

to renege on its TRIPS obligations where it discovers that its implementation of the TRIPS Agreement has failed to improve that country's social and economic well-being. It would thus be correct to state that Article 7 suggests that the TRIPS agreement can and should benefit every society in which it applies. Its success depends on the national implementation of the obligations by the Member States, not on the TRIPS agreement.

The standard used to adjudicate the domestic compliance with Article 7 differs amongst the Member States. Some Member States, in particular the US, take the view that the more extensive the protection and enforcement the more likely one is to attract persons and businesses that innovate and disseminate knowledge. Others feel that the adoption of TRIPS in its most limited form should be sufficient to lead to innovation and dissemination of knowledge.

One major consequence does however ensue from Article 7: intellectual property rights are not a means to an end. Instead they form part of a complex sum aimed to benefit society. Theoretically this provision establishes a barrier to one-sided demands to increase intellectual property protection without due consideration for its effects on other public policies. This 'justification' for limiting the extent of intellectual property rights is however a supple provision. It fails to permit Member States to take active steps to limit intellectual property rights and any limitations must be done in accordance with the scope of the applicable substantive provisions. The practical effect of Article 7 will be limited to its use as reinforcement for an action taken and permitted in other provisions. As the TRIPS Agreement is littered with interpretational nightmares, the ability to justify ones actions under Article 7 may prove sufficient to be label the measures TRIPS-compliant.

The measures regarded as being sufficiently valuable include public interest issues such as social and economic welfare, the transfer of technology and knowledge, the promotion of innovation and the protection thereof. As the relationship is dynamic, should situations require dire measures, Article 7 would not prevent such measures being taken. Such measures will be limited by the notions of reasonableness and proportionality.

### III. An analysis of Article 8.1 TRIPS

#### 'Principles

1. Members may, in formulating or amending their laws and regulations, adopt measures necessary to protect public health and nutrition, and to promote the public interest in sectors of vital importance to their socio-economic and technological development, provided that such measures are consistent with the provisions of this Agreement.'

In implementing the TRIPS agreement, either through new legislation or the amendment of existing legislation, Article 8.1 empowers Member States with the

right to implement the provisions in a manner that protects and enhances the public interest.<sup>154</sup> The express referral to measures necessary to protect public health and nutrition, to promote the public interest in crucial socio-economic and technical areas of development raises the importance of these issues within the TRIPS Agreement. Deciding which measures can be taken is a Member State's prerogative. They may differ from country to country and be justified in one country and not in another. The Member State's discretion is extensive and should, provided it is identified and implemented in good faith and consistent with the remaining TRIPS provisions, be accepted by other Member States.<sup>155</sup> Member States wishing to challenge the public policy measures taken in connection with Article 8.1 will bear the burden of proving that it is inconsistent.<sup>156</sup>

The application of Article 8.1 leads to the question: is Article 8.1 a tool for the interpretation of TRIPS or is it a TRIPS flexibility? Succinctly put, Article 8.1 would be an interpretational tool if it were used to determine if an Member States action itself is permitted or not. On the other hand were Article 8.1 a flexibility, it would permit Member States to implement its contents in a number of differing, but acceptable, ways. The answer to the question is: Article 8.1 can be used as an interpretational tool as well as providing a Member States with certain flexibilities. The wording of Article 8.1 clearly indicates its intention to permit Member States to undertake certain measures. The use of the word 'may' confirms the elective nature of Article 8.1, as is also evidenced in Articles 27.2, 30 and 31. In terms of Article 8.1 Member States are entitled to elect whether to implement certain public interest measures that restrict intellectual property rights. These measures are however only permitted when consistent with the remaining TRIPS provisions. Accordingly, Article 8.1 is of limited significance as a flexibility as it does not permit any additional actions that were not already permitted under other TRIPS provisions.<sup>157</sup> The practical significance of Article 8.1 comes in determining to what extent other flexibilities may be exercised. As a 'principle', Article 8.1 is a 'comprehensive and fundamental' rule of conduct for the implementation of the TRIPS agreement.<sup>158</sup> Article 8.1 confirms the Member States ability to prefer an interpretation which potentially favours public interest issues over rights-holder interests. It needs to be recalled that a flexibility permits numerous TRIPS-compliant implementations. Having said this, the extent of each permissible action under the flexibility is not always certain and has

154 *Gervais*, The TRIPS Agreement: Drafting History and Analysis (2nd edn Sweet and Maxwell London 2005) p. 121.

155 *UNCTAD/ICTSD*, Resource Book on TRIPS and Development (CUP New York 2005) p. 127.

156 *UNCTAD/ICTSD*, Resource Book on TRIPS and Development (CUP New York 2005) p. 127.

157 *Straus*, Implications of the TRIPS Agreement in the Field of Patent Law in: Beier and Schrieker (eds) From GATT to TRIPS – The Agreement on Trade-Related Aspects of Intellectual Property Rights (VCH Weinheim 1996) p. 161, *Gervais*, The TRIPS Agreement: Drafting History and Analysis (2nd edn Sweet and Maxwell London 2005) p. 121.

158 Webster's Third New International Dictionary.

lead certain Member States to challenge the actions of others based upon diverging views over the ambit of a flexibility. The contents of Article 8.1 identify certain values that are held high by the Member States, in particular that of the public interest. The express mentioning of these values and their location within the agreement has ensured that they assume a key role in gauging the intention of the parties. This in turn has meant that the attributes found in Article 8.1 make it a key provision for interpreting the meaning of other provisions within the TRIPS Agreement. The interpretational role of Article 8.1, and Article 7 for that matter, comes further from assisting in creating what is regarded as the greater ‘context’ of the agreement.

Another peculiarity of Article 8.1 is that it seemingly permits Member States to take public policy measures to protect the wellbeing of their citizens. This ‘allowance’ on behalf of the TRIPS Agreement is false for three reasons. Firstly, the TRIPS Agreement desires the ‘effective and adequate protection of intellectual property rights’<sup>159</sup> and, within the scope of the WTO, aims to eliminate discrimination in international trade.<sup>160</sup> Thus the scope of TRIPS does not and cannot extend beyond intellectual property rights and trade. Health and other public policy measures are inalienable from a state and any reading of TRIPS to the contrary would be an *ultra vires* interpretation and unconscionable. Secondly, Article 8.1 permits nothing that is not already permitted elsewhere in the agreement. Thirdly, the permission to take certain public interest measures does not entitle a Member States to limit or exclude the rights and/or obligations found in TRIPS.<sup>161</sup>

The entire provision rests on the premise that the measures taken do not conflict with the remaining operative provisions within the TRIPS Agreement. Thus, Article 8.1 does not permit an action that is not already permitted elsewhere in the TRIPS Agreement. The inclusion of this proviso confirms the role of Article 8.1 within the TRIPS Agreement as being a general provision which does not permit measures that conflict with other TRIPS provisions. The use of the proviso contrasts with existing GATT practice where Article XX(b), similar in language to Article 8.1, does not require such measures to be consistent with the other GATT provisions. As this constraint requires Member States not to adopt measures that are inconsistent with the TRIPS Agreement, it can be presumed that measures taken to address public health, nutrition and matters of vital socio-economic importance are consistent with the TRIPS Agreement.<sup>162</sup> Thus, the burden to prove the inconsistency of the measure rests on the Member State that avers the inconsistency.<sup>163</sup>

159 TRIPS Preamble.

160 *de Carvalho*, The TRIPS Regime of Patent Rights (Kluwer The Hague 2002) p. 120.

161 In the WTO *Brazil – Retreaded Tyres* case the Panel stated it was not within their scope to judge on the desirability of a Member State’s policy goal or its level of protection, instead it is only to decide on the WTO-compliance thereof. See WTO *Brazil – Retreaded Tyres* p. 166-169.

162 UNCTAD/ICTSD, Resource Book on TRIPS and Development (CUP New York 2005) p. 127.

163 A similar burden of proof applies to Art XX GATT. See WTO *Brazil – Retreaded Tyres* p. 150.

Article 8.1 requires that all actions that be ‘necessary’. This obligation infers that there must be a direct connection between the measures taken and their impact on the public interest.<sup>164</sup>

Article 8.1 is not a once-off entitlement. It enables Member States to take public interest actions at any time. The contents of Article 8.1 limit the permissible measures to ‘laws and regulations’.<sup>165</sup> Article 8.1 only permits two types of measures: the *protection* of public health and nutrition and the *promotion* of the public interest, provided the areas being promoted are of vital importance to the development of that Member State. Thus Article 8.1 permits health, nutritional and developmental measures, provided the latter is vitally important to that Member States.

The formulation of Article 8.1 denotes that Member States implementing health policies will be presumed to act in compliance with the TRIPS Agreement. This therefore implies that a Member State challenging the TRIPS-legitimacy will bear the burden of proving its inconsistency.<sup>166</sup>

The existence of Articles 7 and 8 provide support for a limitation of the provision preventing the discrimination of patents according to their ‘field of technology’ found in Article 27.1. Whereas a discrimination will always remain unlawful under the TRIPS Agreement, the reference to health, nutritional and developmental measures within Articles 7 and 8 increases the scope and acceptance of what will be deemed a lawful and justifiable ‘discrimination’ of Article 27.1; the DSU terms such limitations ‘differentiations’.<sup>167</sup>

To conclude, Article 8.1 is an interpretive principle that entitles Member States to take public policy actions that possibly limit intellectual property rights provided they are justifiable actions and consistent with the other obligation contained within the TRIPS Agreement. Phrased in the reverse, public policy measures will fail if they exceed what is necessary to promote and protect the public interest or if they are unnecessarily trade-restrictive.

#### IV. An analysis of Article 8.2 TRIPS Agreement

Article 8.2 ‘Appropriate measures, provided that they are consistent with the provisions of this Agreement, may be needed to prevent the abuse of intellectual property rights by right holders or the resort to practices which unreasonably restrain trade or adversely affect the international transfer of technology.’

Notwithstanding Article 7, which requires a balance of rights between the rights holders and the users, Article 8.2 accepts that intellectual property rights can be

164 *de Carvalho*, The TRIPS Regime of Patent Rights (Kluwer The Hague 2002) p. 119.

165 Administrative actions would therefore seem to be excluded from Article 8.1 of the TRIPS Agreement.

166 *Abbott*, Quaker Paper 7 (2001) p. 25.

167 WTO *Canada – Pharmaceuticals* p. 170-171. See Chapter 5(C)(I)(2)(c) below for a discussion on discrimination and differentiation.