a form of structural power.”²⁰⁷ This ability to set the rules of the game becomes apparent in the context of TRIPS when one observes that the USA and the EC initiated twenty-one of the twenty-three WTO complaints under TRIPS; the remaining two, by Brazil and Canada, were reaction complaints against the United States and EC, initiated to gain some bargaining power.²⁰⁸ However, Drahos based his argument regarding the TRIPS Agreement on “unequal power relations and disparities in information and organisational resources.”²⁰⁹ He identified four basic sources of power in the context of international treaty negotiations. These are: (1) the market power of the powerful states such as the USA; (2) commercial intelligence networks, which includes a state’s trade bureaucracy, its business organisations and its individual corporations; (3) enrolment power, which Drahos defined as a state’s capacity to enrol state and non-state actors in a coalition; and (4) a state’s domestic institutions restricting its negotiators within certain norms, which is exemplified by the European Commission, which deals specifically with trade issues.²¹⁰

Drahos is supported by Shaffer, who discussed inequality in international negotiations in the context of reduction in developing countries’ “participation in the international trade dispute settlement system in complaints against developed countries” in the WTO, compared to their relative participation under the less legalised GATT.²¹¹ Following Drahos, Shaffer also suggested that developing countries must pool their resources through national, regional and international centres specialising

²⁰⁶ See Conversation with Susan Strange, available at http://www.geocities.com/jt_revino41/STRANGE.DOC; She also argues that it is “only by looking at the structural power exercised –often unconsciously–over other states, markets, private individuals, and firms by the agencies of the United States can the extent of the asymmetries of state power be appreciated.” See Susan Strange, *The Defective State*, 124 *DAEDALUS* 55, 64 (1995).

²⁰⁷ See Gathii, *supra* note 11, at 269.

²⁰⁸ See Gregory Shaffer, *Recognizing Public Goods in WTO Dispute Settlement: Who Participates? Who Decides? The Case of TRIPS and Pharmaceutical Patent Protection*, 7 *J. INT’L ECO. L.* 459-482, 472 (2004) (“As for the complaints under the TRIPS Agreement, either the United States or EC initiated 21 of the 23 TRIPS complaints brought through January 2003 (15 by the United States and 6 by the EC). Brazil and Canada each initiated one TRIPS complaint, but these were merely symbolically claims that they filed in response to WTO complaints. . . . As regards TRIPS complaints that resulted in an adopted panels or Appellate Body report, the United States was a party in all seven, and the EC in six of the seven, cases.”).

²⁰⁹ See Drahos, *supra* note 13, at 80.

²¹⁰ See Sophie Meunier, *What Single Voice? European Institutions and EU-US Trade Negotiations*, 54 *INT’L. ORG.* 103-135 (2000).

²¹¹ See Shaffer, *supra* note 213, at 472.

in trade-related intellectual property issues, as well as through developing closer relations with the US and EC domestic institutions to neutralise the clout of large pharmaceutical firms and work with generic pharmaceutical industries in their own countries. However, Shaffer did not appear to be hopeful of the success of such policies in the presence of the “extra-legal coercion” that the United States and, to a lesser extent, the EC could employ.²¹² Steinberg also discussed the inequality in the WTO negotiations, attributing it to the lack of market power of developing countries compared to that of the USA and EC, along with the lack of internal transparency.²¹³

However, the power structure discussed by Gathii, Drahos, Shaffer and others misses the point that power is not limited to its structural formulations, but also comprehensively affects the relationship between developed and developing countries, and that it is not the inability of the developing countries to form a coherent group which undermines their negotiating capabilities, but rather the fact that power comes with a string of negatives such as exclusion, rejection, barriers, denial and dissimulation, which prohibits the formation of a coherent group capable of resisting the unrestricted use of power by developed countries.²¹⁴ This development can be seen during the TRIPS negotiations, where India and Brazil were isolated and pushed into submission through the use of Special 301 by the USA. Similar developments were witnessed during the paragraph 6 negotiations when African countries disassociated themselves from the main group for no apparent reason or benefit.

The developments leading up to the Paragraph 6 solution suggest that developing countries are not in a position to participate effectively and meaningfully in international treaty negotiations. The weakness of developing countries becomes evident when in their Draft Ministerial Declaration, they found themselves forced to protect themselves by requesting that each member “shall refrain from imposing or threatening to impose sanctions and refrain from employing the grant of incentives or other benefits in a manner which could curtail the ability of developing and least developed country Members to avail themselves of every possible policy option to protect and promote public health.”²¹⁵ This weakness is further illustrated by paragraph

²¹² See *id.* at 476.

²¹³ See Richard H. Steinberg, *Judicial Law-Making, Internal Transparency, and External Transparency: Recent Institutional Developments at the WTO*, 37 INT'L LAWYER, (Spring 2003, at <http://www.law.berkeley.edu/cenpro/ils/papers/steinbergwtO17.pdf>).

²¹⁴ Anna Bennett, *Recognising Power: A Discourse Analysis of Power Relations*, A thesis submitted in fulfillment of the requirement for the degree of Doctor of Philosophy, The University of New South Wales, 2000. Bennett refers specifically to Foucault's understanding of power.

²¹⁵ Developing Countries' Proposal, *supra* note 10, at 10.

6(h) in the Proposal from the African Countries,²¹⁶ which says that bilateral and multilateral treaties should not be used to remove the flexibilities provided in the TRIPS Agreement.²¹⁷ The Revised Bangui Agreement between sixteen of the world's poorest African countries, which included exceptionally strict patenting provisions at the behest of WIPO as its technical consultant, is another example of the way in which these countries' sovereignties have been compromised at such negotiations.²¹⁸ The developing countries' proposals in the Doha Round were simply a reaffirmation of TRIPS as interpreted in terms of customary rules of interpretation, along with an attempt to introduce the rule of law and decency in international agreements; yet even this was rejected at the negotiations, despite the fact that no amendment to any of the provisions of the TRIPS Agreement was requested: it was only a question of simple interpretation in terms of Articles 7 and 8 of the TRIPS Agreement. To deal with such a request by attempting to introduce amendments to Article 31 and institutionalising an elaborate and extensive procedure to nullify the flexibilities present in TRIPS practically amounts to rewriting TRIPS.

Both Drahos and Gathii have described the power relationship between developed and developing countries appropriately, but the concept of power has another aspect in terms of Foucaultian perceptions of power. The underlying power not only sets ever-shrinking boundaries for less powerful nations but also significantly affects the group-formation behaviour of weaker nations and eliminates any possible significant resistance from a cohesive, goal-driven group.²¹⁹ This aspect of dysfunctional group behaviour became apparent when the African nations left the main group of developing countries during the final phase of submission and made their own submissions. It appears that the African nations made a separate deal with the USA which removed the possibility of an Article 30 solution for the Paragraph 6 of the Doha Declaration from the discussion. The Paragraph 6 solution included a diluted version of the African proposal of treating the regional grouping as a single market, which anyway should not have been a disputable issue even otherwise. The United

²¹⁶ See African Proposal dated 24th June, 2002, *supra* note 108 at 6(h).

²¹⁷ Oxfam has also made similar observations. See Oxfam, *US Bullying on Drug Patents: One Year After Doha*, Oxfam Briefing Paper No. 33, Nov. 2002, <http://www.oxfam.org.uk/policy/papers/33bullying.html>.

²¹⁸ See Oxfam, Conference Report: *Implementation of the Doha Declaration on the TRIPS Agreement and Public health: Technical Assistance-How to Get it Right*, 28th March 2002, International Conference Centre of Geneva (CISG).

²¹⁹ M. FOUCAULT, THE SUBJECT AND POWER: AN AFTERWORD BY MICHEL FOUCAULT" at 222, MICHEL FOUCAULT: BEYOND STRUCTURALISM AND HERMENEUTICS, H. DREYFUSS AND P. RABINOW (Eds) (1982). Also See M. FOUCAULT, THE HISTORY OF SEXUALITY VOL. I: AN INTRODUCTION, TRANS. R. HURLEY (1990), ORIG. 1976, p. 102.

States and the five member countries of the Southern African Customs Union (SACU) – Botswana, Namibia, Lesotho, Swaziland and South Africa – launched a free trade agreement on June 2, 2003 (South Africa also has a free trade agreement with the European Union). If other recent free trade agreements with the USA are any indicator, this free trade agreement will expand the industrial and other monopolies in SACU member countries, some of which are the world's main suppliers of gold and diamonds and are being mostly controlled by Western mining interests. These countries do not appear to have gained any advantage from this free trade agreement, and the USA's motives seem to be clear from Robert Zoellick's letter to Congress in which he stated: "We also see the negotiations (US-SACU Free Trade Agreement) as an opportunity to advance US objectives for the multilateral negotiations currently underway in the World Trade Organisation (WTO)."²²⁰

B. The Process of Power

Although inequality in international treaty negotiations and in subsequent interpretations of such treaties is clearly evident, what has not been discussed at length is how this power actually gets transformed into concrete unilateral documents. One example of this is the Argentina US Mutually Agreed Solution, which was a result of Argentina agreeing to all of the USA's demands under the auspices of the WTO's Dispute Settlement Understanding because of the pressure of its International Monetary Fund loan, which affected Argentina's financial institutions and caused a considerable amount of economic vulnerability. Once Argentina entered into the Mutually Agreed Solution with the USA pertaining to patenting issues which were not even in the complaint submitted by the USA to the DSU, the repayment was apparently postponed.²²¹ Similarly, the USA's use of Special 301 played a significant role in Brazil's capitulation during the TRIPS negotiations. However, the factors during the finalisation of the August 30, 2003 decision were quite different. There was no apparent use of Special 301 and no visible sign of IMF or World Bank interference. One possible reason for the capitulation of negotiators from developing countries is their weakness and susceptibilities to various attractions. There is no direct evidence of any outright corruption but the circumstances – the fact that the General Council allowed the Paragraph 6 Solution as prepared by Eduardo Motta on the basis of the US and EC proposals to be passed just eleven days before the Cancun Ministerial Meet, which was the authorised forum for any decision pertaining to the waiver of

²²⁰ Robert B. Zoellick, USTR Notifies Congress Administration Intends to Initiate Free Trade Negotiations with Sub-Saharan Nations, (May 11, 2002) available at http://www.ustr.gov/Document_Library/Letters_to_Congress/2002/USTR_Notifies_Congress_Admin.

²²¹ See generally, Daya Shanker, Argentina-US Mutually Agreed Solution, Economic Crisis in Argentina and Failure of the WTO Dispute Settlement System, 44 IDEA 565 (2004).

the conditions of Article 31, suggests that the negotiators did not maintain much transparency or rectitude during this negotiation. No reason has been given by any of the major developing countries to date regarding their total abandonment of the Article 30 solution. The use of Article 30 to manufacture and export the patented product does not need any authoritative interpretations at all. Any manufacture which did not affect the commercial market place of the patent holder in the territory of the patent could have easily been brought within the Article 30 exceptions. The total abandonment of any Article 30 solution by the developing countries' negotiators without any explanation points to some amount of corruption and compromise, howsoever small, involving the use of influence by the interested parties, including the Western pharmaceutical industry. The Criminal Law Convention on Corruption adopted in 1999 describes such use of influence as a corrupt act.²²² Former UN Secretary-General Annan argued that corruption undermines the rule of law,²²³ but there is also another question that arises: if the rule of law can be undermined in such a manner, is there not a need for a change in the system that permits it?

An important factor to consider is the economic influence of multinational corporations, who were active participants in the Paragraph 6 negotiations and seem to have played a role in the incorporation of exports as one of the patenting rights in the Paragraph 6 solution. Webb, while discussing the United Nations Convention Against Corruption, observed:

"...the huge economic influence of multinational corporations (MNCs) and the consequent leverage they have in relation to states, means that they are an actor that cannot be excluded from an international anticorruption strategy... These powerful non-state actors can make deals with developing country governments that represent a sizable share of a state's national income or resource endowments; they often negotiate with top public officials and, if it is a corrupt environment, the MNC must decide whether to participate actively, quietly refuse to deal, or report the corruption."²²⁴

²²² Council of Europe Criminal Law Convention on Corruption (COE Criminal Convention), done at Strasbourg, 27 January, (entered into force 1 July 2002), E.T.S. 173, available at <http://conventions.coe.int/Treaty/Html/173.htm>.

²²³ UN Secretary –General Kofi Annan, 'Message to the Third Global Forum on Fighting Corruption and Safeguarding Integrity,' delivered by Dileep Nair (Under-Secretary –General for Internal Oversight Services), 29-31 May 2003.

²²⁴ Phillip Webb, The United Nations Convention Against Corruption: Global Achievement or Missed Opportunity?, 8 J. OF INT'L ECONOMIC L. 191 (2005). See also BRAITHWAITE & DRAHOS, *supra* note 42.

The vulnerabilities and susceptibilities of the negotiators from developing countries can be reduced, if not completely eliminated, by introducing transparency in international negotiations, the lack of which has proved to be its Achilles' heel. Given the absence of any explanation from the Third World negotiators regarding the change of position during the TRIPS and Paragraph 6 negotiations, the explanation that TRIPS was the handiwork of Arthur Dunkel and Lars Anell and that the Paragraph 6 solution was the handiwork of Eduardo Motta and others in the TRIPS Council and the General Council would not cut much ice with the general public. To combat this, there should be a statute similar to the USA's Freedom of Information Act, which provides access to the information relating to such negotiations. For example, through the use of the Freedom of Information Act, the Center for International Environmental Law gained access to the documents leading to the US-Chile Free Trade Agreement.²²⁵ The absence of transparency in such negotiations, particularly on the part of the developing countries' negotiators, is a continued threat to the sovereignty and independence of the developing countries.

VII. SUMMARY AND CONCLUSION

Patenting in the context of access to medicines, particularly with respect to HIV sufferers from Africa, Asia and Latin America, has become a grave issue, which was exacerbated when a number of countries had to introduce strict patenting provisions under TRIPS which resulted in a large section of the world population not being able to access medicines at affordable prices. This resulted in the developing countries' proposal that the manufacture and export of medicines under the Article 30 exemption should cover a situation where a number of countries issuing compulsory licences do not have sufficient manufacturing capacity to produce such medicines. During the Ministerial Conference at Doha, this request was not accepted by the developed countries, and the matter was referred to the TRIPS Council as Paragraph 6 of the Doha Declaration on Public Health. A number of proposals were subsequently submitted to the TRIPS Council by various countries. The proposals from developed countries were based on modifications to Article 31 of the TRIPS Agreement and added a host of extra regulations, whereas the developing countries mostly wanted

²²⁵ Center for International Environment Law v. USTR, Civil Action No. 01-2350, US District Court (D. Col. 2002). Also see Earthjustice, Securing Public Participation in the Development of New Trade Rules, available at <http://www.earthjustice.org/urgent/print.html?ID=57> (While the US-Chile trade agreement was finalised last week and now heads to Congress for approval, this decision sets a legal precedent for a more transparent and democratic process that has been sought by public interest and environmental organisations for years but denied by both the Bush and Clinton administrations. This legal precedent will lead to more transparency in future trade negotiations.”).

authoritative interpretations of Article 30 to permit such activities. The common elements of the two sets of proposals were that the export of patented products would be restricted under TRIPS.

The major issue, however, is that a patent should not be granted that where the patented goods cannot be manufactured, i.e., enabled, since the limited monopoly extended to patented products is for the advancement of science and is not to be treated as property in itself. The incapacity to manufacture would also invite issue of compulsory licences for failure to work under Article 5A(2) of the Paris Convention. Since patenting is completely territorial under Article 4bis of the Paris Convention and the export of patented products cannot hurt the interests of the patent-holder in a country where the said patent right either does not exist or has been suspended, there is no merit in the USA's assertions that Article 30 of TRIPS would be violated. The exclusion of the developing countries' proposals by the Chairman Motta from his Note and from the final Paragraph 6 solution, echoing the exclusion of their proposals from TRIPS, is condemnable; and its legal basis is questionable. This marginalisation of developing countries' views is a result of the manipulation and coercion of MNCs and developed countries, as well as the vulnerabilities of the negotiators from developing countries. In the wake of the HIV pandemic, the urgent need for drugs in countries that do not have the requisite manufacturing capacity is more than ever before, and developing countries are often put in a position where they are forced to compromise to get some access to medicines rather than none at all, a situation that is clearly unacceptable given the state of the pandemic in developing regions such as sub-Saharan Africa. If international instruments are to be truly "international" in nature, then the voices of developing countries need to be taken note of and not brushed aside when drafting a final document that will be binding on those very countries. Since the voluntary introduction of transparency in international negotiations has not occurred, a freedom of information statute at an international level would help to combat this problem and prevent obligations from being unilaterally imposed on developing countries in the way that the Paragraph 6 solution and TRIPS before it were.