By adopting the waivers and moratorium the Member States have created a skeleton for a system based on exceptions to international trade obligations. In order for this skeleton to function, Member State will be required to add the muscle, i.e. to implement the system – and its conditions – into domestic law.[819]

II. The scope of the Decision

The adoption of the Decision came as a direct response to the dilemma set out in paragraph 6 of the Public Health Declaration. The Decision's preamble clearly confirms this. Accordingly, the Decision must be seen within the scope of providing those affected Member States with a means to effectively make use of their compulsory license system when their domestic pharmaceutical sector prevents or inhibits this.

The scope of the Decision also makes it clear that the central feature of the Decision, the system resolving the paragraph 6 dilemma, is not unlimited but is instead a 'drug-by-drug, country-by-country, case-by-case system'.[820] The qualifications to this system play a key role and seek to limit the scope by ensuring the system is only used to benefit the needy countries and not to the advantage of other Member States. The barrage of safeguards confirms this.[821] In addition to the system and the safeguards, the scope of the Decision is characterised by issues not initially foreseen in the Public Health Declaration. Although not mandated, the Member States agreed that the issues were sufficiently connected and important to justify their inclusion.[822] These issues sought to further the transfer of technology[823] and to prevent dispute proceedings[824] in respect to the system. Despite the introduction of a system to resolve the paragraph 6 problem, the Member States did at no time prior to the adoption of the Decision intend the Decision to be the final system; its role was merely a

819 This is a prerequisite for the exporting country. Cf. *Correa*, Implementation of the WTO General Council Decision on Paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health (WHO Geneva 2004) p. 6, *Vandoren and Ravillard*, 8 JWIP 2 (2005) p. 105.

820 *Oh*, 10 Bridges 1 (2006) p. 22-23.

821 Compare Chairman's Statement which states that 'Members recognize that the system that will be established by the Decision should be used in good faith to protect public health and, without prejudice to paragraph 6 of the Decision, not be an instrument to pursue industrial or commercial policy objectives'. Cf. General Council Chairman in the WTO General Council Minutes (13.11.2003) WT/GC/M/82 p. 6. Further, the remaining Art 31 provisions will continue to apply. Cf. *Law*, 18 ELDB 3 (2006) p. 6.

822 General Council Chairman in the WTO General Council Minutes (13.11.2003) WT/GC/M/82 p. 7.

823 Decision para 7.

824 Decision para 10, General Council Chairman in the WTO General Council Minutes (13.11.2003) WT/GC/M/82 p. 7.

stopgap measure to ensure there was an interim solution whilst the Member States negotiated a final solution.[825]

III. The legal implications of the Decision

The Decision and the Chairman's Statement introduce a number of formal requirements for Member States, whether as exporter or importer, wishing to apply the solution. Member States will be required to determine when and what pharmaceutical products can be used, which countries are eligible, what safeguards are applicable and how technology transfer must be used to prevent the paragraph 6 problem. These legal implications are dealt with individually hereunder.

1. The pharmaceutical product

For the purposes of the Decision a pharmaceutical product is deemed to be 'patented product, or a product of a patented process, of the pharmaceutical sector'[826] that is needed to address a public health problem.[827] The definition of pharmaceutical product is qualified in numerous ways. Firstly, the product must be a patented product or result from a patented process. This qualification dispels any doubt that both patented products and patented processes can perpetuate the paragraph 6 dilemma. Secondly, the product must flow from the pharma-ceutical sector. This may seem self evident when dealing with pharmaceutical products, however in connection with the third qualification, those public health problems recognised in paragraph 1 of the Public Health Declaration, other sectors may have played a role in countering the public health problems. The nutritional sector for instance, may have patented products that help reduce certain health afflictions. An example hereof is the proposal to produce genetically engineered crops that can reduce allergic reactions or induce certain health effects.[828] Both the nutritional and agricultural sectors can play a significant part in reducing public health problems. In terms of the Decision these products will not fall under the definition 'pharmaceutical product'. This qualifica-

825 Decision para 11.

826 Decision para 1(a).

827 The Decision does not mirror the terminology used in the Public Health Declaration. Instead of referring solely to the pharmaceutical sector, the Decision limits the scope of the Decision to 'pharmaceutical products'. Although potentially viewed as a limitation of the Public Health Declaration its is in fact a better formulation for Member States as it resolves the problem of whether or not the Public Health Declaration scope includes certain medical devices. The choice of terms in the Decision also ensure a greater association with one of the core issues in the Public Health Declaration, the access to medicines set out in para 4 thereof. See Chapter 7(A)(IV) Pharmaceutical sector above.

828 Monsanto purports to have developed a soybean that can 'reduce or eliminate the amount of trans-fats in processed foods'. Cf. '*Monsanto*, (2006)'.