

## **Developing Country Government Perspectives**

### *Peru*

Betty Berendsen (Minister Counsellor, Permanent Mission of Peru to the United Nations Office, Specialized Agencies and to the WTO, Geneva) utilized her presentation to review the advantages and disadvantages of the legal mechanisms recently proposed to the TRIPS Council. Drawing heavily from documents tabled by various countries and country groups to the TRIPS Council, Ms. Berendsen emphasized the benefits of an article 30 solution over other suggestions - including an article 31 based solution, a moratorium on dispute settlement, and a waiver - as the best option for resolving the paragraph 6 issue of the Doha Declaration on Public Health. An authoritative interpretation would be beneficial for members because it would present clear boundaries that would be confined solely to patent rights. Furthermore, it would not require a lengthy modification of the existing TRIPS text. Ms. Berendsen continued by questioning the legal predictability offered by the waiver solution. Turning to the specific elements of a paragraph 6 solution, Ms. Berendsen felt that no limitations should be placed on either product coverage or the scope of disease, in order to effectively protect and promote public health objectives. She proposed that no category of member countries be excluded as beneficiary-importing members or as eligible supplying members, though election would be voluntary. The member itself should have the right to assess its own manufacturing capacity as opposed to across-the-board criteria that may not adequately assess actual manufacturing capacity. Conditions for the solution should be broad and not reduce the flexibilities presently afforded by the TRIPS agreement and the Doha Declaration. A transparent mechanism could allow members to review the solution's impact and help encourage competition in price and quality of product supplied. Remuneration to the right holder should be commensurate with the patient's ability to afford the product. Ms. Berendsen concluded her presentation by stating that the best solution was one that was expeditious, legally predictable, and non-burdensome.

### *Egypt*

Amr Ramadan (Counsellor, Permanent Mission of the Arab Republic of Egypt to the United Nations Office, Specialized Agencies and to the WTO, Geneva) described the evolution of the current policy debate concerning access to medicines that had begun much earlier in developing countries. Mr. Ramadan began his presentation by referencing the TRIPS agreement as an important development tool that could harmonize the socio-economic goals of developing countries and the economic goals of producers. Mr. Ramadan encapsulated the goals of developing countries in this debate as: firstly, to reach a common understanding among WTO members on the flexibilities provided by TRIPS with regard to pharmaceuticals; and secondly, to clarify its pharmaceutical-related provisions. Mr. Ramadan reflected on the proposed solutions and points of discussion brought to the attention of the TRIPS Council by the various countries and country groups. New elements thrown onto the table during the discussions of the TRIPS Council had led to a divergence of views and subsequent complications, thereby preventing the TRIPS Council from reaching an expeditious solution. Mr. Ramadan underscored the need for an effective, non-burdensome, legally predictable and permanent solution that would benefit those countries facing serious health crises, and that - by avoiding trade diversion and ensuring transparency - would not cause damage to the patent right holder. Mr. Ramadan reflected on developing country concerns with some practices of the research-based pharmaceutical industry. He recommended that pharmaceutical manufacturers should practice differential pricing, and urged them to take voluntary initiatives outside the TRIPS framework. Pharmaceutical

companies should refrain from patenting practices that were restrictive and behavior that sought to extend exclusive rights. Mr. Ramadan noted that pharmaceutical companies could pay more attention to developing country needs in the areas of health and of technology transfer.

Industry representatives opened the discussion by questioning how pharmaceutical innovation could continue without the support of an incentive system which they submitted would be undermined if a broad solution was adapted. Participants underscored the benefits of the present system offered by the TRIPS agreement and pressed the discussants on alternative incentive solutions. The panelists responded that the present system, in which compulsory licensing already existed, would not be jeopardized under the proposed article 30 solution, emphasizing that proper remuneration would still be made to the patent right holder, and that adequate safeguards would be in place. However, participants highlighted the larger repercussions that an article 30 solution would have on intellectual property rights generally and questioned how proper remuneration would be achieved under this solution. The panelists noted that the threat of compulsory licensing had led to a dramatic drop in prices which companies could practice voluntarily.

## **Developing Country Private Sector Perspectives**

### ***Brazil***

Peter Dirk Siemsen (Senior Partner, Dannemann, Siemsen, Bigler & Ipanema Moreira, Brazil) opened the session by highlighting the current tendency to overemphasize patents and compulsory licensing as an end, rather than a means to an end, in the context of public health crises. In an historical overview of the correlation between patent protection, industrial growth and R&D in Brazil, Mr. Siemsen pointed out that growth and foreign investment in the pharmaceutical sector had been influenced less by patents than by general government policy. The Brazilian government, however, continued to use patents as an issue in international discussions although these had no real effect on Brazil's economy. According to Mr. Siemsen, the outlook toward intellectual property had become more positive since the 1990's and investment in government-sponsored research had increased. Because of the AIDS crisis, the Brazilian government had decided to create a local generic industry. In spite of this, and tough requirements for marketing authorizations, Mr. Siemsen noted that Brazil was currently an attractive market for foreign generic companies. Brazilian patent law allowed compulsory licensing in cases of national emergency or overwhelming public interest. Only two compulsory licences had been granted since 1945. Due to an unfortunate coincidence in timing, a US WTO complaint against Brazil had been linked by politicians to a local discussion over the definition of national emergency and the public interest in the context of compulsory licensing, thus leading to an emotional controversy that was one of the factors leading up to the Doha Declaration. In closing, Mr. Siemsen emphasized that public health circumstances differed from country to country and that the role of compulsory licensing had to be analyzed in the global context of each country. He also encouraged the use of voluntary options before resorting to compulsory licensing.

### ***Malaysia***

V.L. Kandan (Senior Vice President, Asian Patent Attorneys Association, Malaysia) echoed Mr. Siemsen's remarks that the issue of compulsory licensing was being overplayed. Dato Kandan stated that the view that TRIPS could soon be replaced by a TRIPS II was not shared in Malaysia. He noted that multi-national corporations, local companies that manufacture generic products, and non-governmental organizations representing the consumer interest, influenced policy discussions over patents in Malaysia. The Third World Network, for example, which was active both locally and internationally, had put forward proposals on issues of double compensation, flexible use of safeguards and exceptions, and parallel imports. These proposals were intended to strengthen public health considerations in Malaysian patent laws. In combination, the three constituent parts of the private sector in Malaysia effectively provided a voice for both private and public interest goals, such as health. The Malaysian patent system provisions on compulsory licensing already appeared to have achieved an adequate balance between the interest of the patent holder and the needs of the public. Amendments to compulsory licensing and parallel import provisions of the Patents Act in 1983 had taken into account public health considerations at the instigation of NGOs before the Doha Declaration. Dato Kandan concluded that the added flexibilities addressed in the Doha Declaration would therefore seem to have little practical impact on Malaysia.

Participants from the pharmaceutical industry shared information on voluntary initiatives being undertaken in Africa by the pharmaceutical sector. Deeply discounted drugs were being provided in Africa, public-private partnerships were underway and the pharmaceutical industry was one of the biggest philanthropists in the continent. One participant pointed out that an international exhaustion regime for patents was not compatible with a situation where drugs were deeply discounted.

## **Small Economy Perspectives**

### ***Switzerland***

Felix Addor (Chief Legal Officer, Deputy Director General, Swiss Federal Institute of Intellectual Property, Switzerland) used Switzerland as an example to demonstrate how strong intellectual property laws helped contribute to the economic growth of a small country whose only raw material was knowledge. Switzerland's successful positioning as the largest pharmaceutical-trading partner with the EU and as the "worldwide first exporter of pharmaceutical products" had evolved because of its rigorous protection of knowledge. He emphasized the importance of patent law as proof of a country's technological strength, and patents as a key indicator of economic growth. Mr. Addor urged both members and Ministers to continue to commit to the TRIPS agreement as reduced IP protection would lead to less private sector research and therefore fewer drugs. He pointed to flexibilities within the text of the TRIPS agreement, which enabled WTO members to address their public health problems. Turning to the issue of paragraph 6, Mr. Addor elaborated on the elements of the solution under debate including its scope, coverage, and conditions, as well as appropriate safeguards to protect against product diversion. The scope of diseases should cover all those which cause public health problems but especially HIV/AIDS, tuberculosis and malaria. Product coverage should include patented pharmaceutical products such as medicines that are used to treat public health crises, but diagnostic kits and medical equipment needed further consideration. Finally, while all least developed countries would qualify as beneficiary recipient countries, developing countries would qualify only if they proved the absence of sufficient production capacity. Turning to the conditions for the solution, Mr. Addor stated the need for transparency and involvement of the right holder, which would allow the latter to propose a voluntary solution. He stressed that proper safeguards must be enacted to prevent product diversion especially if a solution not based on article 31(f) was adopted. Mr. Addor reviewed the possible legal mechanisms presently under consideration and stressed that the solution should seek to preserve the present incentive system, while promoting the transfer of technology and foreign investment and serving the interests of those really in need.

### ***Lesotho***

Rethabile Mosisili (Counsellor, Permanent Mission of the Kingdom of Lesotho to the United Nations Office and Other International Organizations, Geneva) emphasized that the paragraph 6 issue was a real problem, despite certain allegations that it was theoretical. The Doha Declaration on Public Health had been a great political achievement and had reaffirmed developing countries' commitment to TRIPS, contrary to popular belief. Mr. Mosisili stated that the scope of diseases in the solution should not be limited to HIV/AIDS, tuberculosis, and malaria, but that these should provide an illustrative standard for comparison. The solution needed to be transparent to allow countries to access medicines at the cheapest possible prices. Mr. Mosisili suggested a national tendering process for procurement by governments to achieve this. Additionally, his government supported a mechanism for notifying the TRIPS Council that would not be binding or cumbersome thus allowing countries to address emergencies rapidly and efficiently. Finally, the election by members to be an exporting country should be voluntary. According to Mr. Mosisili, the provision of a multi-year waiver was the most attractive solution to the paragraph 6 issue provided that legal certainty was obtained under adapted WTO procedures, and any safeguards introduced would not frustrate its objectives. Mr. Mosisili proposed that the "domestic market" should be interpreted to include specific groups of countries

or regions to make countries with small domestic markets more attractive for producers and to allow them to pool resources. Mr. Mosisili closed by recognizing that generic drugs also had a price and that the problem lay not in the intellectual property system, but rather in the mobilization of resources.

Some participants disagreed that patent law necessarily fuelled innovation and made the following points. Historically, countries adopted stronger patent protection once they had developed strong technology. However, the ability for a country to choose a level of patent protection that corresponded to its level of technology had disappeared with TRIPS. TRIPS had been accepted by developing countries against the transfer of technology and the opening of agricultural markets. However, technology transfer was a long-term process, and in the meantime, large sums of money were being transferred from developing to developed countries because of TRIPS. Other participants added that using intellectual property protection to further international trade interests through TRIPS had contributed to the problem being addressed today. A participant maintained that the pharmaceutical industry should not be made responsible for the problems of developing countries, which was an international responsibility. A waiver of patent rights in the current context would set a dangerous precedent for the future without solving the real problems. A panelist agreed that developing countries had been very disappointed not to have obtained concessions in agriculture and perceived TRIPS as a one-way street. He submitted that criticism of TRIPS would continue in different forms as long as these underlying problems were not addressed.

## **Closing Remarks**

In his closing remarks, Richard Fawcett (Vice-Chair, ICC Commission on Intellectual Property; Intellectual Property Consultant, Bird & Bird) expressed his belief that the discussions had allowed different factions to better understand each other's views. He emphasized ICC's recognition of public health crises in the developing world as a serious issue. Because of its grave impact on human life, the debate over health crises had increased tremendously in recent years, and helped move it to the political arena. Governments had acknowledged this issue and were seeking a solution. Industry must come together with government, find common ground, and propose a solution with which it could live. Dr. Fawcett said that intellectual property was important for large and small businesses in all countries and that ICC supported maintenance of the current TRIPS agreement. He said that the solution should only involve pharmaceutical products and should have clear, workable definitions to determine which countries could manufacture for export and which countries could import the manufactured product. A legal mechanism was needed to deal with the problems, but it should not open the TRIPS agreement for re-negotiation. Safeguards relating to product liability needed to be implemented, and international exhaustion should be excluded in this context.