# Chapter 7 The solution to the paragraph 6 dilemma

## *A. The identification of the paragraph 6 issues*

Paragraph 6 of the Public Health Declaration is misleading in the impression it gives. A read of the text leads to the thought that a solution could not be far from being achieved: the problem was well defined, the 'culprit' identified and the intention to resolve the problem was present. What paragraph 6 did lack was the identification of the issues at stake. These issues and their potential consequences would lead to the negotiations being strung out and difficult to conclude.

### I. The scope of paragraph 6

Paragraph 6 contains a number of issues that define its scope. Firstly, the problem is identified as being the ineffective use of compulsory license by some Member States without sufficient (or any) domestic production facilities. Secondly, there is no reference (and thus no restriction) to Article 31(f). Although the formulation of Article 31(f) may be the cause of the problem, there is no limitation in paragraph 6 that requires that it should also be the solution. Lastly, paragraph 6 does not limit the solution to public health problems. Instead it restricts the solution to the pharmaceutical sector.[768] This is a clear reference to one of the core Public Health Declaration goals: the access to medicines.[769]

Absent from paragraph 6 is the limitation of its application to LDCs and/or developing countries.[770] One reason for this absence is the fact that some developed countries also lack domestic production facilities.[771] It would have been unwise to limit the use of a paragraph 6 solution to LDCs and developing countries as one cannot rule out the possibility that a developed Member State might some day require the assistance of other Member States in treating a public health problem. The lack of a distinction posed the greatest hurdle to reaching a solution.

768 US in the TRIPS Council Minutes (22.03.2002) IP/C/M/35 p. 14.

769 Public Health Declaration para 4.

770 Whereas the para. 1 of the Public Health Declaration refers to the public health problems being experienced by LDCs and developing countries, para. 6 refers makes no such distinction. Instead it refers to Member States in general

771 Examples of wealthy states without any pharmaceutical production facilities are: Luxembourg, Lichtenstein, Iceland, Bahrain and Andorra. Examples of wealthy states with only the capacity to produce finished products are: Brunei, Hong Kong, Kuwait, New Zealand, Saudi Arabia, Singapore, Taiwan and the United Arab Emirates. Cf. *Balance et al*, The World's Pharmaceutical Industry: An International Perspective on Innovation, Competition and Policy (Edward Elgar Aldershot 1992) p. 8-9.

The mandate the Member States had given was limited to a system that would enable those Member States without an adequate domestic pharmaceutical sector to acquire help in exercising their compulsory license from abroad. The mandate did not authorise Member States to extend the scope to other sectors where Member States have no domestic manufacturing facilities. Further, the mandate did not call into question the application of patent rights for Member States without a domestic manufacturing sector. Despite the recognition that a problem exists in the TRIPS Agreement, the mandate in no way detracts from the basic tenet that implementation of an adequate and effective patent system, inclusive of the grant and limitation of rights, remains a principal obligation of each and every Member State.

## II. Manufacturing capacity

In order to be able to determine when a Member State has an insufficient or no manufacturing capacity, there must be a common understanding on what 'manufacturing capacities' can encompass. The text of the Public Health Declaration permits two views: either there is a lack of production facilities or there is an inability to produce. The former refers to the physical absence of a pharmaceutical manufacturing facility and does not include the manufacture of components or chemical compounds used in the final production. If the Member States were to limit their interpretation to a portion of the pharmaceutical production process (i.e. the lack of one chain in the production process) it would effectively defeat the purpose of paragraph 4 of the Public Health Declaration by limiting the Member States right to take comprehensive measures to protect the public health.[772] Further, any attempt to identify which stages of the production process would have to be absent would ensure that such a solution would drown in bureaucratic regulation.

The latter however, the inability to produce, is broader in scope and refers to the inability to domestically produce any/all elements at any/all stages of production of a pharmaceutical product. This would therefore include all operations commencing at the purchase of materials and products, production, quality control, release, storage and distribution of pharmaceutical products and the related controls. It would also mean that any if any one stage could not be produced domestically that this stage alone could be fulfilled by a compulsory license. This approach would thus better reflect the object and context of the Public Health Declaration as it would allow the Member State ultimately to elect which portions of the manufacturing process it wishes to undertake and/or if it would rather import the finished pharmaceutical.[773]

772 *Correa*, Implications of the Doha Declaration in the TRIPS Agreement and Public Health (WHO Geneva 2002).

773 The WHO also takes this expansive view of 'production'. Cf. *WHO*, WHO Expert Committee on Specifications for Pharmaceutical Preparations Technical (WHO Geneva 2005) p. 63.