III. National policies and measures

The first developed Member State to adopted measures that reflect the Public Health Declaration was Belgium. In 2004 the Belgium legislature introduced for the first time a compulsory license to remedy possible access problems in the field of health care. The public health compulsory license made express reference to the TRIPS Agreement and the Public Health Declaration.[1081] Its scope reflects a liberal reading of the TRIPS Agreement and makes use of the flexibilities found therein. The compulsory license does not however extend to compulsory licenses for export to countries without their own production facilities.

An example of the consequences the TRIPS Agreement and the Public Health Declaration has had on developing countries can be seen in the case of Ghana. With the expiry of the transitional periods in the TRIPS Agreement Ghana brought its patent system in line with the TRIPS standards.[1082] Simultaneously, Ghana took advantage of the flexibilities mentioned in the Public Health Declaration to ensure the patent system would not ultimately stand in the way of its public health measures. Measures legislated include:

- The parallel importation of pharmaceuticals put onto any market with the patent holder's consent (i.e. international exhaustion system)[1083]
- Compulsory licenses to remedy abusive patent practices and excessive prices[1084]
- Compulsory licenses for insufficient local working of the patent[1085]
- Administrative guidelines for determining 'adequate remuneration' for compulsory licensed patents[1086] and
- Shortened the compulsory license process by entitling licenses to be granted by ministerial authorisation.[1087]

Other Member States have taken more direct measures to gain access to compulsory licensed pharmaceuticals. Zimbabwe, for example, declared a state of emergency allowing the state or its authorised agent to domestically 'make or use any patent … used in the treatment of persons suffering from HIV/AIDS'.[1088] The state of emergency further permits the importation of any generic drug for these pur-

1081 *Van Overwalle*, 37 IIC 8 (2006) p. 908-909.
1082 Ghanaian Patent amendment act no. 657 of 2003. Ghana, for example, did away with the powers to temporarily exclude the patenting of pharmaceuticals (formally sec 8) and licenses of right (formally sec 54).
1083 *Cohen et al*, 1 Globalization and Health 17 (2005) p. 5-6.
1084 *Cohen et al*, 1 Globalization and Health 17 (2005) p. 5.
1085 Adequate importation will also fulfil the local working requirement. Cf. *Cohen et al*, 1 Globalization and Health 17 (2005) p. 5.
1086 *Cohen et al*, 1 Globalization and Health 17 (2005) p. 4.
1087 *Cohen et al*, 1 Globalization and Health 17 (2005) p. 5.
1088 Declaration of Period of Emergency (HIV/AIDS) Notice 2002 (24.05.2002) sec 2(a). The emergency was declared for a period of 6 months.

poses.[1089] The approach taken by Zimbabwe was applauded as the first move to apply the Public Health Declaration.[1090] The view that Zimbabwe's actions derive from concessions made in the Public Health Declaration indicates the continued lack of understanding for the TRIPS Agreement. Although Zimbabwe's actions may have been motivated by the swell in public and political support flowing from the Public Health Declaration for such action, the provisions of the TRIPS Agreement never prevented Zimbabwe or any other Member State from taking such action.

Zambia,[1091] Mozambique,[1092] Namibia,[1093] Indonesia,[1094] Taiwan[1095] and Malaysia[1096] have also issued compulsory licenses with express reference to the Public Health Declaration or for the treatment of epidemics referred to in the Public Health Declaration. Thailand is another country making use of compulsory licenses to provide additional access to medications. The Thai policy of 'universal access to medicines' has however extended beyond medication to treat HIV/AIDS and has encompassed medication to treat heart diseases.[1097]

Brazil, a proponent of pre-empting intellectual property rights with health policies, has also acted on the swell in international support for the use of compulsory licenses to make use of the compulsory license system, either directly[1098] through a grant or indirectly as a negotiating ploy, to reduce pharmaceutical prices.[1099] Like the Zimbabwean measures, the entitlement to carry out such action does not flow from the Public Health Declaration; it is an entitlement contained in the TRIPS Agree-ment.

The adoption of a modern competition law system in South Africa has provided a platform for individuals to challenge the practices of certain pharmaceutical companies. To this effect the South African competition officials have heard complaints concerning excessive pricing, refusal to license and the lack of access to technology

1089 Declaration of Period of Emergency (HIV/AIDS) Notice 2002 (24.05.2002) sec 2(b).

1090 ICTSD 'Zimbabwe becomes the First Country to Invoke Declaration on TRIPS and Public Health' *Bridges Weekly Trade News Digest* (12.06.2002) 15. At present the WHO recognises a further 45 countries as suffering from health crises or emergencies. Cf. *WHO*, (2006).

1091 Zambian Compulsory License No. CL 01/2004 (21.09.2004).

1092 Mozambican Compulsory License 01/mic/04 (05.04.2004).

1093 -- 'Namibia uses TRIPS to make anti-AIDS drugs' *TRALAC* (24.06.2003).

1094 Indonesian Decree of the President Regarding the Exploitation of Patent by the Government on Anti-Retrovirals 83/2004 (05.10.2004)

1095 ICTSD 'Taiwan Issues Compulsory License For Tamiflu' *Bridges Weekly Trade News Digest* (30.11.2005) p. 11-12.

1096 Malaysian Authorisation for the Exploitation of Patented Invention (29.10.2003).

1097 Thai authorities have based their compulsory license for Clopidogrel on cost grounds. Their calculation is that the use of generic versions would enable the Thai healthcare system to afford 10 times the amount of medication. *Ministry of Health (Thailand)*, Facts and Evidences on the 10 Burning Issues Related to the Government Use of Patents on Three Patented Essential Drugs in Thailand (Sangsue Thailand 2007) p. 15.

1098 *Stewart*, WSJ (2007), *Ministry of Health (Brazil)*, Efavirenz (2007).

1099 *Abbott*, 7 Bridges 2 (2003) p. 22, *CIPR*, (2002) p. 43,

essential to pharmaceutical production.[1100] The use of the competition system, as done in the US and the EU, is a TRIPS-conform and a TRIPS-advocated process; it is not a procedure that stems from the Public Health Declaration.

The spread of intellectual property protection that has occurred with the expiry of the transitional periods under the TRIPS Agreement has reduced the number of states not required to enforce or implement pharmaceutical patents. This has prompted leading Indian generic pharmaceutical producers to consider shifting their operations to Bangladesh where they would be able to take advantage of its status as a LDC and continue to produce generic versions of pharmaceuticals patented in non-LDC countries.[1101]

G. Conclusion

In addition to Switzerland a number of other countries have briefly mentioned that they are considering implementing the Article 31*bis* system into domestic law.[1102] None of these countries have identical systems; whereas some are similar others differ considerably. This mixture of rules and procedures will make comparisons between the manufacturers seated in the various countries extremely difficult. The lack of universal transparency and the 'hidden' potential to subvert or delay the process further hinders the systems use. The lack of an active demand for the pharmaceuticals from the needy country will not encourage manufacturers to actively enter the market, thus preventing competition and knowledge of how the systems will function. The national implementation of the Article 31*bis* system has thus further complicated an already formalistic system and has as a result further distanced itself from the original goals of providing an expeditious solution to the problems caused by insufficient domestic pharmaceutical production capacities.

Although the systems are themselves a hurdle to solving the paragraph 6 dilemma and will most likely deter their use, the success of the system can only truly be determined once it is used. The unwillingness to use the system infers that either the current public health problems are not sufficiently serious or the existing avenues for acquiring assistance are adequate for the needy countries situations. [1103]

1100 *Baker,* Process and Issues for Improving Access to Medicines: Willingness and Ability to use TRIPS Flexibilities in Non-Procuring Countries (Fretwells London 2004) p. 45-46.

1101 *Matthews*, 7 JIEL 1 (2004) p. 106.

1102 For example China, France, Indonesia and Korea.

1103 Roche has licensed the sanquinavir patents and know-how to 3 African generic pharmaceutical producers. This measure is part of Roche's policy of not filing or enforcing its patents in LDCs or sub-Saharan Africa. Cf. -- 'Roche gibt Know-how für Aids-Generika frei' *NZZ* (23.09.2006).