PARAGRAPH 6 OF THE DOHA DECLARATION ON THE TRIPS AGREEMENT AND PUBLIC HEALTH

We are committed to helping countries that are experiencing public health crises. We want to find a real solution to problems that prevent Members from being able to address health problems associated with access to pharmaceuticals. We want all Members to be able to use the full flexibility of the TRIPS Agreement to help provide their citizens access to affordable medicines in times of crises.

We note that the Doha TRIPS declaration recognizes that the exclusive rights provided by patents are an important incentive to development of new drugs. Patents provide market incentives for innovators to risk time, energy and resources to develop and bring to market new technology. A system of patent rights and enforcement of those rights for pharmaceuticals provides numerous benefits to society; the availability of exclusive patent rights for pharmaceutical products spurs research and development of new medicines, including those resulting from biotechnology, to treat and cure diseases. The TRIPS Agreement recognizes that compelling innovators to relinquish patent exclusivity is a limited remedy for special circumstances. Clearly, under TRIPS, compulsory licenses are appropriate, but it must be borne in mind that these are exceptions, rather than the norm.

The TRIPS Agreement allows Members to use compulsory licenses, if they wish, to help address supply problems that can arise during health crises. The Agreement establishes conditions for the use of compulsory licenses that ensure these licenses will be limited and carefully drawn. The Agreement also recognizes that time is of the essence in a national emergency or other circumstances of extreme urgency by waiving the requirement to seek first a voluntary license from the patent owner.

In paragraph 6 of the Doha Ministerial Declaration on the TRIPS Agreement and Public Health, Ministers recognized that certain WTO Members, those with "insufficient or no manufacturing capacities in the pharmaceutical sector," could have difficulty using the compulsory licensing provisions of the TRIPS Agreement. The TRIPS Council is instructed to find an expeditious solution to this potential problem and report to the General Council before the end of 2002.

Obviously, many factors must be addressed in helping countries with limited means address public health problems. Among these factors are issues of infrastructure, financing, elimination of impediments such as tariffs and internal taxes, training, etc., most of which must be addressed in other appropriate fora. In addition, all countries must recognize that there are many people in the world who are unable to afford needed medicines at any price and under any TRIPS-related solution there would still involve a cost.[1] It is for those who cannot afford needed medicines that the Global Fund is essential and we encourage all countries that can to contribute to that fund and for those countries that can benefit from the fund to avail themselves of it.

[1] See discussion on access to medicine in *Macroeconomics and Health: Investing in Health and Economic Development*, Report of the Commission on Macroeconomics and Health, 20 December 2001, chaired by Jeffrey D. Sachs: "The poor lack access to essential medicines for many reasons, all of which must be addressed in a comprehensive manner. The most important reason, by far, is poverty itself...in the absence of large-scale donor support, poor countries in sub-Saharan Africa with high HIV/AIDS prevalence have been unable to avail themselves, at any significant scale, of these lower prices. The same problems are observed in the access to TB drugs, even those that are off patent, as well as many vaccines that are off patent yet still too expensive for use in the low-income countries in the absence of adequate donor financing."

CONSIDERATIONS FOR DEVELOPING AN EXPEDITIOUS SOLUTION

It must be kept in mind, when considering particular TRIPS provisions related to patents, as is the case here, that TRIPS obligations exist only when a patent exists. If an innovator has chosen not to obtain rights for a pharmaceutical invention in a particular market, if a country does not currently provide patent protection for pharmaceutical products,[2] or if the patent on a particular medicine in that market has expired,[3] anyone may make, use, offer for sale, sell the product in that market, or import the product involved into the market, or use the process. They also may produce the product for export.

The Council should, in carrying out its work under paragraph 6, develop information regarding where patents exist currently on pharmaceuticals to treat the diseases cited in the Declaration afflicting poor countries that lack or have insufficient manufacturing capacities in the pharmaceutical sector. This information will provide Members with an idea of the scope of the potential problem and help us formulate a practical solution.

We note that there are developing countries (i.e., those taking advantage of the Article 65.4, that possess the technological capability to manufacture pharmaceuticals and are not, and will not be, subject to Article 31(f) TRIPS requirements until 2005. In the event a patent exists on a needed pharmaceutical in the territory of a Member that lacks or has insufficient manufacturing capacities, that Member may grant a compulsory license to import and distribute foreign-manufactured product on its local market, including from the developing countries currently taking advantage of the provisions of Article 65.4. The expeditious solution the TRIPS Council must devise, therefore, will apply for the most part to situations arising no earlier than January 1, 2005.

Obviously, even if a patent existed in a country that lacked or had insufficient capacities for manufacture in the pharmaceutical sector, the country would have no need for compulsory licensing if the patentee is supplying the market in sufficient quantities at prices equal to or lower than the cost of drugs obtained using a compulsory license.[4] Similarly, if there is no patent in force in the country in need, the country would have no need to employ the solution if generic pharmaceuticals were available. Whenever possible, the country ought first, before granting a compulsory license, seek accommodation from the patent owner in order to be assured of a supply of quality product.

Paragraph 1 of the Ministerial Declaration on the TRIPS Agreement and Public Health makes clear that Ministers were addressing "public health problems," with special reference to "those resulting from HIV/AIDS, tuberculosis, malaria and other epidemics." The Ministers' direction in paragraph 6, to seek an expeditious solution to potential problems, is limited to the pharmaceutical sector. The significance of discussions relating to modifying the TRIPS Agreement, thereby altering the equilibrium of concessions arrived at under the Uruguay Round,

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[2] As is the case currently with India and a number of other developing and least developed countries. Developing countries availing themselves of the transition period permitted under Article 65.4 will not be obliged to provide patent protection for pharmaceutical products until 2005.

[3] Either because the term has ended or because the patentee has not paid the maintenance fees.

[4] We note that a component of the overall price of a drug obtained pursuant to a compulsory license will be an amount associated with the required payment of adequate remuneration to the right holder.

should not be discounted. Therefore, the Council should focus on fashioning a solution to improve access to pharmaceuticals to treat diseases referred to in the Declaration, such as HIV/AIDS, malaria, tuberculosis and other epidemics.

The phrase "with insufficient or no manufacturing capacities in the pharmaceutical sector" will have to be analyzed in connection with any solution. We do not believe it is appropriate to extend this solution to developed countries or to countries that choose not to manufacture certain drugs based on policy, economic or other reasons. This solution should reach out to those poor countries that are truly not capable of manufacturing sufficient supplies of needed pharmaceuticals. In this connection, we think it would be helpful for more information to be gathered for consideration by the Council with respect to current levels of pharmaceutical manufacturing capacity worldwide such as the work already done by the United Nations Industrial Development Organization.

In summary, we reiterate our firm belief that the application of an expeditious solution to access to pharmaceuticals should be applied to address diseases referred to in the Declaration, such as HIV/AIDS, malaria, tuberculosis and other epidemics in poor countries that lack sufficient pharmaceutical manufacturing capacities.

One further question to consider is whether it would be appropriate for this solution to be employed by entities other than government or other non-commercial actors, (e.g., commercial entities for profit). Given that we are trying to address situations where access to pharmaceuticals is required so that governments and other non-commercial actors can address major health problems afflicting their populations, we seriously question whether there are any circumstances under which this solution should employed by commercial entities on a for-profit basis.

SAFEGUARDS TO ENSURE THAT THE SOLUTION IS EFFECTIVE

In order to ensure that an expeditious solution is effective in addressing the situation identified in paragraph 6 of the Ministerial Declaration on the TRIPS Agreement and Public Health, the TRIPS Council will need to monitor the application of the solution in each case, and the results are achieved. Any solution devised should, therefore, include a means for informing the Council when the solution is being employed and for providing ongoing information regarding the nature and quantity of pharmaceuticals being exported to a Member, the numbers of people benefiting from the solution, and the results achieved, and any evidence of diversion of products authorized for production under the solution.

We believe that the TRIPS Council must develop, as part of any solution, a commitment by all Members to take the necessary steps to prevent diversion of the relevant pharmaceuticals. Likewise, the entire output of the relevant pharmaceuticals manufactured subject to the compulsory license should be exported to the Member in need. Whenever a particular pharmaceutical or pharmaceuticals are being supplied to a Member through application of the solution devised by the TRIPS Council, all Members should have an obligation to ensure that the medicines in question are not diverted from the Member's citizens for whom they were intended into other countries. The submission of information mentioned earlier would alert all WTO Members of the particular medicines involved, their source and destination, and the quantities involved, thereby enabling the Members to take appropriate steps to prevent diversion into their markets. It should be noted as well, that notification of the right holder as provided in Article

31(b) will aid in ensuring that action is taken with respect to any diversion to markets in which patents exist.

PROPOSALS TO DATE

In carrying out the task assigned by Ministers in paragraph 6 of the Declaration, the Council should seek the solution least prejudicial to balance of rights and obligations negotiated during the Uruguay Round. Absent such an approach, it will be difficult to achieve agreement in future rounds of multilateral trade negotiations, since Members will not be able to have confidence that rights and obligations will be respected.

Article 30

One suggestion made prior to Doha involved an interpretation of Article 30 to include a limited exception to patent rights for export of medicines to countries lacking or having insufficient manufacturing capacities in the pharmaceutical sector. Article 30 authorizes limited exceptions to patent rights, for such things as research exemptions, prior user rights, pre-expiration testing, so long as those exceptions do not unreasonably conflict with a normal exploitation of the patent and do not unreasonably prejudice the legitimate interests of the patent owner, taking account of the legitimate interests of third parties. The limited exceptions to patent rights authorized by Article 30 do not require a government decision in each case. Article 30 contains no requirements for notifying a patent owner of use, for establishing particular terms and conditions, for expiration if circumstances change, or for remuneration to the patent holder. We believe that an interpretation of Article 30 to allow exceptions to patent rights to permit otherwise infringing acts to supply a patented pharmaceutical for purposes of export would seriously prejudice the rights and obligations of Members under the TRIPS Agreement.

Article 31

Another proposal that has been discussed calls for interpretation or amendment of Article 31(f) in order to permit a Member to grant a compulsory license under an existing patent to a local manufacturer for purposes of export to a Member that lacks or has insufficient manufacturing capacities in the pharmaceutical sector. Because Article 31 already establishes agreed terms and conditions for compulsory licensing to ensure balance in situations in which use is permitted without authorization of the patent owner, consideration of solutions based on Article 31 as a whole have merit.

For example, Article 31 requires that decisions on compulsory licensing be made case by case; that, except in cases of national emergency or other urgent circumstance, or of government non-commercial use, the potential licensee attempt first to negotiate a voluntary license with the patentee; that the compulsory license be non-exclusive; that the license spell out the term and conditions; that when those conditions cease, the license expires; that the patentee be paid "adequate remuneration" in the circumstances of each case, taking into account the economic value of the authorization.

One approach to examine in considering a solution based on Article 31 would be for Members to agree to a moratorium on dispute settlement in instances in which a Member grants a compulsory license, under circumstances clearly delineated by this Council, for purposes of

export to a poor country that lacks or has insufficient manufacturing capacities in the pharmaceutical sector. Such an agreement would not require amendment of the TRIPs Agreement and application of the solution could be overseen by the TRIPS Council, including to insure that medicine being supplied to a Member that lacks or has insufficient manufacturing capacity is not diverted into other markets, away from the people it is intended to help. It is worth considering whether such a solution would not in fact be the most expeditious and least prejudicial to the rights and obligations of Members under the Agreement.