

# Negotiations in the WTO TRIPS Council pursuant to Paragraph 6 of the Ministerial Declaration on the TRIPS Agreement and Public Health

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To be overbearing when one has wealth  
and position

Is to bring calamity upon oneself.

Lao Tzu, *Tao Te Ching*

Book I, Chapter IX

# Genesis of Current Impasse

- Problem of conjoined expiration of TRIPS Agreement transition period for pharmaceutical patents and Article 31(f) compulsory licensing limitation recognized by developing WTO Members well before Doha Ministerial.
- As of January 1, 2005, world supply of off-patent (generic medicines) will substantially contract as mailbox applications processed and new medicines under WTO-wide patent.
- For compulsory license issued under Article 31, TRIPS Agreement, “(f) any such use shall be authorized predominantly for the supply of the domestic market of the Member authorizing such use;”
- Compulsory licenses serve dual function of (a) permitting production or importation of products under patent (b) providing leverage in price negotiations as “background” possibility, or explicit lever (as in U.S.-Bayer cipro negotiations or Brazil-Roche ARV negotiations).

# Pre-Doha Developing Member Text of 12 September 2001

- “5. A compulsory license issued by a Member may be given effect by another Member. Such other Member may authorize a supplier within its territory to make and export the product covered by the license predominantly for the supply of the domestic market of the Member granting the license. Production and export under these conditions do not infringe the rights of the patent holder.”
- “7. Under Article 30 of the TRIPS Agreement, Members may, among others, authorize the production and export of medicines by persons other than holders of patents on those medicines to address public health needs in importing Members.”

## Ministers in Doha Put Off Resolution of Problem Set in Paragraph 6 of Ministerial Declaration (14 November 2001)

- 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.

# Paragraph 6 Negotiations Involve Limited Problem Set

- Negotiations are NOT about whether WTO Members may issue compulsory licenses for production or import of medicines. Article 31, TRIPS Agreement, allows compulsory licensing on any grounds, establishing certain procedural and substantive requirements that vary in context.
- Paragraph 6 negotiations ONLY concern the LIMITED case of Members wishing to export predominant part of production under compulsory license (CL), which itself may not be a common phenomenon (because major suppliers, e.g., Brazil, China, Egypt, India, etc. may have substantial local requirements). If a predominant part of CL supply is furnished for domestic supply, the Paragraph 6 solution would NOT APPLY. Article 31, TRIPS Agreement would apply without subparagraph (f) effect.

# Preparations for Negotiations

- Developing Member preparation for Paragraph 6 negotiations initiated shortly following Doha Ministerial. Background papers prepared and conceptual issues discussed.
- Complex problem set. What flexibilities exist under present text? Is it necessary to seek new multilateral solution? If solution is needed, what is the optimum mechanism? (See Study Paper 2a for British Commission on IPRs, Feb. 2002 for detailed treatment of issues)
- Assumption that Pharma would seek safeguards.

# Opening Submissions

- March Submissions to TRIPS Council
  - EC (4 March 2002) discusses Article 31 and Article 30 approaches
  - Kenya on behalf of Africa Group, Brazil, Cuba, Dominican Republic, Honduras, India, Indonesia, Jamaica, Malaysia, Peru, Sri Lanka and Thailand (5 March 2002) discusses Article 31 and Article 30 approaches
  - US First Communication, rejects Article 30, suggests moratorium regarding Article 31(f) with conditions



# Initial Submissions

- In connection with June 25-27 TRIPS Council meeting position papers submitted by various constituencies
- African Group, Brazil et al, Egypt, EC, UAE and U.S.
- Coverage range of options
  - African Group sought comprehensive solution across range of issues and mechanisms
  - Brazil on behalf of Bolivia, Brazil, Cuba, China, Dominican Republic, Ecuador, India, Indonesia, Pakistan, Peru, Sri Lanka, Thailand and Venezuela focused on Article 30 mechanism
  - Egypt identified problem set and potential solutions
  - EC proposed amendment of Article 31(f) with multiple conditions, including preferences for patent holders and extensive safeguards
  - UAE identified problem set and potential solutions, appearing to favor Article 30
  - U.S. suggest moratorium or waiver with limitations and conditions (beneficiary countries, supplying countries, patent holder preferences, safeguards, etc.) . At this stage does not suggest “scope of diseases” limitation, but does reference Paragraph 1 of Doha Declaration.

# Key Development

- EC position in favor of Article 31(f) amendment reached after extensive internal Council and Commission debate with sharply conflicting views among member states. EC had initially floated Article 30 option as possibility. The EC internal decision rejecting Article 30 approach effectively doomed that option in Geneva negotiations. Dissenting member states continued to object internally throughout negotiations, but never sufficiently to change Council course.

# Norway Meeting

July 20-23, 2002

- Sponsored by Norway Government and Quaker United Nations Office (Geneva)
- TRIPS Council Delegates (including Chair), WTO Secretariat, WHO, NGOs, Pharmaceutical Industry, Academics
- Constructive dialogue though within confines of government positions.
- Summary of meeting and legal options papers at <http://www.quno.org>

# Scope of Diseases at Norway

- EC-US promote theory that Paragraph 1 of Doha Declaration intended to limit “scope of diseases” covered by Paragraph 6
- Serious objections
  - Negotiators and Ministers rejected explicit attempts to restrict Doha Declaration to “pandemics”, HIV/AIDS, malaria and tuberculosis. Broad reference to “public health” adopted
  - Central “agreement” of Ministers, Paragraph 4, refers broadly to protection of public health and access to medicines for all
  - Paragraph 5 recognizes right to grant compulsory licenses and “the freedom to determine the grounds upon which such licences are granted”
  - Paragraph 6 addresses manufacturing capacity for products in the pharmaceutical sector. No reference to disease scope.

# Lists of Elements Stage August - September

- Subsequent TRIPS Council meetings result in list of elements proposed by Members, but little movement toward common ground
- Secretariat prepares paper on waivers and on manufacturing capacities
- Scheduling of Sydney mini-Ministerial intended to provide target for agreement in principle
- US and EC exert pressure on capitals, and accelerate agenda to split developing Members, focusing on smaller African states

# Developing Member Common Substantive Position

- October 15 and forward coordination
- Two stage process
  - Initial agreement on substantive and procedural elements
  - Subsequent discussions regarding implementation mechanism
- Members agree in principle on common substantive ground, but delays based on coordination with capitals ultimately results in submission by South Africa accompanied by statements of support from other developing Members

# Chairman's Note of 17 October 2002

- Takes developing Members by surprise because of lack of consensus on approach in TRIPS Council
- Negotiations increasingly moving toward small group consultation, frustrating many Members not considered sufficiently “important” by Secretariat
- Small group process favors EC and U.S. because these Members do not share developing Member problem of intra-group coordination
- System is non-transparent even within hallways of WTO
- Secretariat gradually segregates “importing beneficiaries”, focusing on Africa, and potential exporters, focusing on Brazil and India
- Substantively text includes significant proportion of elements advocated by EC-U.S. including suggestions regarding limitations on potential importers and exporters
- Scope of diseases proposal troublesome on textual grounds (use of “referred to in paragraph 1 of the Doha Declaration”) and issue of diagnostics left open
- Legal mechanism left open
- Regional trade arrangements begin to be addressed

# Pre-Sydney

- Developing Members focus on finalizing common substantive position – African Group continues work on additional paper
- Urgency of Sydney preparations, publication in Inside U.S. Trade (Oct. 25) and development of EC proposal results in submission by South Africa with indications of support.
- “4. Scope of diseases : Paragraph 1 of the Declaration does not in any manner qualify "public health" in paragraph 4; neither does it limit the scope of diseases that may be addressed when finding an expeditious solution to the problem referred to in paragraph 6. There must therefore be no *a priori* exclusions regarding diseases that may be addressed by importing and exporting Members or the products in the pharmaceutical sector used to address public health. It is neither practicable nor desirable to predict the pharmaceutical product needs of Members desiring to protect the public health by promoting access to medicines for all.”



# Pre-Sydney

- EC circulates proposal highly objectionable to developing Members across range of issues, including country coverage, methods of determining capacity and safeguards. On scope of diseases proposes:
- “The solution will apply to ‘Cases where the gravity of public health problems afflict developing countries, especially those resulting from ...’”
- EC proposal was vague. Developing Members noted that disease burdens do not divide themselves into “grave” and “non-grave”. How many people must be at risk of death before a public health problem is “grave” – 50; 200; 2,000; 50,000; 1,000,000? Moreover, how did the EC propose to deal with HIV/AIDS. The HIV virus targets the immune system making individuals vulnerable to a wide range of diseases. Are only antiretrovirals covered because they address HIV/AIDS? If not, then all possibilities must be considered, including cancer treatments, antibiotics, and so forth. This whole area is not susceptible to advance determination.
- Secretariat circulates paper affirming absence of requirement for annual voting to continue waiver

# U.S. Elections

- Election of Republican majority in U.S. Senate anticipated to harden USTR positions.
- In U.S. constitutional system, Congress regulates commerce with foreign nations, making Executive dependent on congressional authorizations. Pre-election, USTR required to be responsive to Democrat majority in Senate

# Chairman's Note of 10 November 2002

- Timing raises serious concern among developing Members because of short period to review and coordinate with Ministers for Sydney Mini-Ministerial (Nov. 14-15). Nonetheless, responsive positions are coordinated
- Core objections on products and disease coverage  
“Patented products, or products manufactured through a patented process, of the pharmaceutical sector needed to address public health problems **referred to** in paragraph 1 of the Doha Declaration on the TRIPS Agreement and Public Health. It is understood that these products include the active ingredients used in their manufacture as well as diagnostic kits needed for their use.”
- Because Paragraph 1 of Doha Declaration illustratively lists certain diseases, there was manifest concern that EC-U.S. would claim that Paragraph 6 solution was limited to diseases specifically “referred to” in Paragraph 1. Developing Members categorically insisted (at a minimum) that solution broadly address public health problems “**as recognized**” in Paragraph 1.

# Kenya, Coordinator of African Group

- Provides detailed grounds for rejecting limitations on scope of diseases
- Highlights Paragraphs 4 and 5 of Doha Declaration
  - Member sovereignty to determine public health needs
  - Objective of promoting access to medicines for all
  - Paragraph 1 illustrative

# Chairman's Text of 19 November 2002

- First concrete draft proposal
- Restates elements of 10 November note without adequately addressing developing Member concerns
- Product definition continues “referred to” language, though expanded to include test kits
- Developing Members want clear that vaccines included and prefer expansion on diagnostics
- Criteria for determining adequate capacity raise issues
- Problem of “dual licensing” not addressed, nor potential double compensation
- Restrictive suggestions on recoloring or reshaping of products
- Regional market definition raises issues on multiple licensing
- Waiver to amendment formulation leaves uncertainty
- Chairman/Secretariat continues small group negotiations

# Chairman's Text of 20 November

- USTR intervenes in attempt to block distribution by Chairman
- Vehemently protests addition of “it being understood that the reference to public health problems is not limited to the three specific diseases mentioned therein or to epidemics”
- Japan objects to inclusion of “vaccines”
- Makes U.S. intent with respect to existing text clear

# Chairman's Text of 24 November 2002

- Adopts “public health problem as recognized in paragraph 1” formulation
- Multiple problems remain
  - Failure to address streamlining of licensing (e.g., through recognition)
  - TRIPS-plus safeguards on diversion
  - Poorly designed regional market mechanism
  - Transfer of technology weak
  - Issues remain on determination of adequate capacity
  - EC and US continue to propose options for limiting eligible importing and exporting Members (e.g., footnotes with lists)

# Chairman's Text of 16 December 2002

- Retains 24 November formula recognizing public health problems in Paragraph 1
- Developing Members retain substantial objections
- Perception ultimately that sides have exhausted room for concession and express willingness to accept proposal
- U.S. insists on limiting application of system to HIV/AIDS, malaria, tuberculosis or other infectious epidemics of comparable gravity and scale, including those that may arise in the future, appending list of infectious diseases
  - USTR asserts asthma, diabetes, cancer should be excluded, surprising public health experts
  - USTR/Pharma later focuses on “Viagra” and obesity
- USTR argues to delegates that if U.S. proposal constitutes rewriting of Doha Declaration, so be it
- USTR begins aggressive campaign to suggest developing Members, particularly export-capable (Brazil, China, India) acting in bad faith



# Flaws in U.S. Approach

- Establishes world public health system that discriminates against the developing world
  - The U.S., EC, Switzerland and Japan can meet their public health needs by compulsory licensing, but developing Members' health needs are pre-selected by USTR
- For developing Members the U.S. proposal is a step backward from Doha, rewriting the Ministerial Declaration
- The “risk” to the WTO system and U.S. is that people in developing countries will have too great access to low price medicines – this is not a real risk
- U.S. focus on Viagra is an insult to developing Members and the millions suffering without treatment for disease
- The U.S. proposal on limiting scope of diseases makes no sense from a public health standpoint
  - HIV/AIDS, for example, is an immune deficiency disorder resulting in a myriad of opportunistic infections, cancer and other medical conditions. It is not by any means only about antiretrovirals
  - For what reason would we want to preclude application of system to asthma, cancer or diabetes? These diseases are enormous problems in developing Members

# Flaws in U.S. Approach

- The U.S. and EC will remain the world's largest import markets for the indefinite future. The United States has enormous leverage at the WTO. If developing Members abuse the system they know the U.S. will limit market access and capital flow. The risks of abuse are dramatically overstated.
- The OECD Pharma companies are NOT dependent on patent-based profits from developing Members for their research budgets. The Pharma companies are worried that low price medicines will work their way into OECD markets. This is not a realistic concern since U.S. and EC law each prohibit patented pharmaceuticals from entering the market, and since the system of the December 16 text includes substantial safeguards against diversion.
- Failure to carry out the Doha Declaration mandate in good faith is having very serious repercussions among the developing countries, and will influence all other areas of the negotiations.

# Unilateral Moratoriums

- USTR is prepared for adverse press, and on December 20 announces unilateral moratorium based on its perceived interests
- Swiss follow on December 22
- EC floats and later formalizes proposal for WHO involvement. Adopts moratorium based on December 16 text.

# Inadequacy of Unilateral Moratorium

- U.S. unilateral moratorium is of no meaningful use to developing Members – it is a media relations ploy designed to reposition blame for failure of negotiations

- Compulsory licensing involves national administrative and court processes. Pharma actions to block licenses are not brought to WTO. Members remain obligated to implement TRIPS Agreement in national law, and a moratorium does not change domestic legal effect of treaty. Recall that Pharma pursued case against government of South Africa long after USTR announced it would take no action.

Prospective compulsory licensees require legal security, and will not invest under prospect of withdrawal of unilateral moratorium. Even if a nation is estopped from repudiating unilateral commitment without notice, it may still do so with reasonable notice. Developing Member public health would remain under constant threat.

Unilateral moratorium does not address developing Member public health as called for in Doha.

A unilateral moratorium reflects a dramatic failure of the WTO system to address an issue of primary concern to developing Members.

# EU Compromise Proposal

- The European Communities have proposed the addition of a footnote to draft paragraph 1(a) of the Chairman's text of 16 December 2002. The text as amended would state:
    - “ 1. For the purposes of this Decision:
      - (a) "pharmaceutical product" means any patented product, or product manufactured through a patented process, of the pharmaceutical sector needed to address the public health problems as recognized in paragraph 1 of the Declaration.[1] It is understood that active ingredients necessary for its manufacture and diagnostic kits needed for its use would be included<sup>1</sup>;
      - [1] This covers at least HIV/AIDS, malaria, tuberculosis, yellow fever, plague, cholera, meningococcal disease, African trypanosomiasis, dengue, influenza, leishmaniasis, hepatitis, leptospirosis, pertussis, poliomyelitis, schistosomiasis, typhoid fever, typhus, measles, shigellosis, haemorrhagic fevers and arboviruses. When requested by a Member, the World Health Organization shall give its advice as to the occurrence in an importing Member, or the likelihood thereof, of any public health problem.
    - 1. This subparagraph is without prejudice to subparagraph 1(b).”
- [underlining identifies proposed amendment]

# Flaws in EC Proposal

- List of diseases implies presumption of limitation on scope of diseases – “at least” suggests that additional subject matter is subject to justification
- Takes determination whether Member has public health problem out of hands of national government and into hands of WHO. This is contrary to Doha Declaration recognition of sovereignty, to the customary practice of the WTO, and places developing Members in lesser position than Member (e.g., the EC and U.S.) with manufacturing capacity.
- System would be more complex and burdensome than at present, which already will substantially inhibit action.
- The WTO has not before allocated principal decision-making authority to another international organization. WIPO, for example, does not have authority to provide an authoritative interpretation in TRIPS dispute settlement.
- There is no mechanism in WHO for dealing with the EC proposal
  - The Director General could render an interpretation, but under what authority and conditions?
  - The Executive Council and World Health Assembly are political bodies. Their involvement would politicize individual questions of public health
  - The Essential Drugs and Medicines Division could provide view, but acts under ultimate authority of Director General
- The WTO Dispute Settlement Understanding already provides for solicitation of advice on scientific and technical aspects of a problem, and for establishment of an expert review group. The latter must be independent of a government or international organization.

# Prospects for Multilateral Solution

- U.S. has put enormous pressure on capitals throughout the world to change their positions.
- The U.S. has attempted to divide Africa and the potential exporting countries (Brazil, China, India, et al). USTR Zoellick was very clear on this in his remarks in Africa,
- The EC's position as "honest broker" is discounted. They have been and remain a primary "demandeur".
- It is extremely unlikely that developing Members will compromise on scope of diseases. They have made very significant concessions in acceptance of December 16 text, and regard the U.S. proposal as a rewriting of the Doha Declaration.
- All sides are apparently prepared to accept that a multilateral solution will not be achieved.

# Consequences of Failure

- Developing Members in position to rely on Article 30 limited exception to patent rights because action necessitated by refusal of one WTO Member to accept multilaterally agreed solution. Paragraph 4 of Doha Declaration (“the TRIPS Agreement does not and should not prevent Members from taking measures to protect public health”) and necessity to address problem of Members without adequate capacity (as recognized by Paragraph 6) creates situation where action presumed not unreasonable.
- Developing Members have already articulated adverse results for continuing multilateral negotiations. If decisions of Ministers cannot be relied upon as basis for further negotiations – e.g., claim that Paragraph 1 of Doha Declaration intended to limit scope of diseases – then negotiations will need to be conducted in a different way.
- Real losers are people living in developing countries whose governments are placed in position of legal insecurity and for that reason are less likely to have access to low-priced medicines.
- Pharma considers that blocking consensus secures its position in developing Members, but Pharma has put itself in position of having unilaterally blocked reform of TRIPS health mechanism and this affects relations with governments and health ministries around the world. Query whether the short run gains are likely to exceed the long run costs of stimulating a developing country response.
- USTR has generated a substantial reservoir of ill-will among WTO delegations. The implications of this are unpredictable. See Lao Tzu.