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.[164]

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'.[165] 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.[166]

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'.[167]

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.

abused to the detriment of the Member States, other inventors and the user or consumer. Article 8.2 expressly acknowledges that it may be necessary for Member States to take appropriate measures to prevent such abuse within their jurisdictions. In addition to preventing the abuse of the intellectual property system, Article 8.2 also permits a Member State to counter practices that stifle trade, i.e. that are anti-competitive, or negatively impact on the transfer of technology.[168] Intellectual property licensing systems are often targeted as potentially being examples of both intellectual property abuses and unreasonable restraints on trade. Article 8.2 only permits those measures taken to prevent abuse if they are 'appropriate'. This is understood to require the measures to be both adequate and proportionate in relation to the abuse.[169] The abuse must justify the measure, i.e. it must be necessary. The measure referred to in Article 8.2 needs to *prevent* an abuse, i.e. a measure can be implemented to proactively avoid even the occurrence of the abuse and the need to respond to an existing abuse. This Article 8.2 empowers Member States to implement a general policy regime regulating anti-competitive behaviour within the realm of intellectual property rights.[170] Finally, as all intellectual property rights have the potential for abuse, Article 8.2 can be applied to all potential abuses of intellectual property rights.

As the contents of Article 8.2 face the same limitations as Article 8.1, i.e. neither provisions entitle measures that are not already permitted elsewhere in the TRIPS Agreement, the legal value of the provision is limited to that of an interpretational aid whilst examining the extent of other provisions within the TRIPS Agreement. An example of the application of Article 8.2 would be the granting of a non-exclusive license by a national governmental agency enabling the third party use of a patent without the patent holder's consent in order to rectify the patent holder's anti-competitive actions. Although these actions are provided for within Article 31, Article 8.2 can be used to evaluate the extent of the actions permissible. Article 8.2 therefore introduces a legal standard – the requirement of 'reasonableness' – requiring Member States to evaluate whether certain measures to prevent competition abuse are compatible with the TRIPS Agreement.[171] Aside from providing the TRIPS provisions with a degree of legal certainty when dealing with anti-competitive behaviour, the extent of influence of Article 8.2 is hemmed by the operation of Article 40, concerning the control of anti-competitive practices in contractual licensing of intellectual property rights.

168 *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. 121.

169 *de Carvalho*, The TRIPS Regime of Patent Rights (Kluwer The Hague 2002) p. 132.

170 See further in this regard *de Carvalho*, The TRIPS Regime of Patent Rights (Kluwer The Hague 2002) p. 133.

171 The scope of Art 8.2 of the TRIPS Agreement extends to three types of practices: abuse of rights, anti-competitive practices and acts that have a negative impact on the transfer of technology.

V. The influence of the international customary rule of interpretation on the object and purpose provisions

In adjudicating a dispute, both panel members and the Appellate Body are bound in terms of Article 3.2 to pursue the clarification of the WTO agreements in light of the '*customary rules of interpretation of public international law'*. Accordingly, WTO adjudicators are required to abide by certain basic rules of interpretations. The Vienna Convention on the Law of Treaties is considered the best collection of the customary rules of interpretation.[172] The golden rule, Article 31(1) of the Vienna Convention, requires adjudicators to give the disputed text its 'ordinary meaning'. In determining the ordinary meaning the terms must be interpreted within 'their context *and* in the light of its object and purpose' (emphasis added). This therefore means that the ordinary meaning of a treaty's provisions is not limited to the meaning of the words but instead a more comprehensive meaning has to be given, a meaning that complies with and gives effect to the object and purpose of the treaty.[173] A treaty provision cannot be interpreted on face value only. Its meaning derives from the treaty as a whole, preamble and annexes included.[174] The ordinary meaning cannot be isolated from the objects and principles of the treaty as it is often these provisions that reflect the common intention of the parties.

The objectives and principles laid down in the TRIPS Agreement, the preamble as well as Articles 7 and 8, are not merely an aid for determining a meaning of a vague term or provision; they are instead a mandatory consideration factor that must be considered when determining the ordinary meaning of the TRIPS Agreement. Developing Member States expressed their concern that the DSB was failing in this regard, thus effectively enforcing a treaty that no longer represented the common intention of the parties. In addition there was growing concern that the role of the object and purpose provisions in examining the TRIPS Agreement was being progressively sidelined. It was hoped that the express referral of certain Member States prior to the Doha Ministerial Conference to the interpretational provisions of international treaty law would serve to counter the apparent arbitrariness certain DSB

172 WTO *Japan – Alcoholic Beverages II* p. 11, WTO *United States – Gasoline* Report of the Appellate Body p. 16-17; WTO *United States – Section* 211 (Appellate Body ruling) p. 77. See also WTO Submission by Brazil and others to the TRIPS Council 'TRIPS and Public Health' (29.6.2001) IP/C/W/296 p. 5, *Ehlermann and Lockhart*, 7 JIEL 3 (2004) p. 497.

173 Art 31(1) of the Vienna Convention is a compulsive provision. It states a 'treaty *shall* be interpreted in good faith in accordance with the ordinary meaning to be given to the terms of the treaty in their context and in the light of its object and purpose' (emphasis added).

174 A WTO panel concluded that 'the elements referred to in Art 31 – text, context and object-and-purpose as well as good faith – are to be viewed as one holistic rule of interpretation rather than a sequence of separate tests to be applied in a hierarchical order'. WTO *United States – Sections 301-310 of the Trade Act of 1974* Report of the Panel (22.12.1999) WT/DS152/R p. 305.