Chapter 3 The legalising policy thoughts in the Public Health Declaration

The title of this dissertation identifies two principal elements that are central to determining the importance and influence of the Public Health Declaration. Firstly, the title directs the readers' attention to the policy elements contained in the Public Health Declaration. Secondly, it recognises the intention of the WTO Member States to formalise or 'legitimise' these policies. Whereas the latter forms the main focus of this dissertation, the former requires a brief examination in order to provide a context for this dissertation.

A 'policy' is best described as:

> 'a definitive course or method of action selected (as by a government, institution, group or individual) from among alternatives and in the light of given conditions to guide and [usually] determine present or future decisions'.[48]

As such a policy is a 'blueprint' or guiding principle to bring about a desired state of affairs. The Public Health Declaration exhibits such features.[49] It identifies what is 'wrong', what the solution should incorporate and which routes should be taken to bring about the solution. These points, which will be addressed below, were the result of intense negotiations between government representatives within the realm of an international body. As such, they reflect a common understanding and can be said to constitute policies within the auspices of the WTO.

The problems identified by the Ministers at the Doha Ministerial Conference in 2001 fall under the scope of TRIPS Agreement and public health. More accurately stated, the problems stem from the perceived effects of intellectual property rights have on the measures taken by Member States to protect the public health. Within the debates preceding the Public Health Declaration it was clear that the main focus lay on patent rights. The problems caused by the obligations that flow from these rights were felt to impinge upon the Member States' measures to address their public's health. Whereas public health may refer to any and all measures taken by a government to improve or protect their citizens' wellbeing,[50] the problem in the TRIPS Agreement centre's on the access to medicines that are patented.[51] The prob-

48 Webster's Third New International Dictionary (Merriam Chicago 1971) p. 1754.

49 The WTO itself refers to the 'important guidance' the Public Health Declaration provides to Member States and the DSB. Cf. *WTO*, (Undated).

50 Public health is defined as 'the art and science of preventing disease, promoting health, and extending life through the organised efforts of society'. Cf. *McMichael and Beaglehole*, Lancet 365 (2000) p. 495.

51 The Public Health Declaration was initially titled 'Draft Declaration on Intellectual Property and [Access to Medicines] [Public Health]'. The importance of access to medicines is reflected in para 4 of the Public Health Declaration.

lem of access to medicines derives from the intention of certain Member States to 'break' a patent (i.e. to use it without the patent holder's consent) and allow the generic production[52] of the medicine. It was hoped that the generic production of patented medicines would lower their prices and thus be affordable to more people suffering from illnesses. The Public Health Declaration indirectly notes that the desire to make medicines more affordable was critical to treating epidemics, in particular HIV/AIDS, tuberculosis and malaria. The Public Health Declaration acknowledged these problems and expressly stated that the TRIPS Agreement does not and should not prevent Member States from taking measures to protect the public health. This recognition forms the key policy issue that resulted from the negotiations in Doha.

A second key policy issue reiterated in the Public Health Declaration is the importance of intellectual property rights, in particular their role in furthering future health treatments.[53] The Public Health Declaration confirms the policy that the compliance with the TRIPS provisions will assist in the protection of the public health. This somewhat conjectural policy was nevertheless accepted by all.

The result of these two key policies is that whereas the Member States are free to take measures to protect the public health, the TRIPS Agreement must be complied with.[54] Phrased in another way, Member States must comply with their TRIPS obligations but may do so in a manner that facilitates their health protection measures. The realisation of these policies was identified by the Member States in a number of ways. Firstly, the Member States should be able to use the flexibilities in the TRIPS Agreement to the full. In other words, where a provision permits two or more means to comply, a Member States is free to choose the means to do so.[55] Secondly, the interpretation of the TRIPS Agreement should be done so in a manner that supports public health protection. Hence, where the meaning of a TRIPS provision is unclear, it should be interpreted in a health-friendly manner. Thirdly, there was a commitment to resolve the problem certain Member States have in making effective use of compulsory license system because of inadequate domestic manufacturing facilities. Lastly, the Public Health Declaration identified the special position LDC Member States have within the WTO and pledged to take measures to ease and assist their application and implementation of intellectual property rights and obligations.[56]

52 'Generic' and 'generics' are used within the scope of this dissertation as referring to pharmaceuticals that are bioequivalent to the original patented pharmaceutical, whether they are produced after the expiry of the patent rights or during the patent life with the permission of a body authorised to allow its production (but without the patent holders consent).

53 To this effect the Public Health Declaration noted the exceptions available to patent protection, e.g. compulsory rights, and the flexible interpretations of the TRIPS provisions.

54 The USTR refers to the relationship as 'dual objectives … meeting the needs of poor countries without the resources to pay for cutting edge pharmaceuticals and … ensuring that the patent rights system continues to promote the development and creation of new lifesaving drugs'. Cf. *USTR*, Special 301 Report (2006) p. 10.

55 Four flexibilities were expressly noted in para 5 of the Public Health Declaration.

56 Compare *CIPR*, (2002) p. 39.

Of the four policies, the policy pertaining to the use of the flexibilities, in particular compulsory licenses, stood out as being the key way for Member States to promote access to affordable medicines. Although compulsory licenses are expressly permitted in the TRIPS Agreement, their use was subject to political and legal opposition. The precise scope and extent of the TRIPS provisions on compulsory licenses was not clear. The Public Health Declaration's reference to the compulsory licenses serve as a policy measure as it identifies the compulsory license system as a viable tool within the patent system, especially when addressing the issue of access to affordable medicines.

The codification of these policies represented the first formal step to realising their goals. Their realisation, and the necessity of their realisation, must be seen within the light of the developments leading up to the Public Health Declaration and TRIPS Agreement as a whole.