

Insert the following excerpt and Notes and Questions on page 436 of the casebook (after Note 7) :

DECLARATION ON THE TRIPS AGREEMENT AND PUBLIC HEALTH

Adopted on 14 November 2001, WT/MIN(01)/DEC/2 (Nov. 20, 2001)

1. We recognize the gravity of the public health problems afflicting many developing and least-developed countries, especially those resulting from HIV/AIDS, tuberculosis, malaria and other epidemics.

2. We stress the need for the WTO Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS Agreement) to be part of the wider national and international action to address these problems.

3. We recognize that intellectual property protection is important for the development of new medicines. We also recognize the concerns about its effects on prices.

4. We agree that the TRIPS Agreement does not and should not prevent members from taking measures to protect public health. Accordingly, while reiterating our commitment to the TRIPS Agreement, we affirm that the Agreement can and should be interpreted and implemented in a manner supportive of WTO members' right to protect public health and, in particular, to promote access to medicines for all. In this connection, we reaffirm the right of WTO members to use, to the full, the provisions in the TRIPS Agreement, which provide flexibility for this purpose.

5. Accordingly and in the light of paragraph 4 above, while maintaining our commitments in the TRIPS Agreement, we recognize that these flexibilities include:

a. In applying the customary rules of interpretation of public international law, each provision of the TRIPS Agreement shall be read in the light of the object and purpose of the Agreement as expressed, in particular, in its objectives and principles.

b. Each member has the right to grant compulsory licences and the freedom to determine the grounds upon which such licences are granted.

c. Each member has the right to determine what constitutes a national emergency or other circumstances of extreme urgency, it being understood that public health crises, including those relating to HIV/AIDS, tuberculosis, malaria and other epidemics, can represent a national emergency or other circumstances of extreme urgency.

d. The effect of the provisions in the TRIPS Agreement that are relevant to the exhaustion of intellectual property rights is to leave each member free to establish its own regime for such exhaustion without challenge, subject to the MFN and national treatment provisions of Articles 3 and 4.

6. We recognize that WTO members with insufficient or no manufacturing capacities in the pharmaceutical sector could face difficulties in making effective use of compulsory licensing under the TRIPS Agreement. We instruct

the Council for TRIPS to find an expeditious solution to this problem and to report to the General Council before the end of 2002.

7. We reaffirm the commitment of developed-country members to provide incentives to their enterprises and institutions to promote and encourage technology transfer to least-developed country members pursuant to Article 66.2. We also agree that the least-developed country members will not be obliged, with respect to pharmaceutical products, to implement or apply Sections 5 and 7 of Part II of the TRIPS Agreement or to enforce rights provided for under these Sections until 1 January 2016, without prejudice to the right of least-developed country members to seek other extensions of the transition periods as provided for in Article 66.1 of the TRIPS Agreement. We instruct the Council for TRIPS to take the necessary action to give effect to this pursuant to Article 66.1 of the TRIPS Agreement.

NOTES AND QUESTIONS

(1) **Article 31(f) and the Article 28 Right to Import.** Article 31(f) of the TRIPS Agreement states that “where the law of a Member allows for other use of the subject matter of a patent without the authorization of the right holder. . . any such use shall be authorized predominantly for the supply of the domestic market of the Member authorizing such use.” Article 28 grants the owner the exclusive right of importing. Suppose Burkina-Faso decides that a compulsory license is necessary for a pharmaceutical product, but there is no local licensee capable of supplying the market. Does Article 31(f) allow the state to “authorize” a manufacturer in India to supply Burkina-Faso’s domestic market?

(2) **Impact of Doha Ministerial Declaration on TRIPS and Public Health.** According to the United Nations, more than 25 million Africans now have HIV or AIDS. In eight African countries, more than 15 percent of the adult population is now infected with the virus, and the United Nations predicts that one-third of all Africans may eventually be infected. In the context of HIV/AIDS, access to medicines is more than just the cost of drugs. There are six subtypes or “clades” of HIV-2. Retrovirals used in the developed countries have only been tested in HIV-2 subtype B. None have been tested for HIV-1. The health delivery regimen consists of 20 pills a day which must be taken with meals. Public health officials warn that if the medicines are not taken according to the prescribed regimen, resistance will increase, as has happened with antibiotics. The regimen has serious side effects. The medicines must also be kept refrigerated.

To what extent is the Doha Declaration on TRIPS and Health a political document and to what extent is it a legal one? According to the Director-General of the International Federation of Pharmaceutical Manufacturers Associations, “the final text of the declaration maintains the current legal provisions of TRIPS.” Can the United States, after Doha, assert a claim against a country such as South Africa for failure to negotiate with a drug company prior to the grant of a compulsory license? What about parallel imports, the treatment of which was excluded from the TRIPS Agreement by Article 6? Can

the United States exert pressure on South Africa, outside of the obligations of the WTO, not to allow parallel imports from India? See, e.g., Frederick M. Abbott, *The TRIPS-Legality Of Measures Taken To address Public Health Crises: A Synopsis*, 7-SPG WIDENER L. SYMP. J. 71, 77 (2001); R. Scott Rogers, *WTO Weakens IP Protections for Pharmaceuticals, Slightly*, Corp. Legal Times Int'l, 8 (Jan. 2002).

The Doha Round of the WTO is sometimes termed the "Development Round." Is it now "payback time" for the developing nations who thought that they ceded so much on intellectual property during the Uruguay Round? Does it appear that the parties to the new negotiations intend to build *upon* the TRIPS Agreement, or to *undermine* it?