Chapter 9 Definitive consequences of the Public Health Declaration

The policy thoughts contained in the Public Health Declaration have not amounted to much in a formal or objective sense. Despite the fact that the TRIPS Agreement has been amended to include an exception to the Article 31(f and h) problem expressed in paragraph 6 of the Public Health Declaration and the fact that the transitional periods for LDCs have been extended for pharmaceutical products there has been no further tangible incorporation of the Public Health Declaration's policy thoughts into the international intellectual property system. Why is this so?

To answer this question a distinction need be made between the changes in the international legal forum and those in the domestic legal system. On the international level the TRIPS Agreement – as discussed above – objectively required little changes. The TRIPS Agreement is a well balanced and flexible treaty that permits Member States to structure the manner in which they seek to implement the TRIPS provisions. The problem many Member States had with the TRIPS Agreement was their lack of confidence to interpret the agreement in ways that – although correct – were contrary to the views held by other Member States. In other words, the problem lay not in the TRIPS Agreement but in its application. The result is that the Public Health Declaration helped to redress the values that underlined the interpretation of the TRIPS Agreement; no real or substantive amendments were required to the core rules underpinning the protection of patent rights.[1104]

On a domestic level there was also little legislative action that flowed directly from the Public Health Declaration.[1105] Aside from certain Member States legislating laws to facilitate the Article 31*bis* system, there have been few attempts to amend domestic laws to take advantage of the flexibilities the TRIPS Agreement permits and the Public Health Declaration confirms. The absence of any significant statutory reaction to the Public Health Declaration further reinforces the position that the policy thoughts in the Public Health Declaration were not significant enough to necessitate legislative amendments.

The lack of formal consequences flowing from the Public Health Declaration does not mean that the Public Health Declaration has been without consequences. Consequences, subjective in nature, flowed *en masse* from the Public Health Decla-

1104 The para 6 dilemma identified in the Public Health Declaration represents the only real problem that required the TRIPS Agreement obligations to be reconsidered. The extension of the transitional periods for LDCs reflects a concession that will in a practical sense have effect on the relevant Member States.

1105 The much publicised court action in South Africa concerning the introduction of a compulsory license system permitting international exhaustion system for pharmaceuticals in certain circumstances was settled prior to the Public Health Declaration.

ration. At an international level Member States have agreed that the TRIPS Agreement permits diverging yet valid interpretations. This so-called flexibility has been anchored in the Public Health Declaration and forms the central achievement in the Public Health Declaration. This policy of permitting and accepting flexible interpretations has spread beyond the scope of the TRIPS Agreement. Analogies have been made to other WTO Agreements and to future developments in the WIPO. The Public Health Declaration has also had an effect on free trade agreements and their negotiations. FTAs that call for additional intellectual property protection – 'TRIPS-plus' protection – are often accompanied by 'side-letters' that reaffirm that the provisions agreed to in the FTA do not run contrary to the Public Health Declaration. In some FTA negotiations a final agreement seems unlikely because of calls for TRIPS-plus provisions. These consequences derive primarily out of the better understanding Member States have acquired of the TRIPS Agreement through the Public Health Declaration and their negotiations. This increased knowledge has boosted the confidence of the Member States seeking more flexibility and has resulted in them being more self-assured in their views and more assertive in negotiations in the WTO.

The course that the Public Health Declaration took created well-defined opponents. The access to healthcare brought developing Member States together and helped to form a united front against the positions held by the developed Member States. As a unit the developing Member States were able to bundle resources and influence to bring about results better suited to themselves. Holding the banner of better health the developing Member States were able to take the moral high ground against the perceived profit-driven developed Member States. The added knowledge, confidence and assertiveness have influenced most WTO negotiations that followed and, arguably, that will follow.

In addition to the added weight the Public Health Declaration has given to public interest concerns in negotiating and implementing treaties there have also been calls for this to be better recognised in dispute proceedings. This was one of the indirect consequences developing Member States had hoped would flow from the Public Health Declaration. The necessity of this was debatable. Although the WTO *Canada –Pharmaceuticals* case required exceptions to be interpreted restrictively, the DSB has largely respected public interest policies when evaluating measures taken under WTO law. Nevertheless, the uncertainty spurred developing Member States to reinforce already existing and accepted interpretative tools used by the DSB. Despite the fact that neither DSB panels nor the Appellate Body will undertake any paradigm shift purely because of the contents of the Public Health Declaration, it will nevertheless assist the DSB in interpreting the TRIPS Agreement in the future. This, together with the display of unity in the Public Health Declaration will likely reduce the threat of challenges under the DSB. In this sense, the Public Health Declaration has affirmed the right to use the TRIPS flexibilities in full; meaning that different views on the interpretation of a flexible provision need not automatically mean that one of the parties is infringing the TRIPS Agreement. Hence, the threat of chal-

lenges has been minimised. This has the effect of making the TRIPS Agreement less oppressive for developing countries and more amenable to peculiar domestic factors.

Matthews notes that '[o]n the face of it, the TRIPS Agreement deals adequately with the issue of patents, access to essential medicines and the public health crises'.[1106] This dissertation extends *Matthews*' comment by confirming that, subject to the abovementioned exceptions, the TRIPS Agreement is not only superficially adequate but also substantively capable of coping with current concerns; the 'problem' lies in the way in which it is interpreted and implemented.[1107] This therefore confirms the US's statement that 'the TRIPS Agreement has struck a proper balance between offering incentives for innovation and ensuring that there is access to needed medicines'.[1108]

The conclusion of the Public Health Declaration, the extensions given to the implementation of certain TRIPS obligations and the Article 31*bis* system have removed the real and perceived legal barriers that stood in the way of access to medicines have been removed. Whether or not the Member States calling for the changes are willing to act on their demands remains to be seen. Current circumstances indicate that for the vast majority of the countries, their pleas for assistance were merely rhetoric.

1106 *Matthews*, 7 JIEL 1 (2004) p. 76.

1107 *Anderson and Wagner*, 9 (JIEL) 3 (2006) p. 708.

1108 US in the WTO Special Discussion on Intellectual Property and Access to Medicines in the TRIPS Council (10.07.2001) IP/C/M/31 at p. 36.