

B. The events preceding the Public Health Declaration

I. The GATT system and the Uruguay Round

Towards the end of World War II the coalition parties commenced negotiations on a new world order with economic growth, stable currencies and trade liberalisation as its three pillars. The system they negotiated, known as the Bretton Woods Agreements, sought to realise these goals through the creation of three international institutions. The first two, International Monetary Fund and the International Bank for Reconstruction and Development (now part of the World Bank), were created to manage and finance the system. The third pillar, the International Trade Organisation ('ITO'), would serve to bring about trade liberalisation.⁵⁹ Domestic opposition within the US prevented the completion of the treaty process creating the ITO.⁶⁰ Although the parties were unable to formalise the ITO, they were able to salvage one treaty – the General Agreement on Tariffs and Trade (the 'GATT Agreement'). Making the most of the situation, the 23 signatory parties adopted the GATT Agreement in 1948. To ensure its development the GATT Agreement provided for the implementation of its provisions, the accession of new members and implemented a system of negotiating rounds to expand the scope of the agreement.

As the name indicates, the GATT Agreement governs the use of tariffs and similar trade measures to ensure that GATT Member States are not unreasonably affected by arbitrary or unreasonable measures taken by other Member States. The GATT Agreement recognised that certain circumstances would justify the non-compliance with these rules. To this effect the parties adopted Article XX of the GATT Agreement which allows Member States to ignore the application of the GATT provisions when, *inter alia*, they are 'necessary to protect human, animal or plant life and health'.⁶¹ The exclusions contained in Article XX are extensive; despite this GATT Member States invoking its use have had little success under the GATT Panels.⁶² Beyond tariff measures to protect the public health in accordance with Article XX(b) of the GATT Agreement, the role of health, and intellectual property rights for that matter, played little or no role.⁶³

59 Parry *et al*, *Encyclopaedic Dictionary of International Law* (Oceana New York 1986) p. 188.

60 Matsushita *et al*, *The World Trade Organization: Law, Practice, and Policy* (2nd edn OUP Oxford 2006) p. 1-2.

61 GATT Agreement Art XX(b).

62 For example GATT Japan – Custom Duties, Taxes and Labelling Practices on Imported Wines and Alcoholic Beverages – Report of the Panel (10.11.1987) L/6216 – 34S/83, GATT Thailand – Restrictions on the Importation of and Internal Taxes on Cigarettes – Report of the Panel (07.11.1990) DS10/R – 37S/200, GATT Tuna/Dolphins I – Report of the Panel 39S/155 and its successor GATT Tuna/Dolphins II – Report of the Panel.

63 With the exception of Art XX(d) of the GATT Agreement and the only two GATT disputes concerned with intellectual property protection GATT *United States – Imports of certain automobile spring assemblies* Report of the Panel (26.05.1983) L/5333 30S/107, GATT *United States – Section 337 of the Tariff Act of 1930* Report of the Panel (07.11.1989) L/6439

In 1986 the GATT Member States agreed to enter into a round of negotiations that would encompass a number of issues above and beyond tariffs and trade and ultimately lead to the formation of the WTO. The round, known as the 'Uruguay Round', contained the following mandate:

'In order to reduce the distortions and impediments to international trade, and taking into account the need to promote effective and adequate protection of intellectual property rights, and to ensure that measures and procedures to enforce intellectual property rights do not themselves become barriers to legitimate trade, the negotiations shall aim to clarify GATT provisions and elaborate as appropriate new rules and disciplines. Negotiations shall aim to develop a multilateral framework of principles, rules and disciplines dealing with international trade in counterfeit goods, taking into account work already undertaken in the GATT. These negotiations shall be without prejudice to other complementary initiatives that may be taken in the World Intellectual Property Organization and elsewhere to deal with these matters.'⁶⁴

Negotiating the future TRIPS Agreement was a thorny issue. For a start it was only one agreement amongst a number that were been considered by the GATT parties. The issues under negotiation were not only tariff barriers but also non-tariff barriers. The goal of the Uruguay Round was to create a treaty-enforced harmonisation system that would extend beyond the GATT trade issues. It was clear that the expanse of the negotiations would not only result in the increased regulation of foreign trade practices but also in the limitation of the national sovereign economic policies and a dramatic shift in the internal regulatory discretion and the pre-existing balance of domestic interests.⁶⁵ In addition to the wide scope of negotiations the whole Uruguay Round negotiations were being treated as a single undertaking, i.e. the negotiating parties could only accept all of the agreements to accede to the WTO.⁶⁶ A negotiating party could not subscribe to one agreement and reject the rest. The single undertaking increased the pressure on the negotiating parties to find a mutually acceptable consensus, as whoever objected would not be a party to the WTO and thus would be unable to take advantage of its rules, opportunities and obligations.

Negotiating rights concessions under this 'all or nothing' atmosphere was taxing for the developing countries. Their lack of financial resources, manpower and technical knowledge meant that they were unable to submit meaningful proposals and responses but they were also unable meaningfully comprehend the scope and effect

36S/402. In the latter case, at para 6.1, the Panel expressly noted that their authority was limited to the US provision infringing the national treatment provisions, Art III of the GATT Agreement.

64 GATT Ministerial Declaration on the Uruguay Round (20.09.1986) MIN.DEC para D, *Chasen Ross and Wasserman*, Trade Related Aspects of Intellectual Property Rights in Stewart (ed) *The GATT Uruguay Round: A negotiating History (1986-1992)* (Kluwer The Hague 1993) vol II p. 2264-2265.

65 *Correa*, Health Economics: The Uruguay Round and Drugs (WHO Geneva 1997) p. 1, *UNCTAD/ICTSD*, Resource Book on TRIPS and Development (CUP New York 2005) p. 119.

66 *Gervais*, 1 *JIPLP* 4 (2006) p. 249.

of the issues being negotiated.⁶⁷ These shortcomings were compounded by the fact that negotiations were being conducted in several sectors simultaneously.

Added to the burdens faced within the scope of the WTO negotiations, some negotiating parties were being threatened with coercive actions should they not adopt measures to the liking of other negotiating parties. The US, itself pressed by multinational pharmaceutical companies, exerted considerable unilateral political pressure on countries to adopt additional intellectual property protection, especially in the field of pharmaceutical patent protection.⁶⁸ The extension of the US's Special 301 to intellectual property rights permitted the US to unilaterally withdraw benefits and impose sanctions on those countries it feels are providing insufficient intellectual property protection.⁶⁹ The threat and use of this system led a number of countries to adopt additional patent protection measures for pharmaceutical products.⁷⁰ This threat of unilateral measures flowing from the Special 301 also heightened the discourse at the Uruguay Round negotiations. It was, amongst other reasons, this fear of unilateral reprisals that had a curious response: it encouraged countries to support a treaty on intellectual property rights. The reason for this was the hope that a multilateral treaty would set a fixed and universal standard and prevent other signatories from claiming patent protection above and beyond what was required by the treaty. Where conflicts could not be prevented the treaty, as envisaged by the Uruguay Round, would channel disputes through the multilateral dispute resolution process. This would provide a larger degree of security and, more importantly, impartiality.

67 *Gervais*, 1 JIPLP 4 (2006) p. 249-250.

68 The US was itself lobbied by large US multinational pharmaceutical and agro-chemical businesses. A group of 13 large US businesses formed the Intellectual Property Committee ('IPC') in 1983 in order to 'help convince the US officials that we need to take a tough stance on intellectual property issues'. According to *Pratt*, a former Pfizer CEO, advocate of the IPC and official advisor to the USTR, this pressure led the US to include intellectual property rights in the Uruguay Round of negotiations. See *Pratt*, (1995). *Straus* also notes that the US's initiatives were motivated by the lack of success in the modernisation of the Paris Convention. Cf. *Straus*, Patentschutz durch TRIPS-Abkommen – Ausnahmeregelungen und – praktiken und ihre Bedeutung, insbesondere hinsichtlich pharmazeutische Produkte in Bitburger Gespräche Jahrbuch 2003 (CH Beck Munich 2003) p. 119. *Straus* also refers to the US's 'aggressive unilateralism'. Cf. *Straus*, TRIPS, TRIPS-plus oder TRIPS-minus – Zur Zukunft des internationalen Schutzes des Geistigen Eigentums in: *Ohly et al* (eds) Perspektiven des Geistigen Eigentums und Wettbewerbsrechts (CH Beck Munich 2005) p. 198.

69 Pressure was exerted by the US primarily through the Special 301 system, introduced into the US Trade Act in 1988 by Sec 1303 of Omnibus Trade and Competitiveness Act of 1988 (23.08.1988) P.L. 100-418, 102 Stat. 1851. Cf. *Dwyer*, Trade Related Aspects of Intellectual Property Rights in Stewart (ed) The GATT Uruguay Round: A negotiating History (1986-1994) (Kluwer The Hague 1999) vol VI p. 495-508, 557-560, *Kiehl*, 10 J.Intell.Prop.L (2002) p. 149, *Matsushita et al*, The World Trade Organization: Law, Practice, and Policy (2nd edn OUP Oxford 2006) p. 135-139.

70 Bolivia, Chile, China, Columbia, Ecuador, El Salvador, Indonesia, Mexico, Peru, South Korea, Taiwan, Thailand and Venezuela have been listed as examples of countries that have succumbed to the US pressures after 1986. Cf. *Correa*, Health Economics: The Uruguay Round and Drugs (WHO Geneva 1997) p. 3-4.

Just as other negotiations on intellectual property rights before it, the central topics of the Uruguay Round negotiations on intellectual property rights, focused primarily on the rights and obligations of the rights holders.⁷¹ The length, scope and nature of patent rights dominated discussions. Developing countries, primarily India and Brazil, were concerned about the effects of the introduction of intellectual property rights without having remedial measures to counterbalance the rights of the rights holders and prevent abuse of their monopoly rights.⁷² The social and economic consequences of the introduction of intellectual property rights under the future TRIPS Agreement was never a real consideration in the negotiations.⁷³ There was an attempt by civil society to draw attention to the effect that intellectual property rights would have on access to pharmaceuticals, especially their prices, but this was largely ignored by the developed countries.⁷⁴

The development of negotiations for the TRIPS Agreement does however indicate that developed countries resources were strained. The developing countries were unprepared and under qualified for such negotiations. The developed countries had on the other hand presented a common position that was comprehensive and designed to enable a fast-paced negotiation process.⁷⁵ This tactic was chosen to diminish the developing community's opportunity from putting up a competent defence or submitting counter proposals.⁷⁶

71 The Paris Convention does not contain any specific measures for attending to health issues that conflict with intellectual property rights.

72 *Raghavan*, IFDA (1989) II, *Straus*, Implications of the TRIPS Agreement in the Field of Patent Law in: Beier and Schriker (eds) From GATT to TRIPS – The Agreement on Trade-Related Aspects of Intellectual Property Rights (VCH Weinheim 1996) p. 168-170. *Straus* correctly notes that each negotiating country had to weigh up the advantages and disadvantages of being bound to the WTO rules. Whereas some provisions may have brought stricter intellectual property rules they it is unlikely that would have been agreed to without such being outweighed by the benefits that such countries would acquire in joining the WTO.

73 *Correa*, IFDA (1995), *Gregg Bloche*, 5 JIEL 4 (2002) p. 825.

74 *Singh*, UNCTAD (2003) p. 17.

75 *Singh J Wriggle Rooms: New Issues and North-South Negotiations during the Uruguay Round* presented at the Conference on Developing Countries and the Trade Negotiation Process (UNCTAD Geneva 06/07.11.2003) 16-17.

76 *Straus*, Patentschutz durch TRIPS-Abkommen – Ausnahmeregelungen und –praktiken und ihre Bedeutung, insbesondere hinsichtlich pharmazeutische Produkte in Bitburger Gespräche Jahrbuch 2003 (CH Beck Munich 2003) p. 120, *Raghavan*, IFDA (1989) I. It is also mentioned that some developing negotiators suspected that the GATT Chairman and the Secretariat came with a well-prepared programme to achieve a quick result. This suspicion was confirmed by J Enyart who stated we 'went to Geneva where we presented (our) document to the staff of the GATT Secretariat. What I have described to you is absolutely unprecedented in GATT. Industry has identified a major problem in international trade. It crafted a solution, reduced it to a concrete proposal and sold it to our own and other governments ... The industries and traders of world commerce have played simultaneously the role of patient, the diagnostician and the prescribing physician.' Cf. J Enyart, quoted in *Keayla*, Conquest by Patents. The TRIPS Agreement on patent laws: Impact on Pharmaceuticals and Health for All (CSGTSD New Delhi 1998).

Notwithstanding the pressures exerted, developing countries were not forced to accept the final act. It became clear to developing countries that the TRIPS Agreement was the lesser of the two evils; it would leave them better off than being exposed to the vigorous unilateral threats and actions of the US.⁷⁷ As a compromise for the acceptance of the future TRIPS Agreement, the developing negotiating parties were able to obtain concessions in the agricultural and textile sectors and, within the TRIPS Agreement, on compulsory licensing, patent protection for pharmaceuticals and the special needs in connection with development.⁷⁸ In addition thereto, the developed negotiating parties agreed to include additional provisions that would benefit developing countries. They included provisions providing for the transfer of technology to developing states,⁷⁹ the gradual enforcement of the provisions according to the country's level of development,⁸⁰ a sympathetic preamble with corresponding objective and principle provisions⁸¹ and technical assistance in favour of developing countries.⁸² So it was that the TRIPS Agreement was accepted and, on the 1st of January 2005, that it came into force.⁸³

II. The implementation of the TRIPS Agreement

As stated above, developing Member States were able to secure a number of minor concessions. The most obvious concession was the transitional arrangements found

77 Singh, UNCTAD (2003) p. 11-12, Dwyer, Trade Related Aspects of Intellectual Property Rights in Stewart (ed) The GATT Uruguay Round: A negotiating History (1986-1994) (Kluwer The Hague 1999) vol VI p. 571-574, Hauser and Roitinger, 64 ZaöRV (2004) p. 642, Straus, TRIPS, TRIPS-plus oder TRIPS-minus – Zur Zukunft des internationalen Schutzes des Geistigen Eigentums in: Ohly et al (eds) Perspektiven des Geistigen Eigentums und Wettbewerbsrechts (CH Beck Munich 2005) p. 197.

78 Straus correctly notes that the TRIPS Agreement was part of a 'package deal' and the concessions made in respect to intellectual property are to be viewed together with the gains obtained in goods and services. Cf. Straus, TRIPS, TRIPS-plus oder TRIPS-minus – Zur Zukunft des internationalen Schutzes des Geistigen Eigentums in: Ohly et al (eds) Perspektiven des Geistigen Eigentums und Wettbewerbsrechts (CH Beck Munich 2005) p. 199. See also UNCTAD/ICTSD, Resource Book on TRIPS and Development (CUP New York 2005) p. 4, WTO Canada – Pharmaceuticals p. 28, Dwyer, Trade Related Aspects of Intellectual Property Rights in Stewart (ed) The GATT Uruguay Round: A negotiating History (1986-1994) (Kluwer The Hague 1999) vol VI p. 525-527.

79 TRIPS Agreement Art 66.

80 TRIPS Agreement Arts 65-66, 70.

81 TRIPS Agreement Arts 7-8, UNCTAD/ICTSD, Resource Book on TRIPS and Development (CUP New York 2005) p. 11.

82 TRIPS Agreement Art 67.

83 Templeman, 1 JIEL 4 (1998) p. 604 states that the TRIPS Agreement itself was also obtained by 'the threat and reality of trade sanctions and the withdrawal of aid'.