

The availability of the extensive flexibilities found in the TRIPS Agreement to Member States was seldom recognised – let alone exercised – in the early and uncertain years of their application. Despite the wording of the TRIPS Agreement, Member States were unable to agree on the existence, let alone the scope and extent, of the flexibilities. Although initially theoretical, the differences of opinions became ‘real’ when dealing with the effect of the TRIPS Agreement on the access to affordable medicines. The extent of public health problems like HIV/AIDS and the public attention to the discussions pressured the Member States to clarify, reaffirm or alter the TRIPS-provisions and their flexibilities in order to ensure that they would not hinder measures to protect the public health. The product of their efforts was the Public Health Declaration.<sup>640</sup> Although hailed at the time, it contains not novel law or solutions. It is little more than a reiteration of existing laws. Its role is however more subtle; it identified real problems and removed large portions of uncertainty in applying the TRIPS Agreement – at least psychologically.

The Public Health Declaration is important to the TRIPS Agreement for two reasons. Firstly, it mandates two problematic issues that require active attention. Secondly, it seeks to clarify a number of contentious issues in the TRIPS Agreement. These, together with the legal implications of the Public Health Declaration are analysed briefly in ‘A’ and ‘B’ respectively hereunder. The effects of the Public Health Declaration on the TRIPS Agreement are discussed in ‘C’ thereafter.

### *A. The scope of the Public Health Declaration*

Essentially, the Public Health Declaration seeks to clarify the relationship between the intellectual property rights and public health. In addition to the clarification of this relationship, the Public Health Declaration also mandated the Member States with two modalities: to resolve an inadvertent ‘technical’ problem and to grant an extension to certain obligations for LDCs. These three points are briefly elucidated below.

640 Declaration on the TRIPS Agreement and Public Health, 14.11.2001, WT/MIN(01)/DEC/2 (Annex I hereto)

## I. Clarification of the relationship between the TRIPS Agreement and public health

In an unusually clear formulation the Public Health Declaration confirms that:

‘... the TRIPS Agreement does not and should not prevent Members from taking measures to protect public health’.<sup>641</sup>

This statement has helped resolve a dispute that lay at the bottom of a number of intellectual property disputes:<sup>642</sup> what role do public health policies play in interpreting the TRIPS-flexibilities? The answer given by the WTO Member States is that intellectual property obligations will not stand in the way of measures taken to protect the public health. To this effect the TRIPS-provisions and flexibilities should be interpreted in a ‘manner supportive of WTO Members’ right to protect public health’. This clarification does not imply that Member States implementing public health measures are entitled to ignore their intellectual property obligations under the TRIPS Agreement. The TRIPS-obligations remain; their implementation and interpretation however can be effected in a manner that supports the protection of health. This statement is of utmost importance when seen in relation to the numerous flexibilities vesting in the Member States’ implementation of the TRIPS Agreement. Added to this, it was further agreed that the flexibilities in the TRIPS Agreement may be exercised to the fullest extent for the purpose of protecting the public health.

The Member States further took to clarifying the flexibilities by specifically addressing four specific issues. The Member States agreed that:

- the interpretation of the TRIPS Agreement must take into account the object and purpose of the agreement, as set out in the customary rules of interpretation of public international law
- they have a sovereign right to determine the grounds for compulsory licenses and to provide for their use<sup>643</sup>
- they have a sovereign right to determine what constitutes extreme urgencies<sup>644</sup> and

641 Public Health Declaration para 4.

642 *Abbott* notes that much of the implementation difficulties expressed by developing countries arise from the political and economic pressure applied on these countries to conclude the agreement and the lack of understanding of the obligations they consented. *Abbott*, Quaker Paper 7 (2001) p. 3. This is confirmed in WTO Proposal by the African Group *et al* to the TRIPS Council ‘Ministerial Declaration on the TRIPS Agreement and Public Health’ (04.10.2001) IP/C/W/312 p. 2. Compare *Abbott*, CIPR Study Paper 2a (2002), *Sykes*, 3 Chi. J. Intl. L (2002) p. 50-61, *Sum*, 15 EJIL 1 (2004) p. 123-131. *Straus* provides empirical evidence that the TRIPS Agreement can, and has, benefited certain countries. Cf. *Straus*, 6 J. Marshall Rev. Intell. Prop. L 1(2006) p. 4-9. Contrast *Gervais*, 1 JIPLP 4 (2006) p. 252-253.

643 WTO Communication from the EC ‘The Relationship between the Provisions of the TRIPS Agreement and Access to Medicines’ (12.06.2001) IP/C/W/280 p. 2-3, WTO Proposal by the African Group *et al* to the TRIPS Council ‘Ministerial Declaration on the TRIPS Agreement and Public Health’ (04.10.2001) IP/C/W/312 p. 3.

- they have the freedom to establish national regimes for the exhaustion of intellectual property rights.

The heading given to the Public Health Declaration is the ‘Declaration on the TRIPS Agreement and Public Health’. This being the case, does the scope of the Public Health Declaration only permit the expansive implementations of the TRIPS flexibilities with respect to measures based on public health? The formulation of paragraph 4 and 5 of the Public Health Declaration seems to suggest that this is indeed the case:

‘In this connection, we reaffirm the right of WTO Members to use, to the full, the provisions in the TRIPS Agreement, which provide flexibility for this purpose’.

This statement clearly acknowledges that public health actions necessitate a permissive implementation of the flexible provisions contained in the TRIPS Agreement.<sup>645</sup> The question that naturally follows is: is the full use of the TRIPS flexibilities restricted to public health circumstances? General interpretational rules state that the inclusion of one means the exclusion of others. This rule however will only apply, to the extent that the negotiating parties desired it to apply. This does not seem to be the case here. The reason lies firstly in the negotiations leading up to the Declaration. India and the USA took turns in stating that the Public Health Declaration should not lead to a restriction of either the Member States rights or the rights holder’s rights.<sup>646</sup> Secondly, the rule is unlikely to apply because of the terminology chosen by the Public Health Declaration negotiators. Paragraph 4 reaffirms the right to use the flexibilities to the maximum advantage. The terminology is not restrictive in nature nor does it limit the application of paragraph 5 to the listed points. Further, the Public Health Declaration does not create a new right; rather it acknowledges the existence of a right (‘we reaffirm the right of WTO Members’). With the exception of LDCs, this right is not expressly mentioned in the TRIPS Agreement. Accordingly, it cannot be excluded that other rights to maximum usage of the flexibilities can, or do, exist.<sup>647</sup> A review of the TRIPS Agreement would seem to suggest that

644 WTO Proposal by the African Group *et al* to the TRIPS Council ‘Ministerial Declaration on the TRIPS Agreement and Public Health’ (04.10.2001) IP/C/W/312 p. 3.

645 This statement reflects an answer to one of the prime demands of the developing Member States. As early as April 2001 Zimbabwe stated that ‘[a]lthough the TRIPS Agreement allowed developing countries the flexibility to apply patents in ways that still enabled the protection of the health of their people, recent legal challenges by the pharmaceutical industry and some Members in national law and under the DSU had highlighted the lack of legal clarity on the interpretation and/or application of the relevant provisions of the TRIPS Agreement’. Cf. Zimbabwe on behalf of the African Group in the TRIPS Council Minutes (01.06.2001) IP/C/M/30 p. 68.

646 India and US in the TRIPS Council Minutes (19.09.2001) IP/C/M/33 p. 33, 37.

647 TRIPS Agreement preamble. Critics of this view may state that the scope of this statement is clearly made within the context of public health and as such should be interpreted in this context (as according to the Vienna Convention). The Vienna Convention does however require that the wording used should be of primary importance. In this context it is important to remember that the statement is merely a reaffirmation. As such this statement confirms that the

other situations may indeed permit the maximum usage of the existing flexibilities within the TRIPS Agreement. They would include nutrition, the promotion of the public interest and the prevention of intellectual property right abuse, as foreseen in Article 8 of the TRIPS Agreement. The right to use the ‘wobble room’ in a treaty is universal – provided it actually exists and provided it is done in good faith. It therefore seems unlikely that, despite the clear restriction of the Public Health Declaration to public health, that the use of the flexibilities will not have a follow on effect on the other measures. Where Member States are faced with similar public interest situations the Public Health Declaration may indeed provide the affected Member States with a degree of guidance and security.

A further issue regarding the scope of the Public Health Declaration arose in submissions made after the Doha Ministerial Conference wherein it was stated that the Public Health Declaration consequences should only be limited to developing and least-developed countries.<sup>648</sup> The reason being that paragraph 1 of the Public Health Declaration refers to public health problems faced by such countries. As the Public Health Declaration seeks to remove the perceived obstacle in the TRIPS Agreement to resolve the problems it was contended that the Public Health Declaration is not to be applied where the Member States are developed countries. Whereas this may be true in regarding the extension of the transitional provisions in paragraph 6, this interpretation is not supported by the contents or the context of the Public Health Declaration. The central paragraph of the Public Health Declaration, paragraph 4, states that the TRIPS Agreement should not prevent Member States from taking measures to protect public health. It refers to all Member States – there is no restriction.<sup>649</sup> The contents of paragraph 4 are subsequently used to ‘qualify’ the scope and use of the flexibilities in paragraph 5.

## II. Countries without domestic productions facilities

The inability that some Member States have in domestically producing pharmaceutical products has meant that granting compulsory licenses in these countries for the domestic production of these products is a fruitless venture; effectively rendering

right existed prior to the Public Health Declaration and, as the TRIPS Agreement was not subject to the public health context of the Public Health Declaration, one can conclude that this right is not restricted to the scope of public health. Accordingly, the scope and purpose reflected in Arts 7 and 8 will be guiding. Cf. *UNCTAD/ICTSD*, Resource Book on TRIPS and Development (CUP New York 2005) p. 131.

648 The US stated that ‘the Doha Declaration on the TRIPS Agreement and Public Health makes it clear that the public health problems addressed by the Declaration are those gravely afflicting many *developing and least-developed countries*’ (emphasis added). Cf. WTO Communication by the US ‘Paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health’ (09.07.2002) IP/C/W/358 p. 2.

649 Paragraph 6 also refers to all Member States, not just developed or LDC Member States.