III. Insufficient or no capacities

Once it has been determined what manufacturing capacities encompass, it is necessary to determine when they are insufficient or absent. Like the manufacturing capacity, absence or insufficiency can be determined in two ways: the absolute non-existence of a pharmaceutical sector or, where such exist, the unwillingness of domestic producers to produce the compulsory license for the licensee. The Public Health Declaration, in particular the inclusion of the word 'insufficient', appears to require the Member States to find a solution to both, i.e. the problem exists not only where there is no production facilities but also where the existing facilities are unable (or unwilling) to assist in the production. This would imply that although there could be an ability to produce, factors prevent this from occurring. These factors are neither limited by paragraph 6 nor by the Public Health Declaration. Accordingly, there does not appear to be a limitation as to what causes the insufficiency. Provided the reason is a reasonable and justifiable ground and not a means to circumvent the protection of intellectual property rights.

IV. Pharmaceutical sector

The reference to the 'pharmaceutical sector' is relevant in that it reflects the context of the Public Health Declaration and ensures that the solution should not extend beyond this scope. One of the goals of the Public Health Declaration was to ensure that Member States were able to afford healthcare treatment. Limiting the solution to the pharmaceutical sector reflects this goal and ensures the solution is tailored to meet this goal and not to be misused for other purposes.

The ordinary meaning of 'pharmaceutical sector' implies that only that sector that prepares, preserves, compounds or dispenses drugs will be considered.[774] This would imply that instruments, testing machinery and other non-medicinal measures used to counter epidemics and other extreme urgencies would not be included.[775] This is, to some extent, reflected by the reference to access to medicines in paragraph 4 of the Public Health Declaration. Notwithstanding this, limiting the meaning to industries producing medicines would not reflect the general context of the Public Health Declaration, i.e. taking measures to protect the public health. Non-medicine products such as diagnostic kits for HIV/AIDS play a crucial role in the treatment of diseases. A narrow interpretation of the concept 'pharmaceutical product' would rule out

774 Webster's Third New International Dictionary (Merriam Chicago 1971) p. 1694.

775 *Correa* makes another proposal. He suggests that the 'pharmaceutical sector' may be interpreted to extend to all those products sold by a pharmacy. Cf. *Correa*, Implications of the Doha Declaration in the TRIPS Agreement and Public Health (WHO Geneva 2002) p. 21.

much of the necessary tools required to treat public health problems.[776] Supporting an expansive interpretation of pharmaceutical sector is the notion that chemical compounds, *per se*, would also be excluded from the definition of a pharmaceutical. An exclusion of chemicals would perpetuate the problem identified in paragraph 6 and would not bring about a real solution.

V. Effective use of the compulsory license system

Paragraph 6 of the Public Health Declaration identified the scope of the problem as being the 'difficulties in making effective use of the compulsory licensing under the TRIPS Agreement'. The inability to make use of a compulsory license system because of absent or inadequate pharmaceutical production capacities meant that the affected Member States were unable to make 'effective' use of the TRIPS Agreement. By making express mention of the effective use of compulsory licenses the Member States directed the solution to the use of compulsory licenses. This formulation did away with certain pre-Doha suggestions that the insufficient production capacities could be resolved, as Canada suggested, through 'other TRIPS flexibilities, such as parallel importation'.[777] Whilst this is indeed a possible solution the Member States clearly identified the problem as being the inability to make effective use of compulsory licenses. Hence, the solution should enable the effective use of compulsory licenses. Other tools that might alleviate the difficulties experienced under Article 31(f) thus bore no further relevance when seeking a solution to the paragraph 6 dilemma. For many Member States being able to use the compulsory license system effectively was one of the safeguards they had bargained for when negotiating the TRIPS Agreement. Being able to use this safeguard, as well as all other safeguards, was a 'right' they sought to exercise. Had the Canadian approach been followed it would have effectively resulted in the loss of a safeguard.

VI. Potential paragraph 6 solutions

A number of alternative solutions and/or justifications were proposed by Member States and academics alike.[778] The proposals made can be divided into 5 distinctive categories: a TRIPS Agreement amendment, an interpretative solution, a morato-

776 The access to medicines by way of compulsory licenses for patented products or processes would be equally affected should there be no domestic pharmaceutical industry. The Public Health Declaration accordingly applies to both patented products and patented processes.

777 Canada in the TRIPS Council Minutes (19.09.2001) IP/C/M/33 p. 42.

778 WTO Secretariat note 'Proposals on Paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health: Thematic Compilation' (11.07.2002) IP/C/W/363, *Matthews*, 7 JIEL 1 (2004) p. 83-94, *Abbott*, Quaker Paper 7 (2001) p. 12-17, *Correa*, Implications of the Doha Declaration in the TRIPS Agreement and Public Health (WHO Geneva 2002) p. 25-35.