

mation of an interpretation and, from a functional standpoint, may be indistinguishable'.<sup>675</sup>

### *C. The effect of the Public Health Declaration on the TRIPS Agreement*

Being a 'subsequent agreement' the Public Health Declaration has the potential to shape the TRIPS Agreement like no other WTO Declaration or collective Member State agreement before it. The extent of this interpretational assistance will depend not only on the contents of the Public Health Declaration but also on the respective TRIPS Agreement provisions. The effects of the Public Health Declaration on the TRIPS Agreement are discussed in respect to the TRIPS scope and purpose, the TRIPS material obligation and the transitional period granted to LDCs.

#### **I. The scope and purpose**

According to the Vienna Convention on the Law of Treaties, the object and purpose help determine the ordinary meaning of the terms of the treaty.<sup>676</sup> In other words, clarity is brought to uncertain clauses and concepts through the use of the treaties object and purpose. As is evident in Chapter 5(B) Seite 47, the scope and purpose of the TRIPS Agreement play an important role in fleshing out the meaning of the numerous flexible provisions of the TRIPS Agreement. The difficulty with the scope and purpose of the TRIPS Agreement is that the provisions incorporating the scope and purpose are themselves flexible and permit a number of diverging, and yet arguably valid, conclusions to be drawn when interpreting the Agreement.<sup>677</sup>

As was intended the Public Health Declaration, as a subsequent agreement to the TRIPS Agreement, will have a vital role to play in clarifying and guiding the use of those provisions containing the scope and purpose of the TRIPS Agreement. The extent of this influence stems from the sometimes express references to the customary rules of interpretation of treaties, the reinforcement of the role of health and, last but not least, the confirmation of the provisions of Articles 7 and 8 of the TRIPS Agreement. These, and their effect on the implementation of the policy thoughts of the Public Health Declaration, are discussed independently below.

675 *Abbott*, 5 JIEL 2 (2002) p. 492. *Correa*, Implications of the Doha Declaration in the TRIPS Agreement and Public Health (WHO Geneva 2002) p. 44. *Straus* notes that part of the Public Health Declaration is to be viewed as an authentic interpretation and other parts as setting mandates for the Member States. 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. 126.

676 Vienna Convention Art 31.

677 Compare WTO Submission by Brazil and others to the TRIPS Council 'TRIPS and Public Health' (29.6.2001) IP/C/W/296 p. 3.

## 1. The customary rules of interpretation

The inclusion of a reference to the use of customary rules of interpretation made for little controversy in the negotiations leading up to the Public Health Declaration.<sup>678</sup> A draft of the Public Health Declaration dating back to the 27<sup>th</sup> of October 2001 included a paragraph stating that the interpretation of all the TRIPS provisions should be done in accordance with its objectives and principles, as required by customary rules of interpretation.<sup>679</sup>

The reason for the general acceptance of the use of the Vienna Convention<sup>680</sup> in the interpretation of the flexibilities of the TRIPS Agreement stems from the fact that the Member States had already accepted their use within the TRIPS Agreement<sup>681</sup> and that all Member States are nonetheless bound to the provisions in the Vienna Convention.<sup>682</sup>

The question that therefore arises is: why was a reaffirmation of the role of customary rules of interpretation necessary?

The answer lies in the political situation at the WTO in the late 1990s. There was an impression that the TRIPS Agreement was being implemented in a manner the Member States had not agreed upon. On the one hand developed countries pressed for a strict interpretation of the rules and on the other side the DSB ruling restrictively interpreted the exceptions worked into the TRIPS Agreement.<sup>683</sup> It was felt that insufficient regard was being given to the objectives and principles set out in Articles 7 and 8 of the TRIPS Agreement.<sup>684</sup> This, as it was felt, was contrary to the provisions of the Vienna Convention. Dissatisfied with the situations developing Member States energetically pushed to include a confirmation of the principles of

678 The Hong Kong representative stated that 'there should be no dispute that all provisions of the TRIPS Agreement should be read in the light of the objectives and principles as set forth in its Articles 7 and 8'. Cf. Hong Kong in TRIPS Council Minutes (19.09.2001) IP/C/M/33 p. 60

679 WTO General Council 'Draft Declaration on Intellectual Property and [Access to Medicines] [Public Health]' (27.10.2001) JOB(01)/155.

680 *Matsushita et al*, The World Trade Organization: Law, Practice, and Policy (2nd edn OUP Oxford 2006) p. 27.

681 DSU Art 3(2)

682 *UNCTAD/ICTSD*, Resource Book on TRIPS and Development (CUP New York 2005) p. 132.

683 The *Canada – Pharmaceutical* case is often cited in this regard. The opposition focused on the sentence that stated: 'The term "limited exception" must therefore be read to connote a narrow exception - one which makes only a small diminution of the rights in question'. WTO *Canada – Pharmaceuticals* p. 155. Brazil put its fear of the DSU as a method for interpretation of the TRIPS agreement bluntly when it said 'avoiding the ... dispute settlement mechanism to enforce restrictive, unbalanced and, indeed, incorrect interpretations of the TRIPS Agreement'. Brazil in Special Discussion on Intellectual Property and Access to Medicines in the TRIPS Council (10.07.2001) IP/C/M/31 p. 9. Cf. *Abbott*, Quaker Paper 7 (2001) p. 22.

684 Compare WTO Submission by Brazil and others to the TRIPS Council 'TRIPS and Public Health' (29.6.2001) IP/C/W/296 at 3, 5-6. Cf. *Abbott*, 8 JIEL 1 (2005) p. 83-84.

the Vienna Convention; their efforts were rewarded when it was agreed at the Doha Ministerial Conference that:

‘In applying the customary rules of interpretation 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.’<sup>685</sup>

By reiterating the role that the customary rules of interpretation of public international law play, Member States have further entrenched the importance of viewing the TRIPS Agreement in a context that includes references to public interest policies, social and economic welfare and the balancing of rights and obligations.<sup>686</sup> The result of paragraph 5(a) of the Public Health Declaration goes a long way in ensuring the policy objectives of the Public Health Declaration are noticed and applied.<sup>687</sup>

## 2. The Public Health Declaration and Articles 7 and 8 of the TRIPS Agreement

The role the Public Health Declaration plays is similar to the role of Articles 7 and 8 of the TRIPS Agreement. Like Articles 7 and 8, the Public Health Declaration reaffirms that health is a valid consideration factor when determining the meaning of a TRIPS provision. Both aid in creating the context in which a provision is interpreted. Both also refer to the importance of the protection of the public interest. As such the Public Health Declaration serves as a reminder of the core values behind the protection of intellectual property rights and ensures that these are not to be overlooked.

In addition to the reaffirmation of the role of the scope and purpose in interpreting the TRIPS Agreement, the Public Health Declaration makes a specific reference to the role of public health in the interpretation of the TRIPS Agreement; paragraph 4 reads:

‘We agree that the TRIPS Agreement does not and should not prevent Members from taking measures to protect public health. Accordingly, while reiterating our commitment to the TRIPS Agreement, we affirm that the Agreement can and should be interpreted and implemented in a manner supportive of WTO Members’ right to protect public health and, in particular, to promote access to medicines for all.’

685 Public Health Declaration para 5(a).

686 *UNCTAD/ICTSD, Resource Book on TRIPS and Development* (CUP New York 2005) p. 132. Although the Public Health Declaration is in principal limited to the role of public health in the interpretation and implementation of the TRIPS Agreement, the general formulation of the chapeaux to para 5 and the contents of pa 5(a) provide an impression that this is to apply to intellectual property rights as a whole. A further result of the inclusion of this provision is that it will likely dispel the role of customary international law as being an autonomous source of law, i.e. no merely as an interpretative tool. Cf. *Matsushita et al*, *The World Trade Organization: Law, Practice, and Policy* (2nd edn OUP Oxford 2006) p. 21.

687 The customary rules of interpretation are however eternally limited as they can only clarify what flexibility existed under the TRIPS Agreement. Compare Switzerland in TRIPS Council Minutes (19.09.2001) IP/C/M/33 p. 47.

By directly addressing the relationship between public health and intellectual property rights the Public Health Declaration has achieved something not previously accomplished; it rationalised intellectual property rights. Intellectual property rights, in particular patent rights, have generally been an autonomous area of law. Its restrictive effects were seen to be justified in the intellectual benefit it brought a country. This conclusion, mainly based on evidence from developed countries, was felt as being a global recipe for development and progress – at least this was one of the reasons given by developed nations to sweeten the acceptance of increased intellectual property rights by developing countries. It was the unfortunate combination of increased public health threats and tightened patent limitations that brought the world's attention to the relationship between public health and the TRIPS Agreement. In the eyes of the public at large it was inconceivable that patent rights could be equated with the right to health. Unable to counter such a vivid image of rich companies exploiting the poor and sick, developed Member States were compelled to react. Paragraph 4 is this reaction. It reflects the single most important 'victory' for developing Member States; they succeeded in shifting the weight of intellectual property rights in favour of the public interest. This political success can only be partially regarded as a legal success. A closer look at paragraph 4 shows that the TRIPS Agreement does not prevent a Member States from taking measures to protect public health. This statement reflects that this is not a new development. According to the Public Health Declaration, the TRIPS Agreement never prevented Member States from taking measures to protect the public health. If Member States felt that this was not the case they erred. From a legal point of view no new rights arise and no old obligations terminate. Notwithstanding this, the legal consequence is two-fold. Firstly, the flexibilities found in many TRIPS provisions can be exercised to the full.<sup>688</sup> This removes any doubt that interpretations limiting the extent of patent rights must be done restrictively. Secondly, paragraph 4 shifts the centre of balance in the interpretation of the TRIPS Agreement. The implementation of the TRIPS Agreement occurs as much from DSB rulings as from international pressure. Uncertain of the extent to which the flexibilities could be interpreted, many Member States succumbed to views held by other more influential Member States. The political consequence of the first sentence of paragraph 4 effectively grants Member States wishing to take advantage of the flexibilities in the TRIPS provisions a moral crutch to resist pressures requiring the contrary. The flexibilities – the wiggle room in the TRIPS Agreement – are also grey areas for the DSB. Uncertain of the extent to which the TRIPS negotiators intended their provisions to be used, the Public Health Declaration gives the DSB an additional body of evidence that will support an interpretation in a certain way. The Public Health Declaration states further in the second sentence in paragraph 4 that the interpretation of the TRIPS Agreement should, where applicable, support a Member State's measures to protect its citizen's health. This statement in the Public Health Declaration is likely to have an effect on

688 Public Health Declaration para 4, second sub-paragraph.

the DSB's policy of 'objective assessment'.<sup>689</sup> The DSB has maintained a rigid policy of assessing exclusionary and trade restrictive measures taken by Member States in a strict manner. Justifications presented by Member States defending their measures have been required to objectively substantiate their actions. In light of the Public Health Declaration's confirmation that the full flexibility can be exercised when taking measures to protect the public health, the DSB will be required to determine whether an objective assessment policy will limit the flexibilities to which the Member State is entitled. Bloche notes that the DSB has increasingly been willing to defer the decision regarding health and environmental matter to the Member States themselves, despite there being objective/scientific uncertainty regarding the measures taken.<sup>690</sup> This is increasingly likely to be the case in respect of measures taken to protect the public health.

The effect of paragraph 4 on the scope and purpose of the TRIPS Agreement can therefore be surmised as fortifying the role of Articles 7 and 8, reinforcing the autonomy of the Member States' public health policies and ensuring that flexibilities can be used to the full and will not be interpreted to the disadvantage of public health measures – all highly relevant aspects in applying the scope and purpose of the TRIPS Agreement. This however does not however alter any material obligations.<sup>691</sup> The proviso in the second sentence of paragraph 4 is a reminder that despite the swing to public interest, the obligations a Member State has under the TRIPS Agreement remain.<sup>692</sup>

### 3. The Public Health Declaration and the right to health

There is no express obligation in the TRIPS Agreement requiring Member States to protect human rights.<sup>693</sup> The TRIPS Agreement and the other WTO Agreements are trade agreements; their obligations pertain to measures to regulate the flow of trade between its members. The WTO obligations do however acknowledge that public interest issues – which by virtue of their scope encompass human rights – can play a role in the implementation and interpretation of the WTO obligations.<sup>694</sup> The Public Health Declaration however marked the first, albeit indirect, reference to the role of human rights, in particular the right to health, within WTO. It stated:

'We agree that the TRIPS Agreement does not and should not prevent Members from taking measures to protect public health. Accordingly, while reiterating our commitment to the

689 *Gregg Bloche*, 5 JIEL 4 (2002) p. 831.

690 Also referred to as the 'precautionary principle'. Cf. *Gregg Bloche*, 5 JIEL 4 (2002) p. 834.

691 The Public Health Declaration has not altered the status of Arts 7 or 8. They remain general or non-operative provisions that assist in the understanding and application of other TRIPS provision. Cf. *Rott*, 25 GRURInt 2 (2003) p. 106.

692 The corollary of para 4 is that public health measures does not and should not prevent Member States from protecting intellectual property rights.

693 *Rott*, 25 GRURInt 2 (2003) p. 104.

694 Compare GATT Art XX, GATS Art XIV.

TRIPS Agreement, we affirm that the Agreement can and should be interpreted and implemented in a manner supportive of WTO Members' right to protect public health and, in particular, to promote access to medicines for all.<sup>695</sup>

This statement confirmed the developing Member States' position that domestic public health policies are not restricted by the TRIPS Agreement. This implies that a Member States is able to prioritise its public health measures over its intellectual property rights system. This does not mean that a Member States can ignore the implementation of its TRIPS obligations;<sup>696</sup> rather it means that in implementing the obligations, a Member States may validly favour an interpretation that prioritises health policies over stricter patent protection and may exercise the exceptions in the TRIPS Agreement to the benefit of health policies. This right to exercise the TRIPS Agreement to the benefit health measures or other public interest measures existed at the very beginning of the TRIPS Agreement. The Public Health Declaration is effectively an affirmation of old rights.

Public health is, as mentioned above, the duty a state has to its citizens to ensure their right to health is respected and performed. The reference in the Public Health Declaration to public health and not the right to health stems from the fact that the TRIPS Agreement concerns itself with the obligations Member States have amongst one another. The TRIPS Agreement cannot out of its own right impose domestic rules. Notwithstanding this the correlation between public health and the right to health is clear. Although perhaps ethereal in nature, the right to health and the tacit acknowledgement in the Public Health Declaration indicates that the TRIPS Agreement is not an island but can and should be to the greater good of mankind.

The role of the right to health will become even more important the more intellectual property rights become entrenched. The right to health, public health and other public interest considerations play an important role in balancing the obligations that flow from intellectual property rights.<sup>697</sup> The more a state is able to ensure the public interest is attended to the greater the chances will be that intellectual property rights will be deemed socially acceptable and better protected.

As a result of the Public Health Declaration and its references to public health, there has and will continue to be added attention to public health and its alter ego the right to health in international relations.<sup>698</sup> This is already evident in bilateral trade treaties, where the US's free trade agreements with Chile, Bahrain, Morocco and Oman all have references to the Public Health Declaration.<sup>699</sup>

695 Public Health Declaration para 4.

696 Art XXIII of the GATT Agreement and Art 64 of the TRIPS Agreement.

697 *Taylor*, 80 WHO Bulletin 12 (2002) p. 976, *Chapman*, 5 JIEL 6 (2002) p. 879.

698 *Gregg Bloche*, 5 JIEL 4 (2002) p. 847.

699 US/Chile FTA c 17 chapeau, US/Bahrain side letter to c 14 of the FTA, US/Morocco side letter to c 15 of the FTA, US/Oman side letter to c 15 of the FTA. For a discussion on the effect of the Public Health Declaration on bilateral trade treaties see Chapter 8(F)(II) below.

## 4. Conclusion

The Public Health Declaration has embellished the role of the scope and purpose of the TRIPS Agreement.<sup>700</sup> As a result there is more substance and form available for Member States to apply when interpreting the TRIPS Agreement. With the added clarity comes the confidence for Member States to actually apply the principles found in TRIPS Agreement's scope and purpose; especially in relations to patents and public health. The added certainty derived from the Public Health Declaration is likely to encourage Member States and the DSB to grant other social interests a greater role in the interpretation of the WTO Agreements. It can therefore be said that the Public Health Declaration has not only cemented the role of public health in the TRIPS Agreement but it has also created more awareness for the role of other rights and public interests in the interpretation and implementation of the WTO Agreements.<sup>701</sup>

### II. The material obligations

The effect of the Public Health Declaration is not limited to the scope and purpose provisions of the TRIPS Agreement; it also provides guidance and clarification with respect to the material provisions of the TRIPS Agreement.

The Public Health Declaration makes references to two material obligations in the TRIPS Agreement: exhaustion (Article 6) and compulsory licenses (Article 31). The latter is dealt with in two sub-groups: the grounds for compulsory licenses (Articles 31 generally) and the prohibition on compulsory license for export purposes (Article 31(f)). Each of these points is discussed separately below.

#### 1. Exhaustion

The exhaustion of intellectual property rights is, as set out in Article 6 of the TRIPS Agreement, the prerogative of the Member States.<sup>702</sup> Despite this and as mentioned in Chapter 5(C)(V) on Exhaustion Seite 149 above, the TRIPS provisions relating to exhaustion has provided much fodder for debate and disputes in the WTO arena. The discussions became more intense when certain Member States, thereunder the US, indicated their desire to restrict the extent to which Member States exercise their exhaustion regime. This 'attack' on the *ultra vires* role of exhaustion intimidated other Member States from exercising Article 6 of the TRIPS Agreement. This uncer-

700 Gervais, 1 JIPLP 4 (2006) p. 251.

701 Gervais, 1 JIPLP 4 (2006) p. 251.

702 Contrast *Straus and Katzenberger*, *Parallelimporte: Rechtsgrundlagen zur Erschöpfung im Patentrecht* (Schweizerische Eidgenossenschaft Munich 2002) p. 38-47