Report No. 57

Doha Declaration on WTO-TRIPS and Public Health
What is in it for Bangladesh ?

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March, 2003

The Centre for Policy Dialogue (CPD)*, established in 1993, is an innovative initiative to promote an ongoing process of dialogue between the principal partners in the decision-making and implementing process. The dialogues are designed to address important policy issues and to seek constructive solutions to these problems. The Centre has already organised a series of such major dialogues at local, regional and national levels. These dialogues have brought together ministers, opposition frontbenchers, MPs, business leaders, NGOs, donors, professionals and other functional groups in civil society within a non-confrontational environment to promote focused discussions. The expectation of the CPD is to create a national policy consciousness where members of civil society will be made aware of critical policy issues affecting their lives and will come together in support of particular policy agendas which they feel are conducive to the well being of the country. The CPD has also organised a number of South Asian bilateral and regional dialogues as well as some international dialogues.*

In support of the dialogue process the Centre is engaged in research programmes which are both serviced by and are intended to serve as inputs for particular dialogues organised by the Centre throughout the year. Some of the major research programmes of CPD include The Independent Review of Bangladesh's Development (IRBD), Governance and Development, Population and Sustainable Development, Trade Policy Analysis and Multilateral Trading System, Corporate Responsibility, Governance, Regional Cooperation for Infrastructure Development and Leadership Programme for the Youth. The CPD also carries out periodic public perception surveys on policy issues and developmental concerns.

As part of CPD's publication activities, a CPD Dialogue Report series is brought out in order to widely disseminate the summary of the discussions organised by the Centre. The present report prepared under the CPD programme on Trade Policy Analysis and Multilateral Trading System, contains the highlights of a dialogue organised by CPD held at ***BRAC Centre Inn, Dhaka*** *on* ***December 15, 2002*** *on the theme of* ***Doha Declaration on WTO-TRIPS and Public Health: What is in it for Bangladesh?***

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Dialogue on

Doha Declaration on WTO-TRIPS and Public Health: What is in it for Bangladesh ?

1.The Dialogue

The Center for Policy Dialogue (CPD), organised a Dialogue on the *Doha Declaration on WTO-TRIPS and Public Health: What is in it for Bangladesh?* at BRAC Centre INN on December 15, 2002. *Mr Amir Khosru Mahmud Chowdhury, MP* the Hon'ble Minister for Commerce, was the Chief Guest. *Mr Kazi Zafrullah*, Hon'ble Member of Parliament and former Chairman of the Privatisation Board, was the Guest of Honour and *Mr Samson H Chowdhury*, Chairman, Square Pharmaceutical Company Limited was present as the Special Guest at the dialogue. *Dr J Anthony Van Duzer*, Professor of Faculty of Law, University of Ottawa and Senior Associate, Centre for Trade Policy and Law (CTPL), presented the keynote paper, *TRIPS and the 'Pharmaceutical Industry in Bangladesh: Constraints, Opportunities and Possible Strategies. Ambassador Dr Toufiq Ali*, made a presentation of his paper on *Intellectual Property: Its Implications for Economic and Cultural Growth* which was first presented at the joint WIPO-WTO Regional Workshop held in Dhaka on December 11-14, 2002.

CPD Chairman *Professor Rehman Sobhan* moderated the dialogue. He presented both *Dr Van Duzer* and *Dr Ali* to the audience. *Dr Debapriya Bhattacharya*, Executive Director of CPD, welcomed the audience with an introductory speech that provided a short background to the dialogue.

The participants included members of the parliament, high level policy makers, chamber leaders and entrepreneurs in the pharmaceutical sector, development activists, trade union leaders, journalists and representatives from the civil society.

2. Introductory Remarks by Dr Debapriya Bhattacharya

In his speech, The CPD Executive Director observed that although the subject of the dialogue was very technical, CPD organised the dialogue because of growing public interest in the issue. *Dr Bhattacharya* further informed the audience that CPD was implementing a trade policy programme in collaboration with CTPL focusing on the impact of the various WTO Agreements on Bangladesh's economy.

Dr Bhattacharya noted that the Doha Declaration on TRIPs offered good prospects for the pharmaceutical sector in Bangladesh. The declaration on public health and trade related aspects of the intellectual property rights agreement, will have direct bearing on the growth of the pharmaceutical industry in Bangladesh. Bangladesh should explore the possibilities to make the best out of the potential benefits emerging from the Doha Declaration.

He also introduced *Dr Ann Weston,* the Vice President of North South Institute, and *Mr Wenguo Cai*, Senior Associate at CTPL who were visiting Bangladesh to participate in the dialogue. The Institute is a premier think tank and development organisation in Ottawa, Canada and it is very well known for its sympathetic views towards developing countries.

3. Session Chair

Professor Rehman Sobhan initiated the dialogue by welcoming the participants including the keynote speaker *Professor Anthony VanDuzer* and *Ambassador Dr Toufiq Ali* and all of those present on the occasion**.**

He mentioned a three-day Workshop on WTO issues would follow the dialogue and about 30 participants form various Ministries and government agencies, research institutions, chambers and non-government organisations would attend the workshop.

4. Keynote Presentation by Professor Anthony Van Duzer

Presenting the keynote paper, *Professor Anthony Van Duzer* first delineated the development of a health centred view of TRIPS. He said the Agreement on Trade Related Intellectual Property Rights (TRIPS), embodies the developed countries' view that pharmaceuticals must be subject to patent protection. He mentioned that by 2001 a consensus had emerged that TRIPS must permit the WTO members to act to promote affordable access to medicines and it was then formally recognised by the Doha Declaration on *TRIPS and Public Health.*

He said the rationale behind pharmaceutical patent protection is that patents are necessary to protect investment in research, development and commercialisation of new drugs. Patent protection ensures incentives to innovate and to transfer technology. It also justified by requirement to disclose invention to public facilitation for future innovation of new drugs. It also facilitates the development of new drugs because of new rules requiring public disclosure of inventions.

He remarked that patent protection is controversial because on the one hand it ensures a host of benefits and, on the other, it imposes extra costs on the life saving drugs and is skewed towards the multinational behemoths.

Explaining, *Professor Van Duzer* noted that the main benefit of patent protection is that it ensures investment in the Research and Development, gains in productivity and cost savings in production. It also paves the way for new and better drugs, acts as a conduit for foreign direct investment to a country which was prospect in pharmaceutical sector, transfers technology from the large multinationals to those in the developing countries and ensures that multinational drug companies will have a hefty profit through marketing their discoveries.

The keynote speaker who is an international legal expert on intellectual property rights, said monopoly cost is a direct outgrowth from the cost of patent incentives and it also has an impact on the reduced availability of products and product

differentiation. Besides, because of patent protection, royalties more easily flows to international drug companies, *Dr Van Duzer* described.

5. The Impact of the Doha Declaration on the Bangladesh Pharmaceutical Industry

Dr Van Duzer said although the pharmaceutical industry in Bangladesh has the capacity to produce finished pharmaceuticals, it does not have the infrastructure necessary to produce therapeuic ingredients, i.e. the raw materials for finished products. Also, the local industry does not invest in innovation or reverse engineering to create generic drugs or develop new drugs.

While the country still enjoys the January 1, 2016 deadline to bring its patent regime into compliance with TRIPS, the Doha Declaration on patent protection is unlikely to encourage domestic innovation, *Dr Van Duzer* added.

However, he mentioned that in the long run, the TRIPS agreement on Patents impact on foreign investment and could limit technology transfer. Moreover, patents may spur drug prices and hurt Bangladeshi consumers whose purchasing power continues to be weak.

Professor Van Duzer provided an overview of TRIPS obligations on patent protection and said the member countries of WTO must grant protection for pharmaceutical products and the processes to produce pharmaceutical products for 20 years. However, the developing and the least developed countries would enjoy transition periods: 2016 for pharmaceutical products and 2006 for processes.

Elaborating, he pointed to some loopholes in the agreement which the developing countries can exploit. Citing Article 30 of the agreement, he showed how members might create limited exceptions to the patent rights as the Canada-EU Patents Case already demonstrates.

Professor Van Duzer said, so long as under TRIPS obligations, member countries might grant compulsory licenses the prospective licensee has attempted to obtain a license from the patent holder on reasonable commercial terms. But, compulsory licensing also has problems as it does not assist countries without domestic producers. To remove the problem, countries must be able to permit generic export which the TRIPs council can do by a mending or waiving Article 31(f) of the agreement.

Professor Van Duzer said under the agreement, the member countries may permit parallel importing, which allows for drugs legitimately sold in another national market. Parallel import can enhance affordable access to medicines in the least developed countries, he explained.

The TRIPS Agreement also has some transitional rules that include a moratorium on non-violation complaints, technology transfer and technical assistance from the developed countries to the least developed countries in order to enable a sound and viable technological base.

Dissecting the various articles of the landmark deal, *Professor Van Duzer* suggested many strategies for the pharmaceutical industries in Bangladesh. Under the current regime and until 2016, Bangladesh is free to continue to permit importation of pharmaceuticals and to produce and to sell pharmaceuticals in the domestic market whether or not they are patented elsewhere.

However, he added, the whole industry might see some sweeping changes once the developed and developing countries are forced to enact protection measures by 2005. From this, he suggested two strategies:

a) Strategies for Situation Prior to 2016

b) Strategies for Situation after 2016

Pre-2016 Situation

By the end of 2005, *Professor Van Duzer* sees disruption of the supply of therapeutic ingredients to Bangladesh, which mostly imports the raw materials from India. Under the TRIPS agreement, the generic suppliers in India and other developing countries like China, from where Bangladesh also imports raw materials, must provide full patent protection by January 1, 2005. As a result, the generic exports to Bangladesh will be prohibited, he warned.

To solve it, he suggested two ways. First, Dhaka could lobby in WTO to adopt an amendment or agree an understanding permitting exports to Bangladesh in order to promote public health. But, this also has disadvantages because the permission to export is not within Bangladesh's control. Besides, this may also impose onerous eligibility conditions upon Bangladesh.

After 2005, the country's pharmaceutical industries cannot import any APIs from India. The long term solution of the problem calls for API production within Bangladesh. The capacity of the pharmaceutical industries, which has not prioritised the production of basic ingredients, will have to be developed quickly and it will require both public and private investment, and technical assistance from abroad.

Demand for Bangladesh pharmaceuticals in the international market, will decline after 2005 because patent protection in some export markets would preclude import of generic Bangladesh products by these countries. Bangladesh companies ought to export to countries that do not issue compulsory licenses to import or to ones that are not the members of the World Trade Organisation. This presents a window of opportunity to the local pharmaceutical industries since, in some of the international markets, the competition from India and other generic producers will be limited after 2005.

Stating that a large Bangladeshi pharmaceutical sector has yet to emerge, *Dr Van Duzer* emphasised the need for public spending to acquire drugs for distribution in the country. He said mobilising public and private resources and wooing international

public finance or funds for the development of the sector is a must if Bangladesh is to ensure affordable access of medicines for its citizens.

Strategies for Situation after 2016

Professor Van Duzer argued that the situation for Bangladesh pharmaceutical industries would change completely following the expiry of the transition period in the year 2016. From that year, the country must provide patent protection to pharmaceutical products to comply with the TRIPS agreement. "Inevitably, this will mean that prices will increase, generic drug producers will be hurt and the access to medicines will be impeded."

Suggesting a possible solution to the problems associated with compliance to the TRIPS Agreement, *Professor Van Duzer* suggested that Bangladesh should issue compulsory licenses to import therapeutic ingredients from countries which either issue compulsory licenses to export or permit the export of generic drugs.

A permanent solution will recognise the need for a development friendly patent law to ensure continuing viability of the local pharmaceutical industry.

Some of the main features of such a development law would be:

1) Limit breadth of patent claims
2) High thresholds of novelty and incentive steps
3) High level of patent disclosure
4) Exceptions to exclusive patent rights and
5) Strong Compulsory licensing

But whatever the advantages of patent laws, there are some limitations, which eventually will affect the public health within a developing country. *Professor Van Duzer* pointed out that appropriate patent rules for the domestic industry would not ensure affordable access to medicines. But there are hopes, that patent protection would only affect a fraction of the drugs manufactured in the world, 75 per cent of the drugs on the World Health Organisation (WHO) list are not currently the subject of patent protection. Besides, he continued, patents are not the only determinant of access to medicines.

In conclusion, *Professor Van Duzer* said that even though there are other factors affecting the price of pharmaceuticals, it is essential for Bangladesh to pursue the right patent policy. In the near future, Bangladesh will have the challenge of developing a patent law which best reflects its interests while complying with the mandates of the TRIPS Agreement.

6. Discussion by Ambassador Dr Toufiq Ali

Dr Toufiq Ali first thanked *Professor Van Duzer* for presenting such an exhaustive study on the TRIPS Agreement and its impact on the pharmaceutical industry in

Bangladesh. He said intellectual property rights were basically designed to encourage creativity and to ensure that individuals retain rights for their creativity with regard to new products, new process, new art, electronic media etc.

The history of intellectual property is interesting, he continued, and the countries which are now developed have been vociferously against granting intellectual property rights to developing countries.

Providing a brief history of intellectual property, *Dr Ali* described how the IP regimes have been used by the countries to further their perceived economic interests. "Between 1790 and 1936, the United States restricted the use of patents to favour its own citizens. In 1836, the patent fees for foreigners were fixed at ten times the rate of US citizens. From 1861, foreigners were treated equally. But for most of the 19th century, the US provided no copyright protection to foreign authors, arguing that it was necessary to copy in order to educate the new nation.

Referring to the IP history in Europe, he said some European countries did not have patent laws for much of the nineteenth century, the heyday of industrial revolution. Switzerland had a patent system from 1799 to 1802, it was not re-established until 1888. The Netherlands prohibited patents from 1869 until 1912. In the 19th century, conferring monopolies was seen as a breach of free trade principles. In Switzerland in the 1880s, industrialists did not want patent laws because they wished to continue to use the inventions of foreign competitors. This opposition was maintained despite that the Swiss were themselves enthusiastic patentees in other countries.

Turning to the East, Dr Ali noted that Japan's first patent law dates back to 1885, but foreigners were not allowed to file the applications until 1899. Even after that, Japan had a go-slow policy towards foreigners. The basic patents on semiconductor technology owned by Texas Instruments, which was the basis for silicon chip business, were filed in Japan in 1960. It took 29 years for Japan to issue the patent. In the meantime, the Japanese semiconductor sector grew to become world's biggest.

"Countries in East Asia took off under weak forms of IP protection. Throughout the critical phase of rapid growth, Taiwan, China and Korea, between 1960 and 1980, emphasised the importance of imitation and reverse engineering. In India, the weakening of IP protection in pharmaceuticals in its 1970 Patent Act is widely considered to have been an important factor in the subsequent rapid growth of its pharmaceutical industry, as a producer and exporter of low cost generic medicines."

Drawing his attention to the ongoing talks about patent protection for pharmaceutical products, the Bangladesh representative to the WTO said there are some experts who think that without patents in developing countries, Research and Development on new drugs won't be encouraged.

"Less than five per cent of the pharmaceutical R&D was concentrated on the health problems of the developing countries while the rest is concentrated on the problems related to the developed world where even one fifth of the world's population does

not live. Maybe it reflects the interest of the market but this is the fact and we should be aware of this and take it into account," he said ruefully.

Doha Declaration on TRIPS Agreement and Public Health

Ambassador Dr Toufiq Ali said whatever is there in the Doha Declaration is basically available in the TRIPS Agreement. In a sense it is nothing new. But as with other parts of the Uruguay Round agreements, most of the provisions that are in favour of the developing countries are in the form of best endeavour.

He said because of the actions of some NGOs, developing countries and LDCs are aware of the problems related to medicine and access to medicines, hence LDCs favour the declaration. "The declaration has very interesting features, one of these being the transition period. The TRIPS agreement gives the LDCs an exemption to patent protection until 2006. But it was extended to another ten years at the initiative of the United States," he said, adding "Most interestingly, the TRIPS deal already provides that upon a duly motivated request from the LDCs, this transition period could be extended and the provision is only for the products."

The Bangladesh representative to WTO confessed that most of the LDCs don't know the implications of this provision. "Why only products and why not process?" he asked and added that only a four or five least developed countries don't provide patents to pharmaceuticals and other products. "In Bangladesh we have been providing patents to a large number of pharmaceutical products and even foreign products are patented and are currently reviewed for by the Patent Office."

He continued to explain that a large number of LDCs are obliged to provide patent protection for not only pharmaceuticals but all other products because of their participation in various regional agreement and deals with the EC or ACP. "So, whatever you find in the transition period are actually meaningless for us because we already provide patent protection, either bilaterally or through other agreements."
Referring to the provision of geographical indications in the TRIPS agreement, Dr Ali said in such indications there is a question of rollback and mostly rollback is forbidden in other areas as well. He said geographical indications referred to wine and spirits and there is a dispute whether the product coverage should be increased. Besides, the question of whether you can rollback in other areas is also being examined.

Patent Protection in Bangladesh

Shedding light on the patent protection scenario, *Ambassador Ali* said Bangladesh is considering drafting a patent law and the draftees are looking into the possible implications of the law on the pharmaceuticals. The question of rollback is also being dealt with and it is an important issue for the country's domestic agenda.

On technology transfer, which is mentioned in the Article 66-2 of the TRIPS agreement, he said that this is one of the few issues in the Uruguay Round which uses the word 'Shall' and makes it mandatory for the developed countries to help the

LDCs. "Whether it has been done, it is an open question. This year, however, we took it up very strongly and there's now at least a decision that developed countries will report to the WTO on what action they have taken for the transfer of technology," he said, noting that the monitoring mechanism that comes with the decision has not been agreed by the LDCs since it provides some genuine problems.

Current Negotiations

Dr Toufiq who participates in the ongoing negotiations in the WTO, pointed out that despite a year of intensive negotiations, there's no implementation of Doha Ministerial agreement. "The chairman of the council of TRIPS reported that there is still no agreement on the following six basic areas:

1) Products and disease coverage. What are the products and what diseases would be covered?
2) Should all public health diseases be covered or only very specific diseases?
3) There is a question of eligibility of the importing and supplying members.
4) Remuneration for compulsory licenses.
5) Notification and safeguard against diversion and
6) Issues related to transfer of technology and the regional cooperation.

According to him, the real problem which stands in the way to decisive agreements is political will. He questioned the willingness of the negotiators to get these agreements through. "There are very easy ways of resolving this if you have the political will. For instance, the issue of diversion is being raised as big issue in the WTO negotiations. The products will go to the LDCs and get diverted. But nowadays, technology has improved, surveillance of customs has improved and you can track down every single shipment wherever it goes," he remarked. He added that to the LDCs it seems that this is an attempt by the big pharmaceutical industries to stop the transfer of products and technology using diversion as an excuse.

While giving his opinion on how the TRIPS agreement will affect the pharmaceutical industry in Bangladesh, he said that among the least developed countries, Bangladesh has the best backbone in pharmaceuticals. Because of this strength, there is a fear among some quarters that if too many concessions are given the Bangladesh pharmaceuticals will perhaps develop further and go forward and do much more than it is doing.

API Production as the Ultimate Solution

Referring to the suggestions of *Professor Van Duzer*, noted pharmaceutical entrepreneur and the chairman of the biggest pharmaceutical industry in Bangladesh, *Samson H Chowdhury* said in order to have Active Pharmaceutical Ingredients (API) in a country, one has to pass through as many as 16 stages. But Bangladesh does not have such a number of facilities because it is thickly populated country. Besides, to

have the competitive edge in such an industry and to be self reliant in all the stages of production, it will require huge investment. In such a process, the industries will eventually eat up the competitive edge.

A possible remedy, could be that the industries in Bangladesh could bring in intermediaries from the third or fourth or fifth stages and then the companies could began API production in the country. “The Indians could export these intermediaries from the fourth and the fifth stages so that we could make our own APIs,” he said.

He proposed that this suggestion be included in the TRIPS negotiation process and that has the potentials to remove many problems of the LDCs. Otherwise, he feared that the big companies will use this provision to establish their monopolistic rein over the industries of the LDCs.

He also said these intermediaries could be imported from any part of the world. It could be from the United States, the United Kingdom, China, Argentina, Mexico, Brazil and India, which is already exporting such intermediaries to Brazil. The pharmaceutical industry in Brazil is worth USD five billion while that of India is worth USD two billion.

Continuing his speech, *Mr Chowdhury* said that TRIPS should include diseases and the health concerns of the third world countries in the Doha Declaration so that in case of emergencies all the diseases of the LDCs could be taken care of.

On patent protection, he said it has become a weapon of the developed countries and big multinational pharmaceutical behemoths. To keep their patent for years together, these companies change the structure of a certain drug and add one or two molecules and then register this as a completely new drug. In this process they keep the patent of the drug for decades, he said.

“In my opinion, in this field if a doctor prescribes a patented drug for 20 years and a local company then starts manufacturing it 20 years later, the company can hardly get 20 per cent of the market,” *Mr Chowdhury* said. He further observed that one has to spend money to conduct research in the pharmaceutical field and it may take ten years to hit the jackpot.

Describing his experience in the field, *Mr Samson Chowdhury* said he signed an agreement with Hoffman Roche back in 1982 to manufacture Valium in Bangladesh. But they charged USD 500 for the patent while the same drug of a Hungarian manufacturer cost around USD40. When he inquired about the difference between the price, the Hoffman Roche official told *Mr Chowdhury* that the standard of these two drugs is not equal. “Whereas we have 20 polymars in our drug, the same drug manufactured by the Hungarian company had three polymars,” said the Roche official. But, that was a gimmick as *Mr Chowdhury* came to learn from the medicine experts later.

According to *Mr Samson Chowdhury*, this is the basic problem about drug patenting. He suggested that the World Trade Organisatoin bring down the patent rights from

20-years to 10-years. Because if one enjoys the market of one drug for 20 years and then takes another patent by twisting the chemical structures of the same drug, then other companies, especially the smaller ones, will simply be out of the markets.

Taking cues from his experience about the medicine market, the Square Pharmaceuticals Chairman suggested that restructuring should not be the justification for granting patents as if the restructured drug were a new drug. And the patent rights should be given only to drugs with completely new structures.

7. Floor Discussion

The presentation by the two keynote speakers and the Chief Guest was followed by a lively discussion which focused on some of key issues raised, and also on new issues which the participants felt to be relevant and important.

Will there be Certainty of the Import of Raw Materials after the Year 2005?

Mr M Islam, the Marketing Director of the Acme Pharmaceutical Limited, questioned *Professor Van Duzer* whether the local pharmaceutical companies, whose raw materials mostly come from other countries including India, can import the materials after the year 2005. Islam reasoned that under the Doha Declaration, the developing countries would be barred from exporting APIs (also known as raw materials) to other countries because of patent regulation.

Professor Van Duzer again pointed out that such a disruption is awaiting the Bangladesh companies after the year 2005. He said India, from where most of the companies of this part of the world import raw materials, will not be able to sell APIs directly to Bangladesh. All the other generic drug producers will also come under the same regulation.

To solve the forthcoming crisis, *Dr Van Duzer* suggested that Bangladesh adopt a resolution in the WTO to address the compulsory licensing provision 31.5. The article says that the compulsory licenses were granted in order to supply a domestic market predominantly.

He said if Bangladesh or the other LDCs can get an amendment to TRIPS agreement or agree an understanding that this kind of export is permitted under article 31.5 for domestic generic markets, only then could the export from developing countries continue. But the only difference would be that whatever requirements are imposed they must be satisfied. He noted that some of the requirements might involve those who would be eligible to be a recipient country or who would be eligible to be a supplier country and whether there is an objective criteria and what that criteria might entail. He stressed that these issues should be negotiated to get the benefit of outsourcing raw materials.

Answering *Mr Islam's* query, *Ambassador Dr Toufiq Ali* agreed that developing countries which have reverse engineering capacities would not be able to do so after 2006. They would not be able to supply Bangladesh or other LDCs any API and these countries would be prevented from doing any kind of reverse engineering. In case of

intermediaries or export of intermediate products, Dr Ali said the same rules would be followed.

For Bangladesh, he continued, this is a major issue and the policy makers and the negotiators at WTO should have a clear understanding of the domestic capabilities and what they really need.

But, he mentioned that unfortunately, within Bangladesh this link between the needs of the domestic industries and the negotiators are not so strong, other than for a few personal cases. To bring an end to such a pathetic system, he suggested that the negotiators need much more systematic support from home to project a stronger negotiating position.

What will Happen After 2016?

Continuing his question, the Acme Marketing Director asked if the developing countries would be barred from exporting their APIs, and what benefits the Bangladesh would get till 2016, the year when Bangladesh must ensure patent protection. And what the industries would do after 2016.

Referring to another development in the TRIPS Council, *Mr Islam* said the developed countries now want to extend the patent rights even further than the existing 20-year period since some years are lost for registration purposes. And, even in the case of new indication of the drugs, he said, companies of the developed countries are trying to get patents in TRIPS. He asked how the development would affect the market and whether there is any mechanism to stop this trend.

Professor Van Duzer said the Doha Declaration set the deadline for putting in place full patent protection in all least developed countries by the 2016. It creates a problem for Bangladesh, as it restricts Bangladesh's access to APIs which the country needs for its domestic industries. He further said that the freedom that the LDCs get during the transition period between 2006 and 2016 would not be very effective, as they cannot have unrestricted access to APIs.

He, however, provided a ray of hope saying that the issue is still being debated at the TRIPS Council and its resolution is still a major strategic issue for the LDCs.

How Compulsory Licensing will be of Effective Use?

Mr Samson H Chowdhury pointed out that under Para 6 of the Doha Declaration it is not stated clearly how the developing countries, having insufficient or no manufacturing capacities in the pharmaceutical sector, could make effective use of the TRIPS agreement. He said the TRIPS Council has been directed to find the solution to the problem before 2002. But nothing has been submitted to the WTO as yet, he said.

Ambassador Ali, who is associated with the ongoing negotiations in Geneva, took up the question of *Mr Samson H Chowdhury* saying that he had hit the nail on the head. He said it is recognised that the LDCs in general don't have manufacturing facilities in pharmaceuticals. So when they need products they should be able to ask another country, which has such facilities to supply it.

"Canada is an excellent example in this regard. When there was an Anthrax scare recently, they issued compulsory licensing to Anthrax drugs without thinking twice. They issued a license to Cipro, which is a patented drug. And an offshore generic company was prepared to supply it at half the cost, which was something like two and a half-dollars. Perhaps, the original one cost four dollars," he said.

Elaborating further, he stated that following the Canadian example the United States was able to negotiate a fantastic deal with the patent holder for the same capsule at about 93 per cent. "It is one of the interesting aspect of compulsory licensing. Incidentally, only developed countries have issued compulsory licensing so far. Not a single developing country has managed to issue compulsory licensing although they do have the need," he remarked.

He informed the audience that this issue is taken up strongly by the LDCs. All the LDCs want a total amendment of Article 31(F) of the TRIPS Agreement and incidentally, they are receiving support from the European Commission on the issue. But there are certain other developed countries that are opposing them, he said.

Patent Protection Scenario in Bangladesh and the Issue of Rollback

Dr Manjur Alam Tipu, a fellow of CPD and a Lecturer at the Independent University of Bangladesh, saw an apparent conflict of opinion between *Professor Van Duzer* and *Ambassador Ali* on whether Bangladesh actually provides patent protection.

On rollback of patents, he posed two questions: first, if the country already provides patent protection then could it be that after 2016, it will get patent protection. Secondly, if the patent of a product is already given, can the country possibly go back and say the patent protection will no longer apply.

Professor VanDuzer replied that there isn't anything specifically in TRIPS that deals with the rollback. Certainly, the TRIPS Council did not contemplate it. So there isn't much guidance to be found in the agreement itself and the matter, actually, is a question of domestic laws.

On the decision of rollback, *Professor Van Duzer* thinks the matter is a political one and it boils down to the domestic matters.

Can the Price Level of the Drugs be Maintained?

Describing the TRIPS agreement as a potential challenge for the Bangladesh pharmaceutical industries, the Managing Director of ACI Pharmaceuticals *Mr Anisuddowla* said till today the industries here have maintained an affordable price level of drugs in the country. He asked whether it would be possible to maintain the same price level after the year 2005 since Bangladesh companies will be barred from importing raw materials from other developing countries.

Former president of the Bangladesh Medical Association, *Professor Rashid-E-Mahbub*, observed that the epoch-making Drug Policy of 1982 paved the way for cheaper drugs in Bangladesh. But the new arrangement, i.e. the TRIPS Agreement, may not keep the drugs cheaper in the local market anymore. In such a case, the WTO

would help the poorer people to have access to cheap medicines, he stated expressing his concern.

To this query, *Mr Samson H Chowdhury* claimed that cheaper drugs is a relative term and drugs in the coming years may not remain as cheap as they were because of the hike in prices of the ancillary items. "The more knowledge one has, the more expensive he is," he said while referring indirectly to the increasing cost of knowledge.

About the future price of drugs in the local market, *Dr Toufiq* said the industries here could continue to access raw materials and could continue to produce them at cheaper prices were they to have access to API production facilities.

With regard to new products, he agreed that the industries would face problems to get the raw materials because they will not have access to these items from the countries that do R&D.

Doha Declaration: A Window of Opportunity?

Session chair *Professor Rehman Sobhan* said there is an implied window of opportunity for LDCs, particularly for Bangladesh, in the TRIPS Agreement. He said investors could be wooed here to locate their factories in Bangladesh and to produce certain types of products, which are permissible within the current dispensation. "What is the realistic expectation of that happening and what is really going to emerge as a practical constraint?" he asked.

Professor Sobhan thinks that the TRIPS deal may eventually pave the way for partnership between the local companies and the major players in the system, which could use Bangladesh as an export platform. This would really give Bangladesh some leverage over competitors like India or other developing countries since they would be excluded from such a unique window of opportunity.

While making his observation, *Mr Samson H Chowdhry* remarked that the pharmaceutical companies here see the TRIPS agreement as an area of opportunity. But to explore that, he thinks the government has to take care of certain things seriously.

"In India most of the drugs are price-controlled and price is maintained seriously. But our pricing here is a funny thing because it acts like a rule of thumb. It does not matter how much you are paying to the employees, how you maintain hygiene in factory and what machines you are using," he said.

While pricing under the present regime, all these things don't come into the picture. The government should take care of these things now," he said, claiming that for the last 12 years, the country did not see any change in the drug pricing system although new taxes were imposed and devaluation has occurred.

Suggesting a possible way out, the Square Pharmaceuticals chairman said that the government must take a pragmatic look into this since no company can sell drugs at cheaper rates unless they compromise with quality.

Explaining further, he said, his company, the biggest pharmaceutical industry in the country, has updated its factory to face the post-2016 situation. "We'll soon do reverse engineering within the next two years. And there are five to six companies here in Bangladesh ready for reverse engineering and massive investment in the Research and Development.

"The companies in Bangladesh are already two to three years ahead. Twelve years time is a long period and with the latest technology, we may not need that much time to come across new molecules," he said, emphasising that the government's pragmatic steps are necessary to overcome any future stumbling blocks.

Registration Still a Big Stumbling Block for Drug Export

Chief Guest *Mr Amir Khosru Mahmud Chowdhury, MP* observed that after getting market access to a country, registration becomes the biggest non-tariff barrier. It is very difficult to remove. But he is hopeful that registration will not pose big problems for Bangladesh companies since the country has the required strength in pharmaceuticals and can extract advantages.

Mr Islam of Acme also thinks that the Doha Declaration has offered a window of opportunity for Bangladesh. He, however, remarked that despite being a value-added industry, the pharmaceutical industries here could not explore their potential properly. The main reason, is that the process of registration is not addressed properly by the concerned government agency.

He stresses that the process of registration is the main constraint for drug export. Whenever, Bangladesh companies want to export drug, the usual questions they face are: whether the drug is MCA approved, or FDA approved or being exported to EU countries. These factors are denying the local companies the opportunity to export drugs abroad.

He mentioned that this regulatory restriction was first imposed by the United Kingdom and then followed by other developed countries. Still they are carrying the procedure forward without amending the registration formalities, he said, pointing out

if this is not addressed properly at the proper negotiating table, it would deny the local companies the right to show the quality of their products.

On this issue, *Dr Toufiq Ali* said that there are a number of elements that influence the export of drugs from one country to another. He said the exporters have to maintain the domestic regulations in the countries where they export. But if there are any unfair barriers to the export, the Bangladesh mission to WTO can take up the matter and negotiate market access. There are two basic points in the issue: one is entering the market and selling the products and the other is how to remove the barriers.

What is the Real Cost of Research and Development?

Mr Kazi Zafrullah, the Special Guest, also opined that the matter should be settled down for the benefit of the technology-poor countries. He said that even in the Egyptian heydays, way back in the fifth century BC, condoms were used and widely

available. But today the poor people of LDCs have to pay a heavy price for the unrealistic R&D cost that big Multinationals allegedly spend every year.

Dr Abdur Razzaq, a Member of the Parliament, remarked that the WTO agreement is full of vague terms like predominant share, limited exception etc. Even R&D isn't defined properly within the WTO agreement.

On the cost of Research and Development, he questioned as to how companies were able to calculate actual costs. Is there a mechanism to find out how novel an invention is? Can the WTO set up a team to monitor and assess the real cost of Research and Development?

Professor Rehman Sobhan replied that the cost of Research and Development is based on particular notions of costing, that incorporates a whole variety of sunk costs, relates those to the marginal cost of R&D and puts the combined costs on to a single product. This means the ensure notion of what's the actual contribution of R&D in the productivities of a commodity and it's cost measurement should be subjected to closer scrutiny. In fact, it is not satisfactorily worked out at all.

He pondered whether any instruments are being developed in the new WTO regime to establish the legitimacy and accuracy of the notions of the cost of patents.

Dr Anthony Van Duzer said its theoretically and empirically impossible to justify the 20-year patent rights and it is very difficult to find out the amount of work and expense gone through in the R&D process. "But when you think that 20-year period applies not only to the pharmaceutical products but to any inventions, whether it is an industrial process, piece of machinery or any kind of composition, then 20-year is a very rough timeframe. Inevitably, it is an arbitrary number, which is used for providing compensation," he reckoned.

"I don't think anyone can say a 20-year period is definitely the right period. It is just a historical accident. Politically, it is unlikely that the developed countries would allow others to tinker with the fundamental situation. It is a rational system, but not a very practical one, " he explained.

Referring to the technical assistance and institutional support to narrow the technological gap between the LDCs and the developed countries, he said that no country should lose the sight of technical assistance for any kind of institutional development. It has been recognised in the Doha Declaration and already there is a provision in the agreement that deals with technical cooperation and technology transfer.

Giving an example, he said that Canada is providing training to the intellectual property officials of the developing and LDC countries. It also provides access to expert services to the valuation of patent claims and so on. But he admitted that the work that the developed countries have done so far is very much inadequate.

Answering the query of *Dr Razzaq, Professor Van Duzer* said the TRIPS agreement is full of vague terms largely because of the diplomatic trade-offs, which reflect compromise and bargaining based on wide variety of interest.

He further said that the vagueness in TRIPS terminology is, in fact, good for the LDCs as it gives a certain amount of flexibility to national governments. When complaints would be made to the dispute settlement process, the meaning and scope of these vague terms would then be determined.

On the cost of R&D, *Dr Ali* said there are estimates of the transfers that would be required if all the intellectual property rights were fully recognised by all countries. He said the World Bank has estimated that it would cost roughly 20 billion US Dollar per year at the current level, if all the IP patents and copyrights were to be respected.

Institutional Support and Capacity Building: the Need of the Hour

Terming the paper as very enlightened and at the same time highly technical, the Chief Guest and Commerce Minister *Mr Amir Khosru Mahmud Chowdhury, MP* said the issue is very pertinent in the present context of the world. He admitted that to deal with the challenges the TRIPS agreement poses for a country, a government cannot operate in the way it did previously.

He said that business and professions have become knowledge-based and that in order to deal with the issue, expert opinions and knowledge workers are needed not only in the private sector but also in the government. “If we cannot recruit them in the government, we have to outsource,” he said.

Referring to his government’s plan to tackle the forthcoming challenges, he said the government has established a WTO Cell in the Ministry of Commerce. There is an advisory group in the cell and under the group there are five working groups to discuss specific areas. “In these groups we try to have all the focal points of all the ministries who matter in WTO affairs. Already there were several meetings and most of them attended the meetings.

He said that all stakeholders including the leaders and experts of the pharmaceutical industries are well represented in the TRIPS Committee, which also is under a certain working group. But he confessed that the formation of committees is not enough and institutional support is essential.

The Minister said the government is working out the issue in two ways. First, the government is setting up a Bangladesh Foreign Trade Institute (BFTI) and it will start operations soon. The TCB Building in Karwan Bazar has been earmarked to house the Institute.

Mr Amir Khosru Mahmud Chowdhury, MP said the BFTI will train the people in the private sector, civil servants and officials from the concerned ministries. There will be a think tank or research cell within the institute and it will also work with the WTO Cell.

As far as the ongoing work is concerned, he said, experts are now working on the patents and the copyrights separately under the same institution. Apart from teaching and training, they'll give inputs to the government and other institutes that matter. He said that the private universities would be involved in this type of work. In return, the private universities can use their students for research, faculty development and give input to the government. It's moving in the right direction, he informed the audience.

Stating that the TRIPS Agreement is a complex issue, *Dr Abdur Razzaq*, a member of parliament, admitted that Bangladesh does not have any other choice but to go through the process against the backdrop of the open market economy. Not that the pharmaceuticals are the only products going through this regulation, plant variety and agro-chemicals also have to undergo similar regulations.

He stressed the need for institutional support and capacity building to address the issues and other regulatory concerns. In the age of globalisation and sweeping privatisation, he feels, the traditional bureaucracy of the country cannot address these problems. We need some kind of cells, institutions or organisations, which have the expertise in these new areas, to tackle these important issues.

He added that the problem with the traditional bureaucracy is that the bureaucrats here have expertise in everything, but they don't have any specialisation. The country needs lawyers, scientists, good managers with proven background to counsel the government and the policymakers on these issues, he said adding that the Ministry of Commerce should set up a team or an organisation to take care of all these matters.

A Cause of Concern for Bangladesh

Mr Kazi Zafrullah, a former chairman of the Privatisation Board and a member of the parliament from the opposition, said the TRIPS deal is gaining ground in the international arena and the country is facing new issues of great concern as a result.

Criticising the basic idea behind the TRIPS Agreement, could be a strategy for the developed countries and their big multinational drug companies to curtail the access and opportunities of the poor, the under-nourished and the helpless- he said. He questioned the motive behind giving concession to the LDCs. He pondered whether the concession would come to help the poor or be an additional burden.

Blasting the profit-making attitude of the pharmaceutical companies, he said one kilogram of rice costs Taka 12, while one gram of diarrhoal medicine costs much more. He said the pharmaceutical industries are very profitable and they make huge profit at the cost of poor people.

He stressed that Bangladesh should have first hand knowledge about the TRIPS agreement offers. "I don't think, there is much for Bangladesh in the TRIPS agreement," he observed.

He also called for dissecting the various provisions and articles of the agreement and to see whether the costs outweigh the benefits. Unless, both the public and private

sectors can provide clear answers to this vital question, he stressed the need for more seminars on this issue so that a common platform could be created.

He said the countries are fighting for the drugs that are mostly controlled by the big league players of the developed nations and these drugs are very important for the poor countries with large population like Brazil, China, India, Pakistan, Bangladesh and most of the countries in Africa because these are the drugs of the future. These drugs are very essential to fight the killer diseases like the AIDS, Malaria, Diarrhea, TB and other stomach related diseases for which some 65- 70 per cent population suffer everyday, he mentioned.

On his part and on behalf of his party, he said since this is a very important issue, none should feel the slightest bit of hesitation to work together to find a uniform stand. There should be close cooperation between the political parties and the between different segments of the society including professors, doctors, civil society leaders to deal with the issue unitedly.

8. Speech by the Chief Guest

The Chief Guest, Hon'ble Minister for Commerce *Mr Amir Khosru Mahmud Chowdhury, MP* described the issue as a very complex and technical and thanked CPD for organising a dialogue on the issue.

Regarding the interaction with the pharmaceutical industry, the Chief Guest said the government is entirely dependent on them to give input about the policies that affect their business. He admitted that the civil servants are not capable of deciding what direction the government should take in such a tricky matter. The government therefore takes input from the representatives of the industry and then translates their input into policy matters. The Government has put forward a few of these suggestions at the negotiating table.

But the real challenge, in the Minister's opinion, is what the public and private sectors are doing at home as homework. He said although the country has been giving patent rights to many pharmaceutical industries and a lot of foreign companies have been given patent rights, there remains a question about the rollback situation.

The Minister said that though such a situation is not an easy option for a country because it might send a wrong signal to the foreign investors and will harm the image of the country. "I don't think it will be accepted by the investors," he felt.

Amir Khosru further said that the government is trying to form a WTO Advisory Centre on Law, which will make sure that all the commercial laws that are now in vogue in the country are WTO-compliant. If a law is not WTO-compliant, the Minister continued, it would not be very effective in the long run. Presently the draft laws are being looked into by an independent panel of experts and by World Intellectual Property Organisation (WIPO). Besides, the Minister told the audience that the government has these laws checked by the Law Centre.

On patent law, he said that the law is very crucial for a country's economic wellbeing. However, he said the government cannot go whole hog to implement the patent law because the developed countries don't implement them fully and yet still provide protection to their own companies. "So we have to strike a right balance to make sure that the domestic investment and creation of knowledge-based products are protected. We have to ensure that foreign investment flows into Bangladesh and at the same time we have to support our own domestic industries," he said.

Blasting the attitude of the foreign countries, he said these nations have shown their typical attitude. Quoting a recent speech of the *Prince of Wales* the Minister said that the Prince said that now that the developed countries have developed themselves by emitting so much of gas, chopping millions of woods and exploring tons of oils, they are preaching against these practices. "For them, it is like the party is over and now you cannot talk about the party," he said, noting that this attitude is very much evident among the developed countries and LDCs have to be very careful about the nitty-gritty and details of any agreements. "We have to decide where to draw the line and how to strike a balance."

On the onslaught of liberalisation and globalisation, he said both have offered Bangladesh opportunities, provided that Bangladesh is capable of taking it and is prepared for it. In the pharmaceutical industry, Bangladesh has very good strength and only a few weeks back the country's medicines got duty-free access to Thailand, he informed the participants.

Another potential area of advantage for Bangladesh is its geographical indications as stipulated in the TRIPS agreement, said the Minister. He called for exploiting the country's competitive edges in Ayurvedic, Unani products.

He said despite promises, the transfer of technology is not taking place and whatever is occurring is between multinationals and multinationals. Overall transfer of technology under WTO is not happening, he remarked

As for the multinational companies operating in Bangladesh, he said the government has to make sure that multinational companies work closely with the local industries. Their operations here centre on marketing and they could easily share this with the local companies.

In conclusion, the Minister said that to face the challenges of the TRIPS agreement in Doha, the best thing for Bangladesh would be to have an integrated effort by the government and the private sector.

9. Concluding Remarks by the Chair

Professor Rehman Sobhan finally thanked everyone present at the dialogue for their active participation and valuable inputs.

List of Participants
(in alphabetical order)

1. *H E Ambassador Dr Toufiq Ali*	Permanent Mission of the People's Republic of Bangladesh to the UN Office at Geneva
2. *Mr Mansur Alam*	Executive Director, Novartis (Bangladesh) Ltd
3. *Mr A S Mohammed Ali*	General Manager, Finance Eskayef Bangladesh Ltd
4. *Ms Selima Ahmad*	Managing Director Nitol Group
5. *Dr Manzurul Alam*	School of Business Independent University
6. *Ms Ferdous Ara*	Joint Secretary, DCCI
7. *Dr Roushan Ara*	NPPP, UNFPA
8. *Mr Amir Khosru Mahmud Chowdhury, MP*	Hon'ble Minister for Commerce Government of Bangladesh
9. *Mr Samson H Chowdhury*	Chairman, Square Groups
10. *Dr Wenguo Cai*	CTPL, Canada
11. *Mr Prosenjit Chakraborty*	Executive, Square Pharmaceuticals Ltd.
12. *Mr M Anis ud Dowla*	Managing Director, ACI Ltd
13. *Mr S Fazlul Haque*	Managing Director Glaxo SmithKline Bangladesh Ltd.
14. *Dr Enamul Haque*	Associate Professor Department of Economics North South University
15. *Brig. General Dr Q S Hafiz*	WHO
16. *Engr Tanzeba A Huq*	Research Fellow, BCAS
17. *Mr G K M Towfique Hassan*	Director, EPB
18. *Mr Md Rafiqul Islam*	Director, Marketing and Sales, The Acme Labs Ltd

19. *Dr Fahmida Khatun*	Research Fellow, BIDS
20. *Dr Omar Farooq Khan*	Senior Development Advisor, CIDA Canadian High Commission
21. *Mr Feroz Uddin Khan*	Managing Director Edruc Ltd
22. *Ms Mona Laczo*	Advocacy Coordinator OXFAM, Bangladesh
23. *Professor Rashid-E-Mahbub*	Pro-VC Bangabandhu Sheikh Mujib Medical University
24. *Mr A M A Muhith*	Former Finance Minister
25. *Mr Abdur Razzak Mondol*	Director, EPB
26. *Dr Nasiruddin*	Executive Director Voluntary Health Services Society (VHSS)
27. *Dr Narayan Chandra Nath*	Research Fellow, BIDS
28. *Dr A K M Masihur Rahman*	Former Secretary, Planning Commission, GOB
29. *Dr Ananya Raihan*	Research Fellow, CPD
30. *Dr A Atiq Rahman*	Executive Director BCAS
31. *Dr Mohammad Abdur Razzaque*	Member of Parliament
32. *Brig. General M Mofizur Rahman psc (Retd)*	Executive Chairman, BEPZA
33. *Professor Mustafizur Rahman*	Research Director, CPD
34. *Dr Hafiz G A Siddiqui*	Pro-Vice Chancellor North South University
35. *Mr R Sivanason*	CIROAP
36. *Mr A K M Shamsuddoha*	Managing Director Dohatech New Media
37. *Dr Ann Weston*	VP& Coordinator of Research, North South Institute

38. *Ms Maksuda Yeasmin*	MIO, Edruc Pharmaceuticals Ltd
39. *Ms Riffat Zaman*	Operations Officer World Bank
40. *Barrister Muhammad Nawshad Zamir*	Supreme Court Bar
41. *Dr Sajjad Zohir*	Senior Research Fellow BIDS
42. *Mr Kazi Zafrullah, MP*	Former Chairman, Privatisation Board

List of Journalists
(in alphabetical order)

1. *Mr Shafiqul Alam*	Senior Reporter, The Financial Express
2. *Mr Tanim Ahmed*	*The Weekly Holiday*
3. *Mr Shamsul Alam Badal*	Special Correspondent, BSS
4. *Mr Zahir Chakhari*	Reporter, The Bahgla Bazar Patrika
5. *Mr Enamul Haq*	Staff Reporter, The Independent
6. *Mr Naimul Haq*	Staff Reporter, The Daily Star
7. *Mr Aleeon Al Haron*	Staff Reporter, The Bangladesh Today
8. *Mr Abu Kawser*	Staff Reporter, The Jugantor
9. *Mr Sujon Mahmud*	Staff Reporter, The Ajker Kagoj
10. *Ms Romana Rumi*	Staff Reporter, ATN Bangla
11. *Ms Sharmin Rinvi*	Staff Correspondent, Channel I