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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?

By Shona Foster, Former Law Student
(Attorney-at-Law http://www.jamesandwells.com/our-people/shona-foster.aspx)

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…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" exists6, 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 take 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 exits."7.
(p. 1)

…The Precautionary Principle is also applicable to risk analysis in other areas of public law, including public health.11
(pp. 1-2)

Accordingly, it could be argued as extending to the risk analysis underpinning the compulsory licensing of pharmaceuticals under 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 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 a precise definition.

…The second major obstacle is the uncertain status of the Precautionary Principle in international law.
(p. 2)

…The Precautionary Principle or Approach as contained in the Rio Declaration has also been re-affirmed more recently in the Cartegena Protocol on Biosafety to the Convention on Biological Diversity.22 Unfortunately, neither instrument gives a definition of the Precautionary Principle. **In fact, although the *Rio Declaration* [is] 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 Kogan24 considers the Precautionary Principle merely requires broad scientific uncertainty whereas the Precautionary Approach can be used only in cases of insufficient scientific evidence.** The Cartegena Protocol does little to help, as it appears to conflate the two terms.

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24 Kogan, "WTO Ruling on Biotech Foods Addresses 'Precautionary Principle'" (2006) 21(38) Legal Backgrounder (Washington Legal Foundation) <http://www.itssd.org/Publications/wto-biotech-foods-dec0806.pdf>
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