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 provisions[81] 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 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'.

in Articles 65 and 70 of the TRIPS Agreement.[84] The staggered implementation of the obligations found in the TRIPS Agreement permitted those Member States without corresponding intellectual property rights an extended time frame in which to adopt the provisions. Although these arrangements provided for a staggered process, they do not permit Member States to deviate from the level of patent protection based upon the development status of a country.[85] The remaining development-friendly country provisions in the TRIPS Agreement played a minor role in the early years of TRIPS implementation.

The spotlight returned to the provisions made in favour of the developing Member States with the rapid spread of the HIV/AIDS disease. In the late 1990s the developing countries slowly awoke to the extent and potential impact of the disease on their citizens. The slow reaction, especially in Africa, was due to cultural differences and ignorance on the part of politicians and the public at large.[86] The lack of manpower and financial resources in the developing world further added to the impact of HIV/AIDS. Faced with the ever increasing problem of HIV/AIDS and the realisation that the developing countries would have to take measures to prevent the collapse of their already feeble public health systems, Member States began to debate the avenues available to them.

One of the areas that gained attention was that of pharmaceutical prices and the access to affordable medicines.[87] Most of the developing countries were reliant on the importation of medication, a portion of which was from the manufacturers who held the patents to the medicines. The dependency of the developing countries on the pharmaceutical manufacturers for their pharmaceutical requirements was further cemented by domestic patent laws, which entitles the patent holder to exclude the importation of a copy of its invention. This right, entrenched in the TRIPS Agreement, was however only valid in those countries where there was patent protection for pharmaceutical products. An example of a developing country with pharmaceutical protection was South Africa.[88] South Africa has the ignominious honour of housing the largest amount of citizens infected with HIV/AIDS. To tackle the HIV/AIDS problem the South African government sought to obtain the medication necessary for the treatment of the disease from producers with lower prices. As most of the HIV/AIDS treatments were under patent protection in South Africa, the then Patent

84 Contrast USTR position in *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. 509-511.

85 *UNCTAD/ICTSD,* Resource Book on TRIPS and Development (CUP New York 2005) p. 352, WTO *United Stated – Section 110(5) of the US Copyright Act* Report of the Panel (15.06.2000) WT/DS160/R p. 50.

86 *Gauri and Lieberman*, 41 SCID 3 (2006) p. 58-59. For a depiction of the HIV/AIDS epidemic and its consequences see *Kiehl*, 10 J.Intell.Prop.L (2002) p. 144-148.

87 For an overview of the disparities in pharmaceutical access see *Cohen et al*, 1 Globalization and Health 17 (2005) p. 1-2.

88 For a depiction of the extent of the HIV/AIDS epidemic in South Africa see *Kramer*, Patentschutz und Zugang zu Medikamenten (Carl Heymanns Verlag Cologne 2007) p. 7-21.

Act,[89] permitted only one way to obtain the medication from sources other than from the sources permitted by the patent holder: by way of compulsory licenses. This option was however an untested legal measure in South Africa and the limitations and compensation that would be awarded by the courts was unforeseeable. In addition to this uncertainty, the local pharmaceutical manufacturing sector in South Africa was relatively small and primarily dominated by research-based producers. To circumvent this situation the South African government decided to amend the Patent Act in order to provide for compulsory licenses that would permit the importation of the protected pharmaceuticals from countries with lower prices for these original products.[90] In terms of the proposed amendment, the:

> 'Minister may prescribe conditions for the supply of more affordable medicines in certain circumstances so as to protect the health of the public, and in particular may –
>
> (a) notwithstanding anything to the contrary contained in the Patents Act, 1978 … determine that the rights with regard to any medicine under a patent granted in the Republic shall not extend to acts in respect of such medicine which has been put onto the market by the owner of the medicine, or with his or her consent;
>
> (b) prescribe the conditions on which any medicine which is identical in composition, meets the same quality standard and is intended to have the same proprietary name as that of another medicine already registered in the Republic, but which is imported by a person other than the person who is holder of the registration certificate of the medicine already registered and which originates from any site of manufacture of the original manufacturer as approved by the council in the prescribed manner, may be imported'.[91]

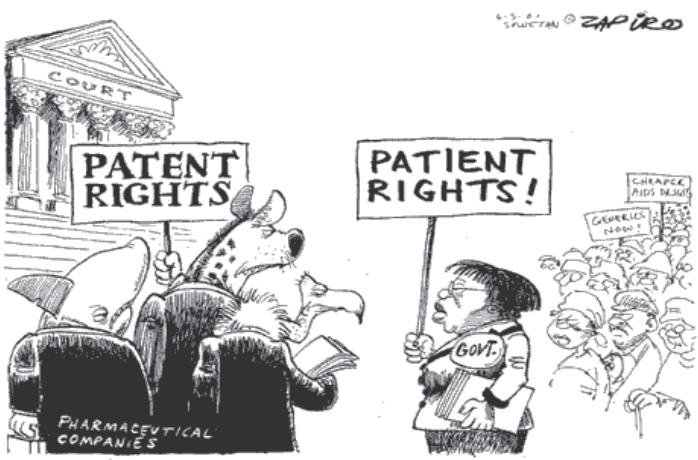
89 South African Patent Act, Act 57 of 1978.

90 For an overview of the political events surrounding the South African measures see *Bond*, 29 Int. J. Health Serv. 4 (1999) p. 765-792.

91 Medicines and Related Substances Control Amendment Act 1997 sec 15 C. For a discussion of sec 15 C and its potential consequences see *Kramer*, Patentschutz und Zugang zu Medikamenten (Carl Heymanns Verlag Cologne 2007) p. 165-177.

Prior to the passing of this Act, a group of 39 multi-national pharmaceutical companies, represented by the Pharmaceutical Manufacturers Association of South Africa (the 'PMA'), challenged the Bill on the basis that, amongst others, it constituted an infringement of the TRIPS Agreement.[92] The US itself made 'strenuous' representations to the SA government during the Bills drafting process and, in April 1998, placed South Africa on the Special 301 Watch List and suspended the granting of certain special trade preferences to South Africa.[93] The US Trade Representative (the 'USTR') stated that 'South Africa's Medicines Act appears to grant the Health Minister ill defined authority to issue compulsory licenses, authorize parallel imports, and potentially otherwise abrogate patent rights' and '[w]e call on the Government of South Africa to bring its IPR regime into full compliance with TRIPS'.[94]

Figure 1: Zapiro, 06.03.2001, published in the South African Sowetan



This PMA case was subject to significant domestic and international attention. It was portrayed in certain parts of the media as an attempt by the pharmaceutical industry to prevent a government from attending to the serious health requirements, by preventing low-cost medication reaching persons infected with HIV/AIDS. In addition to South Africa being in the sights of the US trade officials, Thailand, Argentina and Brazil were also subject to US scrutiny and pressure for similar TRIPS-related reasons.[95] The US had commenced the process of challenging aspects of the Argen-

92 Pharmaceutical Manufacturers Association et al v the President et al, TPD, 4183/98 [not published].
93 *Kiehl*, 10 J.Intell.Prop.L (2002) p. 151.
94 *USTR*, Special 301 Report (1998).
95 *Kiehl*, 10 J.Intell.Prop.L (2002) p. 151.

tinean and Brazilian patent regimes under the WTO's dispute settlement process.[96] Opposition to these actions increased and the pharmaceutical industry and, indirectly, the US were portrayed as greed ridden and inconsiderate of the suffering of those infected with HIV/AIDS.

As a result of the role the TRIPS Agreement played in the PMA case and the US actions against Argentina and Brazil, the TRIPS Agreement became synonymous with the obstructions that patent rights provide for public health and the access to affordable medicines. The public perception that the US and the pharmaceutical manufacturing sector put their financial profits and wellbeing before that of the sick and dying reverberated around the world. It mounted to such an extent that the PMA case became a public relations disaster. The PMA succumbed to the pressure and settled their court action against the South African government. In a joint statement the PMA and the government stated:

'The government of the Republic of South Africa reiterates its commitment to honour its international obligations including the Agreement of Trade Related Aspects of Intellectual Property Rights (TRIPS). In reliance of this commitment, the referenced applicants recognize and reaffirm that the Republic of South Africa may enact national laws or regulations, including regulations implementing Act 90 of 1997 or adopt measures necessary to protect public health, and broaden access to medicines in accordance with the South African Constitution and TRIPS.'[97]

The political backlash also led the US to withdraw its WTO challenges against Brazil[98] and Argentina[99] and deterred if from instituting similar proceedings against Thailand. Despite the US retreat there remained the fear for many developing countries that legal challenges could still be instituted against public interest measures that have the effect of limiting patents.

The feeling that a problem lay within the WTO arena, especially within the TRIPS Agreement, continued to spread throughout the developing Member States.[100] In order to address the TRIPS-deficiencies, within the scope of multilateral

96 WTO Brazil – Measures Affecting Patent Protection Request for Consultations by the US (08.06.2000) WT/DS 199/1, WTO Argentina. – Patent Protection for Pharmaceuticals and Test Data Protection for Agricultural Chemicals Request for Consultation by the US (10.05.1999) WT/DS 171/1.

97 Joint Statement of Understanding between the Republic of South Africa and the Applicants (19.04.2001).

98 WTO *Brazil – Measures Affecting Patent Protection* Request for Consultations by the US (19.07.2001) WT/DS 199/4.

99 WTO *Argentina – Patent Protection for Pharmaceuticals and Test Data Protection for Agricultural Chemicals* Notification of Mutually Agreed Solution According to the Conditions Set Forth in the Agreement (20.06.2002) WT/DS171/3.

100 *Bermudez, Oliveira and Chaves,* Intellectual Property in the Context of the WTO TRIPS Agreement: What is at Stake in Bermudez and Oliveira (eds) Intellectual Property in the Context of the WTO TRIPS Agreement: Challenges for public health (ENSP/WHO Rio de Janeiro 2004) p. 45. Compare *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. 200-205.

WTO Member States began to include health issues in their topics for negotiations in the run up to the Ministerial Conference set for 1999 in Seattle.[101] The failure of the Seattle Ministerial Conference polarised the interests held by developed and developing countries. In the specific case of health and intellectual property rights, it became obvious that discussions on the issue were urgently required and a delay until the next Ministerial Conference could not be justified in light of the extent of the HIV/AIDS problem had assumed. With this thought in mind, the TRIPS Council convened a special meeting to attend to the debate. In a communication made by Brazil, on behalf of the African Group and 15 other Member States, the members made the following submission:

> 'The special discussion on TRIPS and Public Health at the TRIPS Council is not a one-off event. It should be part of a process to ensure that the TRIPS Agreement does not in any way undermine the legitimate right of WTO Members to formulate their own public health policies and implement them by adopting measures to protect public health.'[102]

The demands raised, principally by the developing nations, were ambitious; they sought a formal acknowledgement that 'nothing in the TRIPS Agreement should prevent Members from taking measures to protect public health'.[103] This point and other more concrete discussions regarding the role of compulsory licenses, exhaustion and patent exceptions were all discussed in detail in the months that preceded the Public Health Declaration.

Notwithstanding either the general issues, such as the sanctity of health measures, or the material issues concerning the use of the provisions contained in the TRIPS Agreement, an issue central to all these topics was beginning to emerge: the issue of 'flexibility'. The use of the term flexibility in the context of the WTO and TRIPS Agreement pertains to the ability a Member State has to implement the TRIPS Agreement in a manner it deems best, provided it is consistent with the contents of the provisions.[104] Its history dates back to the Uruguay Round where attaining consensus on strict and finite rules was not possible. In order to appease the multitude of negotiating parties the wording of provisions was deliberately generalised in nature. It was not that the negotiating parties wished to implement a lax treaty; it was simply that the generalised wording was the highest common denominator that was able to achieve consensus. The role of the flexible provisions was acknowledged and was so far accepted that the preamble in the TRIPS Agreement states:

101 WTO *India and others* Preparations for the 1999 Ministerial Conference (11.10.1999) WT/GC/W/354 para 27.

102 WTO Submission by Brazil and others to the TRIPS Council 'TRIPS and Public Health' (29.6.2001) IP/C/W/296 p. 1.

103 WTO Submission by Brazil and others to the TRIPS Council 'TRIPS and Public Health' (29.6.2001) IP/C/W/296 (29.6.2001) p. 1.

104 It is also referred to as 'normative elasticity', 'legislative leeway' or 'wiggle room'. *Watal* notes that the TRIPS Agreement has a 'plethora of legislative options' for implementing the Agreement domestically. Cf. *Watal*, Implementing the TRIPS Agreement in: Hoekman, Mattoo and English (eds) Development, Trade, and the WTO: A Handbook (World Bank Washington DC 2002) p. 363.

> 'Recognizing also the special needs of the least-developed country Members in respect of maximum *flexibility* in the domestic implementation of laws and regulations in order to enable them to create a sound and viable technological base'[105] (emphasis added)

The problem flexibility posed to the Member States arose out of the relation between the preamble, Article 1 ('Nature and Scope of Obligations'), Articles 7 and 8 ('Objectives' and 'Principles') and the material provisions contained in Part II of the TRIPS Agreement. Article 1.1 of the TRIPS Agreement leaves the method of implementation of the Agreement up to the Member States to determine and states that the Member States are not required to implement a more extensive intellectual property protection regime than was provided for in the Agreement. Notwithstanding, the freedom to elect the method of implementation the actual meaning of the provisions to be implemented remained unclear. This lack of clarity is amplified by Articles 7 and 8 which recognise the importance of social-economic issues without detailing its potential influence on the material TRIPS provisions. When it came to the implementation of the TRIPS Agreement by the Member States they proceeded to implement the Agreement in a manner consistent with their understanding of the agreements and the negotiations that preceded its adoption. It became clear that their understanding as to what the TRIPS Agreement meant and what is permitted was not universally identical. The EC and the US took a stance that the TRIPS Agreement, including its exceptions, should be implemented in a formal manner that excluded national measures that readjusted the intellectual property and socio-economic balance in the TRIPS Agreement to suite national circumstances. [106] The WTO *Canada –Pharmaceuticals* case marked the first WTO Dispute Settlement Body (the 'DSB') ruling that made an award that appeared to favour of intel-lectual property rights over health policy measures.[107] In addition to favouring intellectual property rights over public health policies, the DSB set strict standards of TRIPS-com-pliancy, thus limiting the flexibilities available to Member States.[108]

The view that the TRIPS Agreement was transpiring into an ever tightening legal noose grew with each year. The year 2000 and the first 10 months of 2001 marked the beginning of the resurgence of the role of developing Member States within the WTO arena. The fear that the TRIPS Agreement could evolve into an agreement that was never intended and the increasing strain HIV/AIDS was placing on developing Member States culminated in a political standoff; the developing Member States sought clarity on the TRIPS Agreement. Through the negotiations, the influence of

105 TRIPS Agreement preamble.

106 WTO Canada – Pharmaceuticals p. 154.

107 The WTO *Canada – Pharmaceuticals* has often been used as a justification that the WTO rules restrict national health measures. Although this decision is dealt with extensively below, it is to be stated that whereas the decision may have had the effect of delaying the entry of generic pharmaceuticals after the expiry of a patent in Canada it can also be seen as a decision that confirmed that health measures may form the basis for allowing generic producers to fulfil certain market access requirements whilst the patent is still valid. See Chapter 5(C)(III)((2) below.

108 WTO Canada – Pharmaceuticals p. 153, 155.

the 11th of September 2001 terrorist attacks, the US's response to the anthrax scares and the global support for the pre-emption of health over pecuniary interests, an agreement was reached at the Doha Ministerial Conference on the 14th of November 2001, the Public Health Declaration.