Invoking the Waiver Provisions of Article 31: A Matter of Certainty or Precaution?

Should the Precautionary Principle apply to the waiver provisions of Article 31(b) of the TRIPS Agreement?

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Introduction

Fred Abbott claims that the Agreement on Trade-Related Aspects of Intellectual Property ("TRIPS") "emerged from the Uruguay Round negotiations as one of the three pillars of the WTO".[1] In legal terms, TRIPS is a covered agreement under the Agreement Establishing the World Trade Organisation ("WTO Agreement'). It seeks to balance the protection of intellectual property rights with the need to address issues of social and economic welfare[2], including public health[3]. Article 31 of TRIPS sets out the situations in which a Member state may grant a non-voluntary licence of a patent that it would otherwise be required to protect[4]. Further, Article 31(b) sets out the situations in which such a licence may be granted without prior discussion with the patent holder. These situations are limited to "national emergency or other circumstances of extreme urgency" or "public non-commercial use" ("a waiver situation"). [5]

To date, it remains unclear how a Member state is required to determine that a waiver situation exists. For example, while it has been expressly acknowledged that Members may determine for themselves whether a "national emergency or other circumstances of extreme urgency" exists[6], it is not clear to what extent they must demonstrate their method of risk analysis, and what that analysis should reasonably involve. In particular, it is not clear whether the risk analysis must only taken into account risks which can be calculated with scientific certainty, or whether the Precautionary Principle can be applied.

The Precautionary Principle is a "legal mechanism for managing environmental risk in situations where incomplete scientific knowledge of a proposed activity or technology's impact exists."[7] It has been adopted into international treaties relating to the environment and biosafety[8], and is one of the principle tenets of environmental law[9]. Although lacking in detailed specificity, it has been summarised as the principle that "[w]here there are threats of serious or irreversible damage, lack of full scientific certainty shall not be used as a reason for postponing cost-effective measures to prevent environmental degradation".[10] The Precautionary Principle is also applicable to risk

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[1] Abbott, F M "Toward a New Era of Objective Assessment in the Field of the TRIPS Agreement And Variable Geometry for the Preservation of Multilateralism" (2005) 8(1) JIEL 77, 77.
[2] Article 7, TRIPS.
[3] Article 8, TRIPS.
[4] Article 28 TRIPS.
[5] Article 30 also sets out provisions for exceptions. However, the requirements for an Article 30 exception differ from Article 31 and are beyond the scope of this paper.
[6] *Declaration on the TRIPS Agreement and Public Health,* Adopted on 14 November 2001, Ministerial Conference, Doha 9-14 November 2001 WT/MIN(01)/DEC/2, 20 November 2001, Paragraph 5(c).
[7] Puttagunta, P S "The Precautionary Principle in the Regulation of Genetically Modified Organisms" (2001) 9 *Health Law Review* 2, <http://www.law.ualberta.ca/centres/hli/pdfs/hlr/v9_2/puttaguntafrm.pdf> at page 10.
[8] Article 15, *Rio Declaration on Environment and Development* (Annex 1 to the *Report of the United Nations Conference on Environment and Development*, Rio de Janiero, 3-14 June 1992); *Cartagena Protocol on Biosafety to the Convention on Biological Diversity*, Montreal, 2000, entry into force 11 September 2003.
[9] Puttagunta, supra n 1.
[10] Article 15, *Rio Declaration on Environment and Development*, supra n 8.

analysis in other areas of public law, including public health.[11] Accordingly, it could be argued as extending to the risk analysis underpinning the compulsory licensing of pharmaceuticals under TRIPS.

The issue has so far arisen in WTO disputes only in the context the *Agreement on Sanitary and Phytosanitary Measures*[12] *("SPS")*, in relation to which Panel and Appellate Body decisions have left the applicability of the Precautionary Principle open. There is no case law on the applicability of the Precautionary Principle to TRIPS.

This paper puts forward the thesis that, although the waiver provisions of Article 31 recognise the right of Member states to undertake their own risk analysis, the provisions do not go far enough to ensure workability. While the TRIPS Agreement may have scope to allow a weak version of the Precautionary Principle, some obstacles still exist which make it legally difficult, and perhaps impossible, for the Member relying on the waiver provisions to invoke the Precautionary Principle. This is at odds with accepted norms in adjacent areas of international law.

The first major obstacle to the adoption of the Precautionary Principle is its lack of precise definition. Therefore, this paper will firstly seek to outline the scope of the concept and explain how it is relevant to TRIPS. Five key elements will be identified which will form the working definition for the purposes of the paper.

The second major obstacle is the uncertain status of the Precautionary Principle in international law. Therefore, this issue will be discussed and a tentative conclusion reached. This will be followed by an examination of status of the Precautionary Principle in WTO jurisprudence to date. It will be shown that, despite the adoption of the Precautionary Principle into other treaties during the intervening period, the applicability of the Precautionary Principle to the WTO Agreement has advanced little and remains open. However, existing case law is of limited authority with respect to TRIPS, for two reasons. Firstly, there is officially no precedent system in WTO law. Secondly, both cases related to the SPS, which raised different issues of textual interpretation[13]. Therefore, an interpretation exercise with respect to TRIPS may well arrive at a different conclusion.

It is therefore necessary to undertake an interpretation exercise to consider how the Precautionary Principle could, or should, apply to TRIPS. Specifically, it considers whether the Precautionary Principle should apply when determining whether a Member state is experiencing a waiver situation.[14] Focus will then turn to two key issues that are not so easily resolved: the issue of transparency and its nexus with good faith, and the burden of proof. It will be concluded that reasonable transparency would still be required, but that some express modifications may need to be made to the burden of proof. With these provisos however, it will be shown that the TRIPS Agreement does contain implicit scope to use the Precautionary Principle.

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[11] *European Council Resolution on the Precautionary Principles: Submission by the European Communities,* WTO document: G/SPS/GEN/225; G/TBT/W/154; WT/CTE/W/181, 2 February 2001.

[12] Annex 1A, *Agreement Establishing the World Trade Organisation.*

[13] In *EC –Biotech,* at paragraph 124, the Panel stated, " the Precautionary Principle does not, by itself, relieve a panel from the duty of applying the normal … principles of treaty interpretation in reading the provisions of the SPS agreement": Panel Report, *European Communities – Measures Affecting the Approval and Marketing of Biotech Products,* WT/DS291/R, WT/DS292/R, WT/DS293/R, adopted 21 November 2006. Article 31.1 of the *Vienna Convention on the Law of Treaties* requires a treaty to be interpreted in light of its ordinary meaning and context.

[14] i.e., a "national emergency or other circumstances of extreme urgency" or "public non-commercial use".

Having conducted an interpretative exercise and determined that the TRIPS Agreement *could* accommodate the Precautionary Principle, it is then necessary to conduct a policy review to determine whether it *should* do so.

Finally, consideration will be given to whether there is benefit to be had from aligning TRIPS with the Rio Declaration by expressly incorporating the Precautionary Principle. Quite apart from the obvious value that is to be had from international consistency, the issues of environmental safety and public health and environmental safety are often interwoven and there is therefore value to be had from aligning the principles in the relevant instruments.

It will be concluded that the TRIPS Agreement does have scope to accommodate a weak version of the Precautionary Principle. However, there are limitations prescribed by the terms and scheme of TRIPS, and these justify the absence of any express reference to the Precautionary Principle.

What is the Precautionary Principle?

The Precautionary Principle is a "legal mechanism for managing environmental risk in situations where incomplete scientific knowledge of a proposed activity or technology's impact exists."[15]

In a practical sense, the Precautionary Principle is a form of risk analysis.[16] Typically, risk analysis has two distinct phases: risk assessment and risk management.[17] Risk assessment involves an empirical evaluation of all scientific evidence regarding the impact of the proposed activity. The second stage, risk management, involves a broader consideration of scientific evidence along with other factors in order to determine whether the risk is acceptable and how best it should be managed. If the risk assessment is uncertain, then the Precautionary Principle will take effect in the risk management stage when weighing that uncertainty against potential harm to the environment and public health. It "will not accept that an activity is safe just because science cannot prove conclusively that it is dangerous".[18]

The Precautionary Principle has been adopted into international treaties relating to the environment and biosafety[19], and is one of the principle tenets of environmental law[20]. Arguably the most authoritative articulation of the Principle is contained the 1992 Rio Declaration, Principle 15 of which states:

> In order to protect the environment, the precautionary approach shall be widely applied by States according to their capabilities. Where there are threats of serious or irreversible damage, lack of full scientific certainty shall not be used as a reason for postponing cost-effective measures to prevent environmental degradation.[21]

There are two significant points that are of relevance to this topic. Firstly, Principle 1 of the Rio Declaration states:

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[15] Puttagunta, supra n 7 at 10.
[16] The description in this paragraph draws on Puttagunta, ibid, 12.
[17] It is sometimes also said that a third limb is "risk communication". See, for example, World Trade Organisation *Communication from the European Commission on the Precautionary Principle: Submission by the European Communities* WT/CTE/W/147, G/TBT/W/137, 27 June 2000, paragraph 4.
[18] Puttagunta, supra n 7 at 12
[19] Article 15, *Rio Declaration*, supra n 6; *Cartagena Protocol*, supra n 8.
[20] Puttagunta, supra n 1.
[21] Article 15, *Rio Declaration*, supra n 8.

> Human beings are at the centre of concerns for sustainable development. They are entitled to a healthy and productive life in harmony with nature.

This suggests that Article 15 seeks to preserve human life and, by implication, public health via international environment law. Secondly, Article 15 uses the term "shall" rather than "might", implying a requirement, rather than an option, to apply the Precautionary Principle.

The Precautionary Principle or Approach as contained in the Rio Declaration has also been re-affirmed more recently in the Cartagena Protocol on Biosafety to the Convention on Biological Diversity.[22] Unfortunately, neither instrument gives a definition of the Precautionary Principle. In fact, this lack of definition is one of the key obstacles to acceptance of the Precautionary Principle. Its nebulous nature arguably makes it hard to define or implement, and difficult to accept as a principle of international law.[23] In fact, although the *Rio Declaration* widely cited as the most authoritative statement of the Precautionary Principle, it does in fact refer to a "precautionary *approach*" and some commentators draw a distinction between the two concepts. For example, Lawrence Kogan[24] considers the Precautionary *Principle* merely requires broad scientific uncertainty whereas the Precautionary Approach can be used only in cases of insufficient scientific evidence. The Cartagena Protocol does little to help, as it appears to conflate the two terms. This can be seen in Article 10.6, which states:

> *Lack of scientific certainty* due to *insufficient relevant scientific information and knowledge* regarding the potential adverse effects … *taking also into account risks to human health,* shall not prevent that Party from taking a decision …[emphasis added].

However, as Arie Trouwborst points out, most commentators and many international legal instruments use the terms interchangeably.[25] Therefore, for the purposes of this paper, they will be considered interchangeable.

The paradox in all this uncertainty is that the definition is "intentionally imprecise" in order to capture the broadest possible international consensus and allow application in a range of situations.[26]

Saradhi Puttagunta has completed a useful work, which pulls together the various sources of the Precautionary Principle and identifies five core elements to the Precautionary Principle. They are:

1. The threshold for application;
2. The recognition of the inadequacy of existing science;
3. The shifting burden of proof;
4. The ethic of protection; and
5. The proactive and anticipatory approach. [27]

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[22] See Preamble; Articles 1, 10.6 and 11.8, Annex III. .
[23] See, *EC – Hormones,* Appellate Body Report, *EC Measures Concerning Meat and Meat Products (Hormones)* WT/DS25/AB/R, WT/DS48/AB/R, adopted 13 February 1998.
[24] Kogan, "WTO Ruling on Biotech Foods Addresses 'Precautionary Principle'" (2006) 21(38) *Legal Backgrounder* (Washington Law Foundation) <http://www.itssd.org/Publications/wto-biotech-foods-dec0806.pdf>.
[25] Trouwborst, A *Evolution and Status of the Precautionary Principle in International Law* (2002) 4-5.
[26] Nolan, N and Williams, M "Electromagnetic Radiation Emissions and the "Precautionary Principle" (1996) 1 RMB 215, 216.
[27] Puttagunta, supra n 7 at 13.

The first element, the threshold for application, means that the Precautionary Principle applies only where there is lack of scientific knowledge regarding the impact of the proposed activity. Puttagunta claims it is unclear what level of uncertainty is required. The European Commission on the Precautionary Principle has stipulated that at least some potential for harm must have been identified, and that scientific evaluation regarding that harm must be unable to determine that risk of that harm with certainty.[28] The contentious issue is whether the identification of potential harm must be scientifically based or simply precautionary, and the standard of proof that is required. Critics of the Precautionary Principle argue that it always assumes the worst-case scenario; i.e. that negative impacts "might" happen.[29] However, this is not necessary so. In New Zealand, where the Resource Management Act 1991 imports a precautionary approach the Environment Court has held that evidence must be weighed on the balance of probabilities. [30] This means that a risk which has little proven probability may nevertheless be legally significant if it is has a high potential for adverse impact. [31] The Environment Court acknowledged that this assessment of impact might be necessarily less objective than the assessment of probability.[32] The European Commission on the Precautionary Principle also argues that scientific evaluation (whether based on data or reasoning) must logically precede the identification of risk[33]. Having identified the risk, it must then also be scientifically impossible to determine the scope or degree of risk with sufficient certainty.[34]

The second element of the Precautionary Principle recognises that science is often inadequately equipped for conclusively predicting potential harm, which will often only be evident after a period of time and may occur as a result of unforeseen cumulative effects.[35]

The third element is the shifting burden of proof. In recognition of the inadequacy of science, the Precautionary Principle shifts the burden of proof from the party alleging potential harm from technology (as would be usual) to the proponent of the technology, requiring them to prove its safety. The rationale is that harm can often only be proven with the benefit of hindsight, by which time the public has borne the negative effects. The difficulty with this is in proving the negative, especially since science is ill equipped to prove that no-risk exists.[36] Indeed, it has been said that "no risk" is logically impossible to prove.[37] However, others argue that it not necessary to show "no risk", but merely to show that "the risk is acceptable pursuant to a reasonable person test".[38]

Advocates of the Precautionary Principle argue that some shift in burden is justified because it focuses on the ethic of protection. This is the fourth element that Puttagunta

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[28] WTO *Communication from the European Commission on the Precautionary Principle: Submission by the European Communities*" WT/CTE/W/147, G/TBT/W/137, 27 June 2000, paragraph 4.
[29] More, M "The Proactionary Principle" (Version 1.2. 2005) <http://www.maxmore.com/proactionary.htm> .
[30] *Shirley Primary School v Telecom Mobile Communications Ltd* [1999] NZRMA 66, para 114.
[31] Ibid, paras 116-120.
[32] Ibid, para 131.
[33] WTO *Communication from the European Commission on the Precautionary Principle: Submission by the European Communities,* supra n 17, paragraph 44.
[34] Ibid, paragraph 52.
[35] Puttagunta, supra n 7, at 14.
[36] Ibid.
[37] *Shirley Primary School v Telecom,* supra n 30 at para 106.
[38] Somerville, R "Risk, Regulation and the Resource Management Act: the Case of Electricity Generation and Transmission", PhD thesis, University of Otago, August 2001, p 350.

identifies. In stronger versions, this means protecting the intrinsic value of humans and the environment; in weaker versions it takes a more utilitarian approach by weighing these concerns against economic and other costs.[39]

The final element is the proactive and anticipatory approach to risk analysis.[40] Overall, the Precautionary Principle seeks to anticipate possible cause and effects, and to prevent harm occurring. Therefore, it cannot afford to wait until harm is proven through occurrence. Critics argue that this opens the floodgates for fear and irrationality.[41] However, the European Commission has argued that "reliance on the Precautionary Principle is no excuse for derogating from the general principles of risk management" including proportionality, non-discrimination; consistency; examination of the benefits and costs of action or lack of action; and examination of scientific developments.[42]

The status of the Precautionary Principle in international law

The Precautionary Principle is often described as a "general principle of international law".[43] The general parameters of international law have been codified in Article 38.1 of the *Statute of the International Court of Justice* as:

> (a) international conventions, whether general or particular, establishing rules expressly recognized by the contesting states;
> (b) international custom, as evidence of a general practice accepted as law;
> (c) the general principles of law recognized by civilized nations;
> (d) ... judicial decisions and the teachings of the most highly qualified publicists of the various nations, as subsidiary means for the determination of rules of law.

In terms of the sub-clause (a), the Precautionary Principle is embodied in over 50 multilateral agreements[44], with perhaps the most significant being the *Rio Declaration.* However, the *Rio Declaration* is yet to be ratified by many states, including the United States. This means that, for those states, which have not ratified, the Precautionary Principle is not "international law" under Article 38.1(a). The same difficulty applies to sub-clauses (b) to (d). For example, although the US does not recognise the Precautionary Principle, the European Communities[45] have actively and expressly endorsed the Precautionary Principle, as have, for example, New Zealand[46] and Australia[47]. Overall however, there is a growing body of commentary claiming that there is sufficient state practice to argue that it has crystallized into international law.[48]

The second argument against the Precautionary Principle's status as international law is its uncertain parameters. However, as Trouwborst points out, it is no less certain in scope than some other principles, such as the prohibition against use of force, which have attained *jus cogens* status in international law.[49]

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[39] Puttagunta, supra n 7 at 14.
[40] Ibid.
[41] Puttagunta, supra n 7 at 12.
[42] WTO *"Communication from the European Commission on the Precautionary Principle: Submission by the European Communities,* supra n 17 at paras 63-64.
[43] Trouwborst, A *Evolution and Status of the Precautionary Principle in International Law* (2002) 4-5, 34.
[44] Ibid, 286. For a discussion of various examples, see Trouwborst chap 3.1.
[45] WTO *Communication from the European Commission on the Precautionary Principle: Submission by the European Communities*, supra n 17, paras 63-64.
[46] *Greenpeace New Zealand Inc v Minister of Fisheries,* High Court, 27 November 1995, CP 492/93. Gallen J; *Shirley Primary School v Telecom,* supra n 30; Hazardous Substances and New Organisms Act 1996.
[47] Trouwborst, supra n 25 at 227-237.
[48] Ameron, J and Abouchar, J "The Status of the Precautionary Principle in International Law" in Freestone, D & Hey, E (eds) *The Precautionary Principle and International Law* (1996) 29, 52.
[49] Trouwborst, supra n 25 at 53.

Overall, it is probably fair to say that the Precautionary Principle as crystallized as principle of international *environmental* law, but remains an emerging principle of *customary or general* international law.[50]

The status of the Precautionary Principle in WTO jurisprudence

The status of the Precautionary Principle in relation to the WTO Agreement remains even less clear. The seminal case on the issue is the Appellate Body decision in *EC – Hormones.*[51] In that case the measure at issue was the EC's prohibition on importation of meat and meat products treated with certain hormones[52], which the Panel had found to be inconsistent with Articles 3 and 5 of the SPS. The EC argued that Articles 5.1 and 5.2 did not preclude the application of the Precautionary Principle in the process of risk assessment. It further argued that the Panel had erred in finding that the Precautionary Principle may be in conflict with Articles 5.1 and 5.2.[53]

It is worth setting out Articles 5.1 and 5.2 in full. They state:

> 5.1 Members shall ensure that their sanitary or phytosanitary measures are based on an assessment, as appropriate to the circumstances, of the risks to human, animal or plant life or health, taking into account risk assessment techniques developed by the relevant international organizations.
>
> 5.2 In the assessment of risks, Members shall take into account available scientific evidence; relevant processes and productions methods; relevant inspections, sampling and testing methods; prevalence of specific diseases or pests; existence of pest – or disease – free areas; relevant ecological and environmental conditions; and quarantine or other treatment.

The US argued, firstly, that the Precautionary Principle did not "represent a principle of customary international law" and, secondly, that the SPS already provided Members with the ability to determine their own level of protection.[54] Canada also argued that the Precautionary Principle was not yet a principle of international law but that, in any event, the Panel had correctly held that it could not over-ride the provisions of Articles 5.1 and 5.2.[55] The Appellate Body refused to be drawn on the precise status of the Precautionary Principle, finding instead that it simply did not over-ride the provisions of Articles 5.1 and 5.2.[56] However, the Appellate Body did make a number of useful comments. With respect to the general status of the Precautionary Principle, it noted that that even if it had crystallized as a principle of customary international *environmental* law, its status as general or customary international law remained less clear. With respect to the SPS in particular, it made four comments. Firstly, the Precautionary Principle "finds reflection" in Article 5.7 of the SPS. Secondly, this does not exhaust the relevance of the Precautionary Principle, because it is also reflected in the Preamble and Article 3.3. These provisions expressly acknowledge that Members may introduce more cautious levels of protection than those implied in international standards. Thirdly, in determining whether "sufficient scientific evidence" exists, a panel should bear in mind that "responsible, representative governments commonly act from perspectives of prudence and precaution where risks of irreversible, eg life-

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[50] This view was taken by the WTO Appellate Body in *EC – Hormones,* supra n 23, and followed 8 years later by *EC – Biotech,* supra n 13.
[51] *EC – Hormones,* ibid.
[52] Paragraph 2.
[53] Paragraph 16.
[54] Paragraph 43.
[55] Paragraph 60.
[56] Paragraph 125.

terminating, damage to human health are concerned." And, fourthly, the Precautionary Principle does not, of itself, relieve a panel from the duty to apply the normal rules of treaty interpretation.[57]

From this one can infer that the Precautionary Principle was accepted as a rational means of risk assessment or risk management, providing it does not conflict with the specific provisions of the SPS. Furthermore, the Appellate Body did not find that the Precautionary Principle was inconsistent with Articles 5.1 and 5.2. In fact, it appeared to acknowledge that a Member could take a precautionary approach when deciding on which measure to take. This is evidenced in the following two statements:

> We do not believe that a risk assessment has to come to a monolithic conclusion that coincides with the scientific conclusion of view implicit in the SPS measure. ... Determination of the presence or absence of that relationship [between the risk and the measure] can only be done on a case-to-case basis, after account is taken of *all considerations* rationally bearing upon the issue of potential adverse health effects. [Emphasis added][58]

> We consider that the object and purpose of the SPS Agreement justify the examination and evaluation of all such risks for human health whatever their precise and immediate origin may be.[59]

However, the appeal was dismissed because the EC had failed to demonstrate to the Panel that it had conducted a risk assessment within the meaning of 5.1 and 5.2.[60].

Eight years later, the Precautionary Principle was raised again by the EC in the case of *EC – Biotech.*[61] This time the EC argued that the Precautionary Principle had become a fully fledged principle of international law, and pointed to the its inclusion in the *Rio Declaration* and the *Cartagena Protocol.*[62] Again, the US argued that it remained insufficiently defined to become a principle of international law[63], did not over-ride the specific obligations of the SPS[64], and that in any event the EC had failed to show how it would alter the interpretation of the relevant provisions[65]. The Panel followed the decision of the Appellate Body in *EC – Hormones* where it had stated that:

> [T]he precautionary principle does not, by itself, and without a clear textual directive to that effect, relieve a panel from the duty of applying the normal (i.e. customary international law) principles of treaty interpretation in reading the provisions of the SPS Agreement.[66]

The Panel acknowledged that principles of treaty interpretation would include consideration of international conventions, such as the *Rio Declaration,* but only to the extent that they were informative with respect to the issue at hand. It found that the conventions cited by the EC did not inform the interpretation of the SPS.[67]

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[57] Paragraphs 123- 124.
[58] Paragraph 194.
[59] Paragraph 206.
[60] Paragraphs 207-209.
[61] *EC – Biotech,* supra n 13.
[62] Paragraph 7.78.
[63] Paragraph 7.82.
[64] Paragraph 7.83.
[65] Paragraph 7.80.
[66] Paragraph 7.87.
[67] Paragraphs 7.90-7.95.

In the end, the general rule of interpretation[68] requires a panel to address the precise terms and context of the relevant treaty. Therefore, decisions relating to the SPS Agreement are of limited value; the applicability of the Precautionary Principle to the TRIPS Agreement can only be determined after a close examination of TRIPS itself.

The Precautionary Principle applied to Article 31 of the TRIPS Agreement

The TRIPS Agreement is a "covered agreement" under the WTO Agreement.[69] It aims to "reduce distortions and impediments to international trade" by promoting "effective and adequate protection for intellectual property rights" while ensuring that "measures and procedures to enforce intellectual property rights do not themselves become barriers to legitimate trade".[70] Members are required to provide minimum standards of intellectual property protection[71] in a manner consistent with principles of the national treatment[72] and most-favoured-nation treatment[73]. The standards of intellectual property protection are consistent with existing conventions on intellectual property[74]; the key difference is that TRIPS can be legally enforced under the WTO Understanding on the Rules and Procedures Governing the Settlement of Disputes ("DSU")[75] and effectively backed by sanctions[76]. At the negotiation stage, the aim of including TRIPS in the WTO Agreement was to provide an effective mechanism to ensure world wide protection of intellectual property rights[77]; in part a "capture" of public power by private interests[78]. However, the stated objectives in the final version of the TRIPS Agreement strike more of a balance between public and private rights. Article 7 "Objectives" states:

> The protection and enforcement of intellectual property rights should contribute to the promotion of technological innovation and to the transfer and dissemination of technology, to the mutual advantage of producers and users of technological knowledge and in a manner conducive to social and economic welfare, and to a balance of rights and obligations.

Section 5 of the TRIPS Agreement sets out the requirements with respect to patents. Member States are required to provide exclusive rights to patent holders[79], subject to the exceptions set out in Articles 30 and 31.[80]

In turn, Article 30 provides for limited exceptions providing they:

> do not reasonably conflict with a normal exploitation of the patent and do not unreasonably prejudice the legitimate interests of the patent owner, taking account of the legitimate interests of third parties.

Thus the focus of Article 30 is on the reasonable rights of the patent *owner,* and provides for general legislative exceptions to patent rights. Article 31, on the other

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[68] As set down in Article 31 of the *Vienna Convention on the Law of Treaties.*
[69] Annex 1C WTO Agreement.
[70] Preamble.
[71] Articles 1 and 2.
[72] Article 3
[73] Article 4
[74] Article 1.2. For example, the Paris Convention for the Protection of Industrial Property still applies to patents and trademarks under TRIPS.
[75] Article 64 TRIPS, Articles 1-3 DSU.
[76] Articles 21 and 22 DSU.
[77] Sell, S K Private Power, Public Law: The Globalisation of Intellectual Property Rights (2003), Chapter 5. UNCTAD-ICTSDA Resource Book on TRIPS and Development (2005) 462-463.
[78] Picciotto. S "Defending the Public Interest in TRIPS and the WTO" in Drahos, P and Mayne, R *Global Intellectual Property Rights: Knowledge, Access and Development* (2002) 225, 229.
[79] Article 28.1
[80] *Canada – Pharmaceutical Patents,* Panel Report, *Canada – Patent Protection of Pharmaceutical* Products, WT/DS114/R, adopted 7 April 2000, para 7.19.

hand, seems to focus more on the reasonable rights of the patent *user* and allows for non-voluntary licensing of patent rights. It allows States to permit the use of patents, on unspecified grounds[81] but with certain conditions[82], providing the user has tried and failed to obtain authorization from the patent owner[83]. However, the obligation to obtain authorization is waived in the "situations of national emergency or other circumstances of extreme urgency or in cases public non-commercial use".[84] This effectively means that if the Member State can show that any of the three waiver conditions exist, it can unilaterally permit a non-voluntary licence of the patent technology.

The difficulty is that TRIPS does not define "situations of national emergency or other circumstances of extreme urgency or in cases public non-commercial use", nor does it explain what standard of risk assessment or risk management must be used in order to determine whether a waiver situation exists. In the event of a dispute between Members, it would therefore fall to the Panel constituted under the DSU to clarify the provisions of Article 31[85] and determine whether such a situation existed. The role of the panel is to make an "objective assessment of the facts"[86] in light of the relevant provisions of the TRIPS Agreement. It is therefore difficult to determine such an issue in the abstract, but it is possible to make some tentative predictions.

An exercise in treaty interpretation must necessarily start with the "ordinary meaning of the terms of the treaty, in their context and in light of its object and purpose".[87] It has been acknowledged that a public health crisis could fall within the scope of a "national emergency or other situation of extreme urgency".[88] The difficulty in applying the Precautionary Principle is that a "crisis" is a "state of affairs in which a decisive change for the better or worse is imminent".[89] This sets a high threshold in terms of imminence, whereas the Precautionary Principle acknowledges that effects may often be cumulative and long-term.[90]

It could be argued that the threshold should be high given that the Appellate Body has said that waiver situations are generally to be interpreted narrowly[91]. On the other hand, the Principles[92] of the TRIPS Agreement expressly import flexibility. Article 8 states that Members may adopt measures to protect public health, as follows:

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

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[81] The Annell Draft included enumerated grounds on which compulsory licences could be issued but these had disappeared in the Brussels Ministerial Text and never reappeared: UNCTAD-ICTSDA *Resource Book on TRIPS and Development* (2005) 4464-265.
[82] Article 31(a)-(l).
[83] Article 31(b).
[84] Article 31(b).
[85] *Understanding on Dispute Settlement ("DSU"), Annex 2, Agreement Establishing the World Trade Organisation,* Article 3.2.
[86] Ibid, Article 11.
[87] Article 31.1 *Vienna Convention on the Law of Treaties.*
[88] *Declaration on the TRIPS Agreement and Public Health,* supra n 6, paragraph 5(c). Article 31.3(a) of the Vienna Convention on the Law of Treaties mandates reference to the Declaration.
[89] The Oxford Universal Dictionary, 424.
[90] Puttagunta, supra n 7 at 14.
[91] *EC – Bananas III,* Appellate Body Report, European *Communities – Regime for the Importation, Sale and Distribution of Bananas,* WT/DS27/AB/R, *adopted 25 September 1997,* para 185.
[92] Article 8.1.

There has been debate as to whether this statement implies that the TRIPS Agreement should interpreted broadly or whether it is simply an acknowledgement that a certain level of flexibility is already inherent within it. For example, it has been argued, during a dispute over Article 30[93], that reading Articles 7 and 8 together with the Preamble clearly shows that a basic balancing of rights has already taken place during negotiation, and that importing further flexibility would amount to a renegotiation of that balance of rights.[94]

The only authoritative statement[95] regarding Article 31 is the *Declaration on the TRIPS Agreement and Public Health*[96] adopted by the Ministerial Conference at Doha in November 2001. In that document, the Members "reaffirmed" the right of all WTO Members to protect public health and promote access to medicines and to "use, *to the full*, the provisions of the TRIPS Agreement, which provide flexibility for this purpose"[emphasis added].[97] Since the principle of effectiveness in treaty interpretation requires that all terms are given effect[98], the use of the term "to the full" suggests that although the Members did not anticipate a renegotiation of the balance of rights, they did agree that maximum flexibility ought to be allowed in interpreting the waiver provisions. Paragraph 5 of the Declaration then went on to expressly state a number of agreed flexibilities. These included the following:

> (a) 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.
>
> (b) Each Member has the right to grant compulsory licences and the *freedom to determine the grounds* upon which such licences are granted.
>
> (c) *Each Member has the right to determine* what constitutes a national emergency or other circumstances of extreme urgency, it being understood that public health crises, including those relating to HIV/AIDS, tuberculosis, malaria and other epidemics, can represent a national emergency or other circumstances of extreme urgency. [Emphasis added].

When these provisions are read together, along with Articles 7 and 8, it becomes clear that TRIPS does have room to apply the Precautionary Principle. For example, paragraph 5(c), when read with Article 8, would allow a Member to declare waiver situation whenever it felt it was necessary protect against a threat to public health. Having done that, Article 31(b), read together with Paragraph 5(b) of the Decision, allows the Member to grant the compulsory licences without prior reference to the patent owner. Therefore, it could be argued that the TRIPS Agreement has scope for Members to invoke the Precautionary Principle when determining whether "a national emergency or other circumstances of extreme urgency" exists for the purposes of Article 31(b).

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[93] *Canada – Pharmaceutical Patents,* supra n 80.
[94] Ibid, para 7.23.
[95] The *Declaration* has since been affirmed in the *Implementation of Paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health: Decision of 30 August 2003* WT/L/540, WT/L/540/Corr.1. This was adopted by the General Council and, by virtue of paragraph 11, acted as a temporary amendment to TRIPS. It has since been incorporated word-for-word into the *Amendment of the TRIPS Agreement: Decision of 6 December 2005,* WT/L/641. It can therefore be said to represent the shared intention of the Members
[96] WT/MIN(01)/DEC/2, 20 November 2001.
[97] Paragraph 4.
[98] *Korea – Dairy*, Appellate Body Report, *Korea – Definitive Safeguard Measures on Imports of Certain Diary Products,* WT/DS98/AB/R/ para 81.

Similar reasoning could be applied to "public non-commercial use", the wording of which implies a lower threshold of risk. It could apply in situations where a risk is possible, rather than imminent, and pharmaceuticals need to be stockpiled by government agencies in case of an outbreak. The proactive and protective nature of such a measure is entirely consistent with the Precautionary Principle.

Overall, however, the need to balance the stated objectives under the TRIPS Agreement and to weigh up economic and other social considerations against the risk to health means that the Precautionary Principle would necessarily only be permitted in its weak or utilitarian form.[99]

The transparency/good faith nexus

One of the difficulties is that the TRIPS Agreement does not specify whether Members must act transparently in their risk analysis. The General Council has expressed an expectation of transparency with respect to some aspects of Article 31(f)[100], but none has been stated with respect to the original risk assessment under Article 31(b). A requirement for transparency would be consistent with the general principle of transparency that is expressed in other covered agreements.[101] It also must be said that a transparency requirement *per se* would not in derogate from the applicability of the Precautionary Principle. Indeed, the EC's explanation of the Precautionary Principle includes a requirement for transparency[102], as does the Cartagena Protocol[103].

However, there is a tension between any requirement for transparency and the presumption of national sovereignty and good faith that are inherent in the TRIPS Agreement. It has been said that Articles 7 and 8 create a presumption that Members have the right to exercise national sovereignty and make independent decisions, providing that they act in good faith and within the scope of the TRIPS Agreement.[104] In the absence of any express requirements regarding risk assessment, this suggests that a Member need not explain its method of risk analysis[105] providing it has acted in good faith, and the complainant bears the burden of establishing a breach of good faith.[106] The difficulties with this are threefold. Firstly, the concept of "good faith" remains vague and ill defined.[107] Secondly, as yet it has not been possible to establish a case of breach of good faith under the WTO regime without first establishing a substantive breach.[108] Yet, a party cannot establish that a risk analysis amounts to a substantive

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[99] Puttagunta, supra n 7 at 13.
[100] The statement of the Chairman of the TRIPS Council, read by the Chairman of the General Council ("The Chairman's Statement") at the WTO General Council Meeting on 25, 26 and 30 August 2003: *Minutes of General Council Meeting,* 25, 26 and 30 August 2003 WT/GC/M/82, 13 November 2003. In that statement, the Chairman expressed a "shared understanding" that in order to promote transparency Members would provide information on how they had established that they had insufficient manufacturing capacity. Article 32(a) of the Vienna Convention on the Law of Treaties would permit reference to these minutes as an aid to interpretation.
[101] See, for example, Article X *GATT 1994*; Article 12 *Agreement on Safeguards*; Article 10.4 *TBT Agreement.*
[102] WTO *"Communication from the European Commission on the Precautionary Principle: Submission by the European Communities*, supra n 17 at para I(5).
[103] Articles 10 and 11, Annex III.
[104] UNCTAD-ICTSDA, supra n 82 at 126-127. The presumption of good faith is also considered to be a principle of international law: Zeitler, H E " 'Good Faith" in the WTO Jurisprudence: Necessary Balancing Element or an Open Door to Judicial Activism" (2005) 8(3) JIEL 721, 724.
[105] This distinguishes the TRIPS Agreement from the SPS Agreement, which had express requirements regarding risk assessment. It would also be a means of distinguishing the decisions in *EC – Hormones* and *EC – Biotech.*
[106] UNCTAD-ICTSDA, supra n 82 at 126-127.
[107] Zeitler, supra n 104 at 727.
[108] *EC – Bed Linen,* Appellate Body Report, *European Communities – Anti-Dumping Duties on Imports of Cotton-Type Bed Linen from India – Recourse to Article 21.5 of the SU by India,* WT/DS141/AB/RW, adopted 24 April 2003. For a general discussion, see also Zeitler, supra n 104 at 82.

breach without access to information as to how the analysis was made[109], and that information may not be accessible without a requirement for transparency. Finally, even if a substantive breach was not required, logic suggests it would still difficult be to prove breach of good faith without access to evidence. Thus it can be said that transparency and good faith go hand-in-hand.

A further issue is that Article 11 of the DSU requires the panel to "make an objective assessment of the facts". Although the Appellate Body has determined that this does not entitle a panel to undertake a *de novo* review of the evidence, neither does it allow respondents to rely on the principle of reasonable deference.[110] It is difficult to see how the facts can be assessed, therefore, without some degree of transparency.

Furthermore, the issue of transparency is directly relevant to the workings of the DSU and particularly to the burden of proof, which will be discussed below.

The significance of the burden of proof

One of the key features of the Precautionary Principle is that it places the burden of proof on the party who alleges that no harm will occur.[111] This is arguably in conflict with the burden of proof under Article 31 of the TRIPS Agreement.

An overwhelming body of Appellate Body jurisprudence indicates that the burden of proof in WTO proceedings rests initially with the complainant but that once the Complainant has established a *prima facie* breach the burden shifts to the Respondent to establish a defence.[112] A defence might include relying on an exception provision, such as Article 30 or 31 in the TRIPS Agreement. This is consistent with the decision in the only case relating to either Article 30 or 31: *Canada –Pharmaceuticals.*[113] There the Panel concluded that the burden initially rested with the Complainant to establish a *prima facie* case of violation. Then the burden shifted to Canada to demonstrate that its measures complied with the exception provided by Article 30.[114]

If that burden were applied to Article 31, a Member seeking to rely on the waiver provisions would need to show that a waiver situation existed. It would therefore need to *demonstrate* that a "national emergency or other circumstances of extreme urgency" or a "case of public non-commercial use" existed. As already discussed, this is difficult without some degree of transparency. However, if they were entitled to use the Precautionary Principle (as the Declaration suggests), then the threshold for the Respondent would be lower. They would only need to show that there is:
(a) a serious risk of irreversible harm, and
(b) scientific uncertainty about the impact of the disease;

The burden of proof would then shift to the Complainant, who argues that no risk exists. This would create an absurd situation. Firstly, if there is insufficient evidence about the

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[109] The Appellate Body has said the presumption of good faith means there is a presumption that the defending Member's has acted consistently with its obligations unless there is "clear evidence to the contrary": *Argentina Footwear – Safeguard Measures on Imports of Footwear,* WT/DS121/AB/R, adopted 12 January 2000, para 6.14.
[110] *EC – Hormones,* supra n 23 at paras 110-119.
[111] Puttagunta, supra n 7 at 10. Compare with the burden of proof under TRIPS: *Canada – Pharmaceuticals,* supra n 80 at para 7.16.
[112] Consistent with Article 3.8 DSU.
[113] *Canada – Pharmaceutical Patents,* supra n 80.
[114] Paragraph 7.16.

disease to know its effect, then it clearly not possible to show that there is no risk. Secondly, whatever evidence is available is more likely to exist within the Respondent's jurisdiction than that of the Complainant, which creates practical difficulties, especially if the Respondent is not required to be transparent about its risk assessment. Thirdly, a Complainant under the TRIPS Agreement acts to protect its citizen's private patent rights, the value of which depends largely on the public's perception of the need for the patented product. It therefore would be counter-intuitive to demonstrate the harmlessness of any disease for which it can provide a treatment. Consequently it seems unlikely that the TRIPS Agreement could have been intended to include such a requirement.

The alternative for the Complainant would to be to argue that there was not a sufficient causal relationship between the risk analysis and the measure taken.[115] Again, this would be counter-intuitive because it would require the complainant to demonstrate that their drug was a sub-optimal treatment for the relevant disease. Not only would this effectively undermine the value of the patent, it would act as a disincentive to innovation[116] and would thus be contrary to the policy underpinning intellectual property rights.[117] It could also be said that if the drug were already known to be ineffective against the disease then the Respondent would be unlikely to have issued the compulsory licence in the first place, unless it had been issued in bad faith. Even then, to establish breach of good faith, the complainant would need to demonstrate that the relevant drug was inefficacious against the relevant disease, which would still be contrary to the interests of the patent holder.

Broader policy considerations

The above section illustrates the tension between public and private rights that runs through the TRIPS Agreement. The Preamble[118] contains an express acknowledgement that intellectual property rights are private rights. Nevertheless, the TRIPS Agreement expressly seeks to balance the private rights of IP owners with the public rights of IP users.[119] It also expressly recognises that States may need to adopt specific measures to protect public health[120], implying a recognition that in some instances the international regulation of IP rights may fail to facilitate, or even be contrary to, the public interest[121]. Thus it explicitly broadens the grounds for compulsory licenses set down in the *Paris Convention for the Protection of Industrial Property.* Article 5A(2) of the *Paris Convention* states only that:

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[115] *EC – Hormones*, supra n 23.
[116] *Declaration*, Para 3. For a detailed discussion of the philosophy underpinning intellectual property law, see Maniatis, S "Trademark Rights – A Justification Based on Property" in [2002] IPQ 123, See also World Health Organisation ("WHO") *Public health, Innovation and Intellectual Property Rights: Report of the Commission on intellectual property rights, innovation and public health* (2006) 20; Picciotto, supra n 78 at 224-225.
[117] The dilemma of how to provide the incentives for the development of drugs to treat disease, particularly for diseases that occur predominantly in the developing world, is one of the biggest issues currently facing the global economy: Ganslandt, M., Maskus, K, and Wong, E. "Developing and Distributing Essential Medicines to Poor Countries: the DEFEND Proposal" in Fink, C and Maskus, K *Intellectual Property and Development: Lessons from Recent Economic Research* (eds) (2004), 207.
[118] 4th paragraph.
[119] Article 7. It is important to acknowledge that IP rights are also, in some respects, public goods.
[120] Article 8.
[121] Shaffer argues that the three competing but interconnected "public goods" recognized by the TRIPS Agreement are: knowledge, public health, and open trade and competition: Shaffer, G "Recognizing Public Goods in WTO Dispute Settlement: Who Participates? Who Decides? – The case of the TRIPS Agreement and Pharmaceutical Protection" 7 JIEL 2 (2004) 459-482, 459.

> Each country of the Union shall have the right to take legislative measures providing for the grant of compulsory licences to prevent the abuses which might result from the exercise of the exclusive rights conferred by the patent, for example, failure to work."

This broadened scope reflects the ethic of protection implied in Article 8 of the TRIPS Agreement. That is, Article 8 recognises that certain situations may require proactive measures to protect public health irrespective of the behaviour or intentions of the patent holder. This is entirely consistent with the Precautionary Principle.[122]

However, the notion of international reciprocity is another core principle in the WTO Agreement, and one that is inherently at odds with the concept of national sovereignty. Member states cannot seek the benefits of membership without also accepting the corresponding obligations. This means that while they have an acknowledged right to protect the public health of their citizens, they cannot realistically expect to enjoy the benefits of WTO membership without also recognizing the rights and interests of other Members, including the rights of those other Members to protect their economic well-being. Care must also be taken not to create disincentives to innovation, and thereby long term disadvantages to public health worldwide, as might occur if compulsory licences were granted too freely. Again, this suggests that only a weak or utilitarian notion of the Precautionary Principle could be accommodated by TRIPS.

Another aspect of reciprocity is that developing countries agreed to the TRIPS Agreement in exchange for a number of concessions recognising the difficulties that many will face in complying with the requirements of the TRIPS Agreement.[123] The World Health Organisation has stated that "[p]overty, disease, and research capacity all intersect" to create public health challenges for developing countries.[124] The Ministerial Conference[125] and the General Council[126] of the WTO have both recognised that the administrative and manufacturing capability of many developing nations will be sub-optimal. Not only are such countries likely to have difficulty accessing the necessary scientific data in a timely fashion, but they are also unlikely to be able to respond in a timely fashion. Thus, longer lead times may be required to put preventative measures in place.[127] This, also supports the use of the Precautionary Principle.

Finally, there would be some logic in aligning the TRIPS Agreement with the Rio Declaration by expressly incorporating the Precautionary Principle. Quite apart from the obvious value that is to be had from international consistency, the issues of environmental safety and public health are often interwoven. The obvious counter-argument to this is that the Rio Declaration is an instrument, which has been adopted in an entirely different forum and context, with completely different objectives. The focus of the Rio Declaration is to ensure that human beings have a "healthy and productive life in harmony with nature".[128] The WTO Agreement, on the other hand, desires to "reduce distortions and impediments to trade ... promote effective and adequate protection of intellectual property rights".[129] However, the overarching goals of both

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[122] Puttagunta, supra n 7 at 13.
[123] Picciotto, supra n 78 at 226.
[124] WHO, supra n 116 at 2.
[124] *Decision of 30 August 200,* supra n 96 at para 4.
[125] *Declaration* para 6.
[126] *Decision of 30 August 200,* supra n 96 at para 4.
[127] The most appropriate measure may also differ from that which would be "most appropriate' in a developed country.
[128] Principle 1.
[129] Preamble.

agreements include the development of a global partnership for the sustainable development of the world's resources.[130] Logic would therefore suggest that it would be useful to have some consistency between them.

However, the absence of express consistency does not mean that consistency cannot, or should not, be implied. The Appellate Body of the WTO has recognised that the WTO Agreement ought not to be read in "clinical isolation" from general principles of international law.[131] From a pragmatic point of view, there is an argument that international consistency is necessary for effective control of disease. For example, in 2000 the G8 leaders said:

> Only through sustained action and coherent international co-operation to fully mobilise new and existing medical, technical and financial resources, can we strengthen health delivery systems and reach beyond traditional approaches to break the vicious cycle of disease and poverty.[132]

However, although such rhetoric sounds compelling, the legal reality is that any panel is still constrained by the requirement to apply the terms of the relevant treaty in their context.

Perhaps the final word is that there ought at least to be alignment of the terms of the covered agreements. Article XX of GATT allows Members to suspend obligations in certain situations, and it was successfully invoked in *US - Shrimp* to protect dolphins and sea turtles.[133] Even though there is no comparable provision in the TRIPS Agreement[134] it is logical to conclude that if Members intended to allow suspension of trade rights to protect wildlife, then they must surely have also intended to allow for suspension of intellectual property rights to protect human life. However, in it should be noted that the Appellate Body's importation of various international protocols into WTO law remains controversial.[135]

Less controversial, however, is that the TRIPS Agreement itself seems to imply something similar. Article 27.2 allows a Member to exclude patentability where it is necessary to *protect human health.* Surely, if a Member is entitled to *prohibit* patent rights to protect human health, then it ought to be able to *suspend* patent rights on the same grounds. This conclusion is neither contrary to any express wording of the TRIPS Agreement, nor would it impute any new obligations[136]. In fact, it is consistent with principles expressly stated in Article 8. It is therefore a sustainable conclusion.

Conclusion

The Precautionary Principle is a paradox. On the one hand it is deliberately vague; on the other it has been said to be too vague to constitute a principle of international law. However, the general tide of opinion suggests that has now crystallized into a principle of international

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[130] *Rio Declaration,* Preamble; *Agreement Establishing the World Trade Agreement,* Preamble.
[131] *US – Gasoline,* Appellate Body Report, *United States – Standards for Reformulated and Conventional Gasoline,* WT/DS2/AB/R, adopted 20 May 1996.
[132] WHO, supra n 116 at 9.
[133] *US Shrimp,* Appellate Body Report, *United States – Import Prohibition of Certain Shrimp and Shrimp Products,* WT/DS58/AB/R.
[134] UNCTAD-ITDSDA, supra n 78 at 133.
[135] For a summary of views, see Van den Bossche, P *The Law and Policy of the World Trade Organisation* (2005) 59.
[136] The Appellate Body has cautioned that the imputation of new obligations is not condoned by the general rule of interpretation: *India – Patents (US)* Appellate Body Report, *India – Patent Protection for Pharmaceutical and Agricultural Chemical Products,* WT/DS50/AB/R, adopted 15 January 1998, para 45.

environmental law. It could therefore be said that the Precautionary Principle automatically extends to issues of public health, where those issues have an environmental aspect.

However, it is not yet clear whether the Precautionary Principle applies in WTO law. The general rule of interpretation in international treaties requires that consideration be given to the text and context of the relevant agreement. This means that even if the relevant agreement has scope to accommodate the Precautionary Principle, as in the case of the SPS, a Respondent cannot rely on the Precautionary Principle as a means of avoiding their obligations under that agreement.

This paper has considered whether a party invoking the waiver provisions under Article 31 of the TRIPS Agreement would be entitled to rely on the Precautionary Principle. It has been argued that the TRIPS Agreement does have scope to accommodate the most elements of the Precautionary Principle. The terms of Article 31, when read together with the *Declaration* and the *Decision,* make it clear that Member states are entitled to undertake their own means of risk analysis. They also suggest that developing and least developed Member may be entitled to take an even more precautionary approach than developed Members with access to greater scientific and administrative resources.

However, there are limits. The Precautionary Principle could not be used to avoid the implied requirement of transparency in the TRIPS Agreement, which engenders both good faith and due process. Furthermore, it is unlikely that the TRIPS Agreement could sustain the inverted burden of proof that the Precautionary Principle requires, as it could create results that are entirely inconsistent with the scheme of the TRIPS Agreement. The TRIPS Agreement also contains a number of inherent characteristics that limit the extent to which the Precautionary Principle applies. These include the need to balance public health rights against private property rights and national sovereignty against international reciprocity. Because these balancing mechanisms are expressly built into the TRIPS Agreement it could, at most, accommodate only a weak or utilitarian form of the Precautionary Principle.

In terms of consistency in international law, it would be useful if the precise status of the Precautionary Principle with respect to the TRIPS Agreement were clearer. The Appellate Body has recognised that the WTO Agreement does not exist in isolation from other international law, and indeed such an approach is required by the general rule of interpretation. However, that same rule also constrains panellists and the Appellate Body in so far as they are bound to interpret meaning of an agreement according to its text and context. The WTO Agreement and the TRIPS Agreement have a very specific context, which is not necessarily consistent with other multilateral agreements. Nevertheless, the Appellate Body has shown a willingness to strain the textual meaning of GATT by importing other treaty norms, where it was necessary to do so in order to protect the environment on which humans depend. This suggests that there might be a similar willingness to strain the meaning of the TRIPS Agreement in order to protect public health. However, a strained interpretation may not be necessary, as support for the Precautionary Principle can be found within the TRIPS Agreement itself.

In conclusion, it can therefore be said that a party could rely on the Precautionary Principle when invoking a waiver under s 31 of the TRIPS Agreement. However, while they may rely on the Precautionary Principle in making their risk analysis, they need to be aware that the burden of proof is likely to remain with them, contrary to the general rule under the Precautionary Principle. They should also be aware, that Precautionary Principle would not, by itself, be the

sole consideration, as the TRIPS Agreement requires a number of factors to be balanced. Therefore, if these balancing factors have not been considered in the risk assessment, they would be likely to be considered by the panel in the event of a dispute. Similarly, while transparency is not expressly required, it does evidence good faith and facilitate due process, thereby limiting the likelihood of a formal dispute. This, after all, is the essence of being a good world citizen.

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