

law status. So to may general principles of law acquire an authoritative value.<sup>180</sup> Although not expressly referred to in the ICJ Statute, there is general acceptance that decisions of international bodies may potentially be a source of international law. Thus it would seem that decisions of the WTO and its Councils could potentially aid the understanding and implementation of the text of the TRIPS Agreement. The standards used to determine the existence of customary law is: ‘actual practice and *opinio juris* of States’.<sup>181</sup> The ICJ went further and stated that ‘multilateral conventions may have an important role to play in recording and defining rules deriving from custom, or indeed in developing them’.<sup>182</sup>

Thus, a reference to public international law reinforces the obligation adjudicators of the TRIPS Agreement have to grant due consideration for the objectives and purposes of the agreement and ensures that any subsequent agreement reached on the meaning of a TRIPS provision will have the effect of ensuring that the provision retains the meaning given to it by its signatories, whether by virtue of the original intention or by virtue of an direct or indirect meaning given *ex post facto* and by consent.

Finally, the added attention given to customary rules of interpretation of public international law by Member States benefits the role of the DSB which struggles to ensure a balance between respecting the discretions of the Member States and ensuring the ‘security and predictability’ of the TRIPS agreement.<sup>183</sup> The inclusion of references to customary public international law reaffirm that Member States desire a TRIPS Agreement that acknowledges, as a core principle, that the treaty need be interpreted and implemented in accordance with its objectives and principles.<sup>184</sup> The conclusion of a Ministerial Declaration on the application of provisions in the TRIPS agreement also, in terms of the Vienna Convention on the Law of Treaties, further assists the DSB as it guides the adjudicators to the intention of the Member States, towards a ‘clarified’ intention

## VI. The role of ‘flexibility’ in the object and purposes of the TRIPS Agreement

Flexibility plays two roles with respect to the object and purpose of the TRIPS Agreement. Internally, the terminology and phraseology used in the preamble and Articles 7 and 8 permits numerous and often conflicting conclusions as to the intention of the parties.<sup>185</sup> Externally, when an interpreter seeks to determine the scope of

180 Statute of the International Court of Justice 59 Stat. 1031 Art 38(1)(c).

181 Continental Shelf Case (Libyan Arab Jamahiriya/Malta) [1985] ICJ Rep 13 p. 29.

182 Continental Shelf Case (Libyan Arab Jamahiriya/Malta) [1985] ICJ Rep 13 p. 29.

183 DSU Art 3.

184 *Ehlermann and Lockhart*, 7 JIEL 3 (2004) p. 478.

185 Flexibilities found in the TRIPS Agreement are to be distinguished from the application of the *in dubio mitius* principle. The *in dubio pro mitius* principle refers to instances where there is a burden to prove a desired interpretation and not to clauses that permit more than one interpretation. It is however noteworthy that the Appellate Body has applied the *dubio pro mi-*

the application of the flexibilities in the operative provisions of the TRIPS Agreement he will be directed to the provisions of the treaty setting out the object and purpose of the treaty.

### 1. The flexibilities found in the object and purposes provisions

The flexibilities residing in the object and purpose provisions recognise that the protection of intellectual property rights under the TRIPS Agreement can be tempered and directed so as to further public interest policies. This is evident not only in the preamble but also in Articles 7 and 8. The scope of these public interest policies are widespread and include the furtherance of intellectual property rights, which is assumed in itself to further the public interest as it promotes technical innovation, the dissemination of technology, public health and nutrition and socio-economic development.<sup>186</sup> These interests are referred to in both the preamble and part I of the TRIPS Agreement. Thus, the reference to these policy interests enables Member States interpreting the object and purpose of the TRIPS Agreement to incorporate a wide variety of public interest factors into the implementation of the TRIPS Agreement.

The preamble and Articles 7 and 8 make repeated mention of developmental objectives. This reflects the intention the negotiating parties had prior to the adoption of the TRIPS Agreement. The developed negotiating parties repeatedly inferred that intellectual property rights should and would further the development of countries – despite the lack of empirical evidence that this would occur. The developing negotiating parties, sceptical of the inference, sought to ensure that intellectual property rights would not hamper development. The parties' intention that intellectual property rights should promote development objective, or at the very least, not hamper development was thus incorporated into the objective and purpose provisions of the TRIPS Agreement. The measures that are deemed to fall within the scope of 'development' are left largely to the Member States themselves to determine. This is one of the key flexibility factors in these provisions. They are, to a certain degree, directed by Articles 7 and 8 which state that socio-economic and technical development should result from the manner of implementation. A further policy objective that permits a flexible interpretation of these provisions is the acknowledgement that a balance must exist between the rights holder and the user of the intellectual property. This objective can be interpreted to allow Member States to differ in what they consider to be a balance in the intellectual property system. As the needs or concerns

*tius* principle. Cf. *Matsushita et al*, *The World Trade Organization: Law, Practice, and Policy* (2nd edn OUP Oxford 2006) p. 85-86.

186 S 56(1) of the South African Patent Act construes public interest 'in its widest meaning, namely, the interest of the community including every class which goes to construe that body, namely, the purchasing public, the traders and manufacturers, the patentee and his licensees, and inventors generally'.

of users or rights holders in countries differ, the interpretation of this objective will permit Member States to structure their own balance and implement the TRIPS Agreement in a manner most suited to their requirements. The public interest is a further objective that arises out of the object and purpose clauses in the TRIPS Agreement. The term ‘public interest’ refers to the ‘general welfare of the public that warrants ... protection’.<sup>187</sup> What is deemed to be worthy of protection for the welfare of the public at large evades close interpretation. It is a dynamic concept that evolves according to the demands of the public. Further, interests protected in one Member States need not be recognised as such in all Member States. The TRIPS Agreement does however refer to two examples of public interest: health and nutrition. Other examples public interest factors include the protection of the environment as well as culture, transport, education and knowledge. The extent these factors will influence the implementation of intellectual property rights, or *visa versa*, will depend on the specific circumstances.

## 2. The role of the object and purpose provisions in flexibilities found in other TRIPS provision

The intention of the negotiating parties, as set out in the object and purpose provisions of the TRIPS Agreement, and the flexibility in which it can be applied assumes a firm purpose when interpreting the meaning and flexibilities of the operative provisions of the TRIPS Agreement. The presence of flexible provisions within the TRIPS Agreement is extensive. Thus, as Member States debate the scope of provisions and where the ordinary meaning thereof is not clear, the interpretation and application of the flexibilities becomes of vital importance. The WTO Appellate Body has ruled that the interpretation of treaties should follow the customary rules for the interpretation of public international law. Where the interpreter must proceed beyond the ordinary meaning of the text he is, in accordance with the WTO *US – Shrimps* case, required first to determine the meaning in terms of the immediate context of the provision.<sup>188</sup> This requires to the extent applicable determining the meaning of the relevant *chapeau*. Where the meaning and the object and purpose are not apparent from the *chapeau*, the interpreter must turn to the object and purpose of the treaty as a whole. Articles 7 and 8, together with the preamble, are deemed to encapsulate the intention of the TRIPS Member States. In the *Canada –Patent* case the Panel stated:

‘Both the goals and the limitations stated in Articles 7 and 8.1 must obviously be borne in mind when [examining the scope of the Agreement] ... as well as those of other provisions of the TRIPS Agreement which indicate its object and purposes.’<sup>189</sup>

187 *Garner (ed)*, Black’s Law Dictionary (8th edn Thomson West St. Paul 2004) p. 1266.

188 Contrast *Ortino*, 9 JIEL 1 (2006) p. 130-132.

189 WTO Canada – Pharmaceuticals p. 154.

The role of the preamble and Articles 7 and 8 is thus not only to help determine the scope of the TRIPS Agreement as a whole, but also to assist in the interpretation of the flexibilities found in the operative provisions themselves. This is achieved when Member States and other interpreters of the TRIPS Agreement use the contents of the preamble and Articles 7 and 8 to direct their interpretation and implementation of the ‘wobble-room’ present in most of the operative provisions in the TRIPS Agreement. This entitlement of a Member State is not insignificant. It enables Member States the opportunity to tailor their implementation of the TRIPS Agreement. Many gaps and ambiguities can be found in the TRIPS Agreement and are, in the majority of instances, deliberate. They are characterised by either their refusal to regulate an issue, e.g. exhaustion (Article 6 TRIPS Agreement) or the limited intention to comprehensively regulate an issue.

### 3. The relevance given to the role of flexibility in the object and purpose provisions by the Member States

The relationship between the flexibilities present in other TRIPS Agreement provisions and the preamble and Articles 7 and 8 is therefore of significant importance as the implementation of the operational provisions will be guided by these provisions. The importance of these provisions is however dependent on the importance a Member State will confirm to it. The importance of the object and purpose provisions to Member States, especially developing Member States, became apparent in the wake of the HIV/AIDS epidemic and the ensuing debate within the WTO forum.

With the obligation to implement the TRIPS Agreement becoming increasingly relevant to the Member States, the developing Member States realised the extent of their commitments and sought confirmation that the flexibilities were still available to them.<sup>190</sup> The inability developing Member States had in effectively exercising the flexibilities was compounded by the lack of legal expertise and knowledge in these countries. The affected Member States were unsure of the scope and meaning of the flexibilities, which they saw as key to the implementation of the TRIPS Agreement, and sought ‘guarantees and confirmation that the flexibilities under [the TRIPS Agreement] were available for the Members without challenge’.<sup>191</sup> The importance of the object and purpose provisions and their flexibilities was formally discussed in the TRIPS Council special session ‘Special Discussion on Intellectual Property and Access to Medicines’.

190 The Indian representative is quoted as saying this ‘issue is too important to be left either to chance or to future panels. This is why all of us here should collectively recognize and confirm the considerable degree of flexibility offered by the TRIPS Agreement in this regard’. Cf. India in the WTO Special Discussion on Intellectual Property and Access to Medicines in the TRIPS Council (10.07.2001) IP/C/M/31 p. 22.

191 Zimbabwe in the TRIPS Council Minutes (19.09.2001) IP/C/M/33 p. 64.

The developing Member States sought, *inter alia*, to create a generally recognised obligation to apply customary rules of public international law when interpreting and applying the object and purpose provisions within the TRIPS Agreement.<sup>192</sup> The confirmation that customary rules of interpretation should guide the interpretation of treaties was strictly speaking unnecessary.<sup>193</sup> GATT panel rulings and WTO DSB decisions have confirmed the role of customary rules in their decisions.<sup>194</sup> Notwithstanding this, the developing Member States felt that the DSB had afforded insufficient weight to the customary rules and interpreted the object and purposes of the TRIPS Agreement in a restrictive manner. Within the context of the HIV/AIDS epidemic developing Member States focussed more attention on the meaning of the object and purpose provisions of the TRIPS Agreement, especially the references to social welfare and public health. They concluded that the role of the object and purpose provisions of the TRIPS Agreement meant that the protection of intellectual property rights was subordinated to public policy objectives.<sup>195</sup> Only by making this conclusion could the TRIPS Agreement implemented in a humane manner solidifying the primacy of human life and public wellbeing.<sup>196</sup> As confirmation of this standing, the developing Member States sought consensus that ‘nothing within the TRIPS system should prevent Member States from adopting measures to protect public health’,<sup>197</sup> thus seeking to reacquire the full use of the flexibilities found in the preamble and Articles 7 and 8. This was especially evident in their view that the provisos found in Article 8 requiring the compliance with the remaining TRIPS provisions does not ‘neutralise’ the flexibilities of the provisions.<sup>198</sup>

Developed Member States on the other hand took a more sceptical view of the role of the objectives and principles of the TRIPS Agreement. Whilst they confirmed that health protection measures could still be implemented without conflicting with the TRIPS Agreement they felt that the balance struck between the interests of the public and that of the rights holder had already been made and should not be renegotiated.

192 WTO Submission by Brazil and others to the TRIPS Council ‘TRIPS and Public Health’ (29.6.2001) IP/C/W/296 p. 5.

193 Art 3.2 of the DSU states ‘The Members recognize that [the dispute settlement system] serves to preserve the rights and obligations of Members under the covered agreements, and to *clarify* the existing provisions of those agreements in accordance with *customary rules of interpretation of public international law*. Recommendations and rulings of the DSB cannot add to or diminish the rights and obligations provided in the covered agreements’ (emphasis added).

194 WTO United States – Gasoline Report of the Appellate Body p. 17, WTO Japan – Alcoholic Beverages II p. 11, WTO India – Patent Protection I p. 14.

195 Kenya in the WTO Special Discussion on Intellectual Property and Access to Medicines in the TRIPS Council (10.07.2001) IP/C/M/31 p. 22-23.

196 Tanzania in the WTO Special Discussion on Intellectual Property and Access to Medicines in the TRIPS Council (10.07.2001) IP/C/M/31 p. 29.

197 WTO Submission by Brazil and others to the TRIPS Council ‘TRIPS and Public Health’ (29.6.2001) IP/C/W/296 p. 6.

198 Egypt in the WTO Special Discussion on Intellectual Property and Access to Medicines in the TRIPS Council (10.07.2001) IP/C/M/31 p. 41.

tiated.<sup>199</sup> The application of the object and purpose provisions were seen as being of ‘essential importance’ for the interpretation of the TRIPS Agreement but did not permit a Member State to downgrade the intellectual property protection required by the TRIPS Agreement.<sup>200</sup>

## VII. The role of health in the object and purpose of the TRIPS Agreement

Health, nutrition and other public interest factors were factors used to influence and exercise national intellectual property regimes prior to the TRIPS Agreement. The role of public interest in the patent system was also internationally recognised<sup>201</sup> and even an element recommended by the WIPO.<sup>202</sup> With the adoption of the TRIPS Agreement, public interest evolved into a more tangible factor in the evaluation and implementation of intellectual property rights. Of the various public interest issues referred to in the TRIPS Agreement, health and the protection thereof assumes a particularly prominent role. Article 8 expressly states that ‘Members may ... adopt measures necessary to protect public health’. This statement does not however permit Member States to use health issues as a ground for breaching the remaining provisions within the TRIPS Agreement. In terms of the proviso in Article 8, any measures taken to protect the public health must also be consistent with the TRIPS Agreement. The consequence is that health measures cannot override the obligations that Member States bound themselves to in the TRIPS Agreement. This consequence gives the impression that intellectual property protection is more important than health measures; that patent rights are more important than the protection of the public’s wellbeing. This impression is no more than that, an impression. Legally, the Member States bound themselves to abide by the rules set out in the TRIPS Agreement. The *pacta sunt servanda* notion obliges Member States to abide by the rules

199 Switzerland in the WTO Special Discussion on Intellectual Property and Access to Medicines in the TRIPS Council (10.07.2001) IP/C/M/31 p. 44-45. In the same document Pakistan referred to the so-called carefully negotiated balance as ‘rhetoric, especially when the existing flexibilities in the relevant provision hardly do much to provide space to manoeuvre due to the fact that either the relevant provisions have been drafted in a manner which takes away the possible flexibility or these countries lack at the moment in technical expertise and also entrepreneurial skills to undertake production of generic drugs’. See in this regard Pakistan at p. 74. See also Communication by Canada in the Minutes of the TRIPS Council (02.11.2001) IP/C/M/33 p. 40 and the EU position in WTO *Canada – Pharmaceuticals* p. 154.

200 EC in the WTO Special Discussion on Intellectual Property and Access to Medicines in the TRIPS Council (10.07.2001) IP/C/M/31 p. 7-8, EC and US in the TRIPS Council Minutes (19.09.2001) IP/C/M/33 p. 35, 37 respectively.

201 GATT Note from WIPO ‘Existence, Scope and Form of Generally Internationally Accepted and Applied Standards/Norms or the Protection of Intellectual Property’ (15.06.1988) MTN.GNG/NG11/W/24/Rev.1 9.

202 GATT Note from WIPO ‘Existence, Scope and Form of Generally Internationally Accepted and Applied Standards/Norms or the Protection of Intellectual Property’ (15.06.1988) MTN.GNG/NG11/W/24/Rev.1 9.