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American Intellectual Property Law Association

The Future of TRIPS:
Impact of the Doha Public Health Declaration

Conference Report

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AIPLA

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Opening remarks

Maria Livanos Cattaui (Secretary General, ICC) opened the proceedings by highlighting the serious implications of the theme of the conference for communities throughout the world, including business. Public health crises had prompted debate on whether the current intellectual property system achieved an appropriate balance between the need to encourage innovation and the public interest in maximizing access to new technology and products. Mrs. Cattaui affirmed the importance that ICC attached to achieving a proper balance between different interests to ensure continuing support for the intellectual property system She stated that business could contribute to finding solutions to today's grave developmental and public health challenges by creating wealth to alleviate poverty and introducing useful innovations. To play their role fully, however, businesses needed clear rules, certainty and predictability, as well as incentives to innovate. Mrs. Cattaui concluded her presentation by urging leaders to find a sustainable solution that satisfied the immediate needs of accessible healthcare and achieved the long-term goal of economic development and innovation.

Introduction

Adrian Otten (Director, Intellectual Property Division, World Trade Organization) introduced the discussion by mentioning that the Doha Declaration on the TRIPS Agreement and Public Health was adopted in November 2001. The Declaration was a response to concern expressed by some developing countries and by some parts of the NGO community about whether the international rules contained in TRIPS were flexible enough to enable developing countries to pursue certain public health objectives involving, but not limited exclusively to, the HIV/AIDS crisis. The Declaration did emphasize that the TRIPS Agreement does not and should not prevent WTO members from taking measures to protect public health, and it reaffirms the rights of members to use to the full the provisions of the TRIPS Agreement. The Declaration makes it clear that the TRIPS Agreement 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. The Declaration also contains a number of clarifications of some of the flexibilities in the TRIPS Agreement in the area of compulsory licensing and exhaustion. The Declaration recognized the need for balance by emphasizing the scope in the TRIPS Agreement to take measures to promote access to medicine while, on the other side, recognizing the importance of intellectual property protection for the development of new medicines. Further work was called for in two areas by the Declaration. In response the TRIPS Council extended the transition term in regard to pharmaceuticals for the forty-nine poorest countries to 2016 and also deferred the exclusive marketing right provisions obligation in Article 70.8 of the TRIPS Agreement for those countries to 2016.

The other area was paragraph six of the Declaration where the TRIPS Council was asked to find a solution to the problem of a country without manufacturing capacity in the pharmaceutical sector not being able to make effective use of the compulsory licensing provisions under the TRIPS Agreement. A number of proposals to address and seek solutions to the paragraph six issue have been offered and discussed. A thematic compilation was prepared followed by a new informal paper of views previously expressed to be discussed in a TRIPS Council meeting next week. After that meeting the chairman of the TRIPS Council will try to find common language for use at a November TRIPS Council meeting with a view to reporting a recommendation to the General Council by the end of the year. Intensive consultations will also take place between September and November. The thrust of the proposals is to find ways of facilitating exports of generic pharmaceuticals to countries with insufficient manufacturing capacity. The problem is that Article 31(f) of the TRIPS Agreement requires countries that use compulsory licensing do so to predominantly supply their domestic market. This handicaps countries with small domestic markets and limited domestic manufacturing capacity in being able to import or find sources for import using compulsory licensing. Approaches suggested for addressing this issue include amending or interpreting Article 31(f), interpreting the limited exceptions clause of Article 30 of the TRIPS Agreement, the use of a waiver, a possible moratorium on dispute settlement or possible combinations of these approaches. With regard to substance under discussion are the scope and coverage of the decision, product coverage, disease coverage, the sort of importing countries, the extent to which developed or high-income developing countries should be able to benefit, and the sort of countries that should be able to supply. Agreement is also needed on conditions or safeguards regarding diversion of products. Other proposals are directed to enhancing domestic manufacturing capacity and to viewing a regional economic arrangement as a domestic market.

Background on Compulsory Licenses

Europe

David Perkins (Partner, Clifford Chance) noted that the United Kingdom did have a compulsory licensing provision for foodstuffs and medicines in an old act but that was eliminated when the United Kingdom acceded to the European Patent Convention. Since the TRIPS Agreement came into force he was unaware of any reported decisions in any member states of the European Union where Article 31 of the TRIPS Agreement has been involved. There is no such thing as a European patent, just national patents and what is obtained from the European Patent Office is a bundle of national rights dealt with by the national law of each member state. As to the TRIPS Agreement, the European Union and the member states had joint competence to enter into and sign the Agreement. As to implementation of the TRIPS Agreement, and the compulsory licensing provisions in Article 31, some states (dualists) need implementing legislation while for other states (monists) the Agreement is self-executing. The Community Patent Convention, which is not yet in force, has a number of provisions related to compulsory licensing which have been incorporated into most national laws of European Union member states. While the Paris Convention has a compulsory licensing provision, that provision has been overtaken by the TRIPS Agreement for European Union member states. There are three basic types of compulsory licenses, a license in the public interest, a license for failure to work and a license to permit the working of a dependent patent. A fourth type is a government license. While there has not been a final decision in Germany in the past 50 years awarding a compulsory license there is a case where a license was granted for public interest (to treat a medical condition). The license was revoked on appeal, as other treatments were available for the condition. The appeals court indicated that the balancing of interest between a patentee and the public must be subject to the principle of reasonableness. In regard to compulsory licenses for failure to work, in the European Community working in one member state is considered to satisfy the demand in another member state. The third type of compulsory license permits working of a dependent patent with the compulsory licensing of the dominant patent. TRIPS Agreement Article 31 requires that the later dependent patent must represent an important technical advance of considerable economic significance before a compulsory license will be granted.

North America

M. Andrea Ryan (Vice President, Wyeth Research) noted that compulsory licensing is defined in a WHO and WTO joint report as taking place when a government allows a third party to produce a patented product or use a patented process without the consent of the patent owner. The TRIPS Agreement does not use the term and only speaks of "…use without authorization of the right holder." As to the three countries in North America, the United States does not have a compulsory license system, Mexico has a fairly well developed system and Canada recently moved to a system with only limited use of compulsory licenses. Mexico has a traditional system based on a failure to work concept as the basis for the grant of a compulsory license. Mexico provides that importation from the United States or Canada will count for working in Mexico. As for Canada, before 1996 there were many compulsory licenses granted, particularly in the pharmaceutical area. This liberal grant of such licenses for pharmaceuticals ended with a change in Canadian law in 1996. A compulsory license may still be sought in Canada after three years from grant of the patent by applying to the commissioner of patents and alleging that there has been an abuse of the exclusive rights of the patent. Abuse of the exclusive rights is defined as whether the demand for the product is being adequately met on reasonable terms, or trade or industry is unfairly prejudiced by the lack of a license, or a variety of other acts. Since 1996, members of the generic industry in Canada have applied for compulsory licenses and there are cases wending their way through the courts. In the United States in 1948, a law was enacted providing that no license is

needed by the government or its contractors to practice a patented invention, but the government must given reasonable compensation to the patentee. The system in the United States is a compensation system, not a licensing system.

An IP practitioner noted the extensive use of compulsory licenses for failure to work in Spain before Spain joined the European Union and that the compensation that was given to the patentee in most cases was very small. Those that obtained the licenses to supply the domestic market also exported the product. Compulsory licenses may be fair and just provided that they are adequately legally framed and that should be a consideration if a compulsory licensing system is again going to be used.

In response to a question regarding the relationship of Article 8 and Article 31 of the TRIPS Agreement, Adrian Otten noted that Article 8 makes it clear that members are free to take measures to protect public health, provided that the measures are consistent with the provisions of the TRIPS Agreement. What the Doha Declaration makes clear is that there are measures that are consistent with the TRIPS Agreement that can be taken for this purpose.

In response to several questions Andrea Ryan noted that in the United States the government does not have to notify the patentee that it is using the protected invention, and that in some mergers the competition authorities may require licensing as a condition for approving the merger.

Large Economy Perspectives

Europe

Jean Charles Van Eeckhaute (Administrator, Directorate-General for Trade, European Commission) noted that the Doha Declaration represents an important milestone in the history of the TRIPS Agreement and that it arose in the context of the debate on the interrelationship between intellectual property and public health and access to medicines. It also has meaning with regard to other IP topics that will be dealt with in the WTO such as geographical indications, biodiversity, the transfer of technology, and others, some of which are of particular interest to developing countries. For the EC, intellectual property is paramount for creating a regulatory environment that is favorable for research and development and is essential to create wealth. To fulfill these objectives globally applicable core rules on intellectual property are needed, which is why the EC was and is one of the main supporters of the TRIPS Agreement. Concerns expressed by developing countries about the implementation of TRIPS need response and solutions need to be found that don't affect the overall balance and the existing level of protection of the TRIPS Agreement. The Doha Declaration shows that in most cases solutions can be found in the TRIPS Agreement itself. Nevertheless, the EU is prepared to consider a limited amendment of the TRIPS Agreement in the context of paragraph 6 of the Doha Declaration as long as the core principles and the overall balance are not affected. The EC proposes a new paragraph to Article 31 carving out a clearly circumscribed exception to the restriction imposed by Article 31(f) which would allow WTO member states to grant compulsory licenses for export. As to scope in terms of diseases covered, the Doha Declaration sets the scope coupled with a rule of reasonableness in terms of diseases to be covered. In regard to product scope, paragraph 6 refers to pharmaceutical sector and the EC is ready to be flexible on this within the limits of reasonableness. As to importing countries, the solution is designed for developing countries, but not those with sufficient manufacturing capacity. In regard to the scope of countries of production, there is no EC position yet. Manufacturing capacity should be determined from objective criteria to be defined by the TRIPS Council. Both developing and developed countries will have to take preventive measures against diversion of medical products produced under the solution and destine for a developing country. Needed also is a procedure that would give a right holder the possibility to offer the product at a strongly reduced price after being notified of an intent to grant a compulsory license.

United States

Claude Burcky (Deputy Assistant US Trade Representative for Intellectual Property, Office of USTR) noted that the United States had worked with the developing countries in Doha to achieve a political statement with respect to the TRIPS Agreement and public health that also provides clarification regarding what flexibility there is in TRIPS to engage in practices such as compulsory licensing and parallel imports. The United States also was the first WTO country to propose providing an additional ten-year transition period for least developed countries to implement the patent and other provisions related to pharmaceuticals in the TRIPS Agreement. The TRIPS Council approved that ten-year transition recently. The Doha Declaration does not amend the TRIPS Agreement, and the ministers reaffirmed their commitment to the existing balance in the TRIPS Agreement and the importance of intellectual property to the development of new medicines. The TRIPS Agreement is but one small element in addressing problems such as HIV/AIDS. Factors such as health infrastructure and financing weigh heavier in regard to these problems but are not factors TRIPS addresses. Paragraph six of the Doha Declaration recognizes that certain WTO members that don't have pharmaceutical production capacity could face difficulty in making use of compulsory licensing to address their health problems. The United States has offered two papers outlining a framework of a solution. As to the scope of diseases

covered, one should look to the existing language in paragraph one of the Doha Declaration focusing on health crises. With respect to the scope of products, paragraph six of the Declaration refers to the pharmaceutical sector. Expansion of the scope to include test kits could be explored. As to which members should benefit from the solution, more work needs to be done on defining the criteria of production capacity to be used to determine such members. All least developed countries would be eligible importers and all developed countries should be excluded. A legitimate question exists whether advanced developing countries would be eligible importers. As to the countries being able to issue compulsory licenses for export, this should be limited to developing and least developed countries, which will facilitate export opportunities for such countries. Any solution should be based on Article 31 of the TRIPS Agreement. The United States supports a waiver approach with the WTO drafting a waiver to excuse countries from the export restrictions in Article 31(f) in response to a need expressed by a country not able to itself issue a compulsory license to a domestic producer. Waivers are familiar to WTO members, approved in advance, can be granted for multiple years, can be granted quickly, and filing requests for waivers has not been resource intensive or burdensome. The United States supports efforts to ensure that there are safeguards built into the solution to prevent abuse to guard against product diversion, and that there be full transparency in the solution to promote competition among suppliers, both patent holders and the generic competition.

In response to a comment from a member of the German chemical industry that compensation was not mentioned during the last part of the program, Claude Burcky mentioned that an Article 31 solution will maintain the safeguard provision in that Article that adequate compensation must be provided to the right holder.

In response to a question from a representative of a U.S. pharmaceutical association about when the EC would have a position on countries of export, Jean Charles Van Eeckhaute commented that the position is being developed.

In response to a comment from a representative of a developing country mission to the United Nations that including test kits in the scope of products may pose little problem, Jean Charles Van Eeckhaute suggested that it was better to have clear and not open-ended definitions when it was necessary to resolve a situation through legal means.

Industry Perspectives

Europe

David Rosenberg (Manager, Industry Affairs, Corporate Intellectual Property, GlaxoSmithKline) noted that his interests were patents and health and there was no conflict between the two. Recent disenchantment with globalization, the WTO and TRIPS itself has arisen from a worldwide health crisis involving AIDS, and TB and malaria. The vast majority of persons affected are in developing countries without access to appropriate medicines. It is alleged that patents cause high prices for medicines, that generics would charge low prices and that with low prices more persons would get medicines. While that is the argument, it is simply wrong. The US, EU and the North wanted a new trade round but were unwilling to give increasing market access to developing countries, particularly in the areas of steel, agriculture and textiles, so they gave on TRIPS as it applies to pharmaceuticals. They also agreed that TRIPS did not limit the grounds for compulsory licenses, but they failed to note that it was always intended that compulsory licensing would be used in limited, extreme circumstances and not as a matter of policy. In regard to the problem posed by paragraph six of the Doha Declaration, industry favors maintaining the Article 31(f) conditions but to permit a waiver. As to the scope of the products affected and the countries that can import, as these are broadened, IP protection is reduced. Industry believes that only the poorest countries should be able to import and for HIV, TB, malaria and other epidemics. Some want broad product reach and that all developing and least developed countries should be able to import. This will not work because patents are not presently a barrier to access and generics will not supply greater quantities of medicines at greatly reduced prices, and even if they did, the medicines will still be unaffordable for most of those in need. A true solution involves all sectors of the global society, including the pharmaceutical industry, both generic and R&D working together in a new kind of partnership on the problems of access and poverty with the North providing more funding to deal with the existing crisis.

An unidentified attendee commented that the question is not whether we should have patents or not, as everyone agrees that patents are essential for research and development. The question is how patents are used or misused. As to compulsory licenses they could also be given to research-based companies and that's why some believe eligible suppliers should also be drawn from developed countries. Regarding technology transfer, it is a difficult problem given the debt of the developing countries and the fact that over 95% of the research is done at headquarters level of pharmaceutical companies in developed countries.

In response to a comment from Danny Huntington (FICPI) suggesting that the public in general in the developed countries rather than the companies producing the product or doing the research should fund the research, David Rosenberg agreed and indicated that the developed country governments should put up more funding for this purpose.

An unidentified attendee mentioned a Canadian study that showed the effect on health care in Tanganyika through carefully directing an additional expenditure of eighty cents a day. Any increase in funding should be matched by undertakings to deploy such funding in a sensible and useful fashion.

Claude Burcky commented that while he could accept many of the points made by David Rosenberg, what David Rosenberg argued is not the public perception of the matter. The challenge is not up to the negotiators to stand up and do the right thing. The challenge is up to industry to educate the public about the reality of the matter. Industry has ceded ground to the NGOs on this debate. It is up to industry to demonstrate and make the average person more aware of what the reality of the situation is if industry expects the negotiators to achieve a deal with a proper balance.

United States

Ronald E. Myrick (Chief Intellectual Property Counsel, General Electric Company) noted that the TRIPS Agreement contains a number of industry's principal intellectual property objectives and some of the objectives are being called into question in the Doha Declaration on public health and the export compulsory licensing exercise. In the press to address the real and very serious HIV/AIDS crisis, there may have been agreement as to the interpretation of the TRIPS Agreement that may serve as a precedent which could be applied to other industries and other public policy situations. Among the objectives are: an end to discrimination among technological sectors (TRIPS Article 27.1); a limitation on the use of compulsory licensing without authorization of patent holder (TRIPS Article 31); a limitation on the exceptions to the patent right that national patent systems may incorporate (TRIPS Article 30); and a recognition that WTO members may adopt measures necessary to protect public health (TRIPS Article 8) provided these measures comply with TRIPS. Industry's concern is that while today the Declaration and the export compulsory licensing exercise are aimed at pharmaceutical patents, this could be the first step of a broader challenge to the overall value of intellectual property protection for economic development. The relief requested today in regard to exclusive rights to pharmaceuticals because of lack of domestic capacity could evolve to future requests for relief from copyright protection for educational software, or medical texts, or patent protection for medical devices. The act of the ministers discriminating against one sector raises a question about commitment to the non-discriminating treatment of all sectors. Also troubling is the emphasis in the Declaration on the freedom to issue compulsory licenses without the recitation of the limitations on such licenses found in the TRIPS Agreement. Another problem is posed by the suggested use of Article 30, which lists permitted exceptions to patents based on exceptions found in the laws of some countries at the time TRIPS was concluded, for an export compulsory licensing solution. The export compulsory licensing exercise is still underway and US and EU negotiators still have the ability to contain the potential damage to the protection of intellectual property while ensuring solutions to the AIDS crisis.

Japan

Yoshihide Nakamura (President, Sony Chemicals Corporation) cited a WHO report indicating that by December 2001 there were tens of millions of HIV-infected persons and AIDS patients and tens of millions of AIDS deaths. This issue was considered within the TRIPS negotiations. The later debate over providing developing and least developed countries access to medicines led to the Doha Declaration. Recent TRIPS Council discussions are seeking means by which countries with insufficient medicine manufacturing capabilities may make effective use of the TRIPS compulsory licensing provisions. The use of compulsory licensing may diminish the ability of the patent system to motivate inventors to pursue a better future for humankind. This effect may not be limited to the medicine field and it may become difficult to pay inventors in other fields the reasonable compensation necessary for motivation. Further problems regarding compensation of inventors arise from the digital-age ability to make inventions available without payment, or to permit extensive further use of an invention with only a first use payment. These problems damage the motivation of persons engaged in development and creation and are a threat to the realization of a better future for humankind. The TRIPS Agreement should be regarded as a gift of wisdom. In seeking a solution to the public health problem, we should by all means avoid the stopping of technological development and ensure that the inventor is constantly motivated and properly dignified.

Developing Country Government Perspectives

Betty Berendson (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. Berendson 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. Berendson continued by questioning the legal predictability offered by the waiver solution. Turning to the specific elements of a paragraph 6 solution, Ms. Berendson 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. Berendson concluded her presentation by stating that the best solution was one that was expeditious, legally predictable, and non-burdensome.

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 jeapordized 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

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.

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

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.

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.

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