Alignment of Innova-P2 goals with Related Indian and Chinese WTO-work

A Report (D3.2) for

INNOVA P2

Lead Author: Dr Krishna Ravi Srinivas

Research and Information System for Developing Countries (RIS), New Delhi, India, March 2010

The research leading to these results has received funding from the European Community’s Seventh Framework Programme under grant agreement 217665.
Introduction

A decade’s experience with the WTO Agreement on Trade Related Aspects of Intellectual Property Rights (TRIPS) has made developing nations bitter but wiser. A key issue is the relevance of TRIPS for meeting public health needs and ensuring access to drugs, particularly essential drugs. Intellectual Property Rights (IPRs) enable the innovator or his/her licensee to enjoy monopoly rights for a fixed period. The TRIPS Agreement codifies these rights and extends IPR (intellectual property rights) protection to all technologies including pharmaceuticals. Implementation of the provisions of the TRIPS Agreement pertaining to patents has witnessed a series of controversies. In particular those that have arisen as the monopoly rent charged by the patent holder has raised the spectre of higher prices for pharmaceutical products. In such a situation, potential buyers have faced the exclusion or access problem since they cannot afford to pay the price set by the seller/manufacturer. Compounding the above-mentioned problems is the fact that the pharmaceutical majors do not make adequate investments to find effective cures for diseases such as malaria and leishmaniasis, which mainly afflict the population in low-income countries. The primary reason for the occurrence of this phenomenon is that the limited purchasing capacity of the low income population makes the markets unattractive for the profit-oriented pharmaceutical majors. As a result there are no effective drugs for the diseases of the poor and these diseases are hence known as neglected diseases. According to a well-known study of the 1223 new medicines brought to market between 1975 and 1997 less than 1% were developed specifically for tropical communicable diseases.

According to Paul Hunt, the United Nations Rapporteur on the right to health:

> Almost 2 billion people lack access to essential medicines. Improving access to existing medicines could save 10 million lives each year, 4 million of them in Africa and South East Asia. Access to medicines is characterized by a profound global inequity. 15% of the world’s population consumes over 90% of the world’s pharmaceuticals. ¹

But access to drugs cannot be viewed in isolation from global and national developments in trade, IP law and regimes and health governance. Globalization, harmonization of the global trade regime under WTO, the changes in the global innovation system and the emergence of China and India as economic powers have significant implications for access to drugs and the development of new drugs, as well as for re-orienting resources in drug development. The changing demographic profile and the dramatic increase in the number of people afflicted by Type I diseases in developing countries call for new approaches to solve the imminent problems. There is a realization that a pragmatic response demands pro-active steps as well as defensive measures. To sum up, these are challenging times bringing both difficult tasks and exciting opportunities.

This paper approaches the issues with this understanding.

¹ Hunt (2007)
The high price of patented drugs and the need for prevention and treatment of diseases afflicting millions of lives are critical issues in global public health. Many solutions have been suggested to overcome both problems. In view of the large and ever expanding literature on the issues we intend to cite only the most relevant and will not discuss the points raised here in greater detail.

**Debates on Access to Medicine at WTO and WHO**

Access to medicines is one of the Millennium Development Goals and has become an important issue for developing countries and Least Developed Countries (LDCs), particularly after the implementation of the TRIPS regime by many countries. The WHO Report of the Commission on Macroeconomics and Health\(^2\) identified eight important areas: AIDS, malaria, TB, diarrheal disease, acute respiratory infection, vaccine-preventable disease, nutritional deficiencies, and unsafe childbirth. The gap between life expectancy in rich countries and poor countries is a cause of concern. For example in 2000 the average life expectancy in Africa was 47 while in most developed countries it was more than 70. This and many other health indicators show that, unless the global disease burden is reduced considerably, the mortality on account of diseases like malaria, AIDS and TB alone will be in the millions. While developed countries tackled the AIDS issue by providing access to drugs, for most of the countries worst hit by HIV/AIDS, access to medicines was a matter of life and death as these drugs were too expensive. On the other hand lack of new and effective drugs is a stumbling block in reducing the disease burden and mortality from diseases like TB and malaria. There are many factors that constrain access to drugs, but in this section we provide an overview of the debates in the WTO and the WHO on this issue and the initiatives that have been taken to address them.

**WTO**

Access to medicines is a public policy issue and making it an exception from IPR protection in the public interest was debated in the negotiations over the text of TRIPS. The need to balance the provision of IPR with the public interest was highlighted by India in its submission during the negotiations. For instance the communication from India MTN.CNG/NG11/W/39\(^3\) dated 5th September 1989 talked about the primacy of the public interest. During the negotiations India and other developing countries including Brazil, China and Colombia expressed the need to preserve enough flexibility in regulating IPRs to protect public morality, public health and to promote the public interest (e.g. MTN.GNG/NG11/W/71\(^4\) dated 14th May 1990). But during the negotiations, for reasons and circumstances that have been described in detail in the

---

\(^2\) [whqlibdoc.who.int/publications/2001/924154550x.pdf](http://whqlibdoc.who.int/publications/2001/924154550x.pdf) accessed 21.4.10

\(^3\) [http://www.wto.org/gatt_docs/English/SULPDF/92080040.pdf](http://www.wto.org/gatt_docs/English/SULPDF/92080040.pdf) accessed 13.4.10

\(^4\) [http://www.wto.org/gatt_docs/English/SULPDF/92100147.pdf](http://www.wto.org/gatt_docs/English/SULPDF/92100147.pdf) accessed 13.4.10
literature, this position met with strong opposition and the final text of TRIPS was a compromise.\(^5\) Particularly contentious were the provisions on Compulsory Licensing and efforts were made by developed countries to weaken these to such an extent that they would be of little use. Despite such pressure, developing countries managed to retain provisions that permit compulsory licensing but these provisions come with many riders.\(^6\) Thus the overall text finally accepted as the TRIPS Agreement was the outcome of protracted negotiations, and that text has considerably reduced the powers of governments to abrogate or partially negate IP rights for the public good and to meet public health needs.

The right to provide limited exceptions to IPR protection under Articles 13, 17, 26.2 and 30 of TRIPS \(^7\) provides flexibility to governments. However, interpretations of TRIPS by Panels and Appellate Bodies have been narrow, for example in the Panel decision in the Canada-Patent Protection of Pharmaceutical Products (Canada-Patents) WT/DS114/R Panel Report dated 17th March 2000\(^8\). These narrow interpretations and the imbalances in the TRIPS text itself have resulted in a situation in which States find there is limited scope for their intervention through TRIPS to meet public health needs. But their worst fears were realized in the HIV/AIDS crisis in Africa that has become a major public health issue. This crisis also proved to be a test of the limitations and potential of the global trade regime under WTO Agreements to meet the needs of millions who could not afford to pay the prices demanded by manufacturers for drugs that could save or prolong their lives.

For reasons of space we will not go into details about the issues in interpreting TRIPS and treaty interpretation but it would be sufficient to point out that there are competing interpretations of TRIPS. These interpretations cannot be reduced to exercises in undertaking an exegesis of TRIPS. Rather they represent powerful interests and the interests of different stakeholders who are affected in one way or other by TRIPS and the harmonization of the global IPR regime under TRIPS. As Arup puts it:

> The closure that produced the 1994 TRIPs agreement now seems like an extraordinary moment in international intellectual property law making. More treaty making has occurred, notably the WIPO, WCT and WPPT, but the field has become more fluid and less certain. Where treaty making has stalled, the action has moved to treaty interpretation. Increasingly it is difficult to find a straight line through the field. Those wanting more stringent and more relaxed interpretations compete actively. They experiment with a variety of strategies to influence interpretation inside the WTO and outside.\(^9\)

---

\(^5\) For reasons of space we would not go into the details here. Refer to Watal (2001) and UNCTAD/ICTSD (2005) for more information on this.

\(^6\) See Watal (2001) for details.

\(^7\) http://www.wto.org/english/docs_e/legal_e/27-trips_04_e.htm accessed 21.4.10

\(^8\) http://www.wto.org/english/tratop_e/dispu_e/7428d.pdf accessed 13.4.10

\(^9\) See Arup (2008) for an analysis of co-operative and competitive interpretations of TRIPS.
The turning point was the controversy over the rights of governments to use compulsory licensing and parallel imports to provide low-cost drugs to those who could not afford drugs for HIV/AIDS. In 1997 the South African government brought an amendment to its Medicines and Related Substances Act so that the government could use the above-mentioned measures to provide low-cost drugs. At that time, with over 30% of the population infected with HIV, it was becoming a public health crisis. The USA and multinational pharmaceutical companies opposed this amendment and the USA added South Africa to its Section 301 Watch List. In July 1998, the Office of the United States Trade Representative (USTR) used its discretion to withhold trade benefits for a range of South African products that had previously been approved under the Generalized System of Preferences (GSP) program. There was much opposition to such moves and to the pressure put by the USA on the South African government. The South African government contended that its amendment was TRIPS compliant and South Africa had a right to use TRIPS provisions for preventing a public health crisis.

In September 1999, the USTR and the South African government resolved the controversy after the US government agreed not to use sanctions against South Africa, and South Africa, in turn, agreed to adhere to its obligations under the TRIPS Agreement. In February 2001, the Bush Administration affirmed that the United States would not object to WTO Members adopting measures to address major health crises using the flexibilities provided by the TRIPS Agreement. At the same time, the pharmaceutical companies that had challenged the 1997 Amendment to the Medicines and Related Substances Act dropped their cases against the South African government.

The dispute between South Africa and the USA on the use of compulsory licensing for public health purposes and its legitimacy under TRIPS, raised questions about countries’ powers to use the provisions of TRIPS as well as the scope for compulsory licensing under TRIPS. The African Group (supported by most developing countries) took the initiative to discuss the public health concerns arising from the implementation of the TRIPS Agreement, in the run-up to the Fourth Ministerial Conference of the WTO, held in Doha in November 2001.

Developing nations suggested that WTO members should be able to use Article 30\(^{10}\) to authorize production and export to meet the public health needs of a member country. This would enable countries that lacked production to import from countries that had the capacity to produce and export. There would be no need to issue back-to-back licensing and the importing country would be able to use compulsory licensing on its own.

Article 31 of TRIPS permits the right to issue compulsory licenses subject to certain conditions. Under Article 31(f) exports can be made under these licenses, but a rider states, “any such use shall be authorised predominantly for the supply of the domestic

\(^{10}\) TRIPS Article 30, Exceptions to Rights Conferred, “Members may provide limited exceptions to the exclusive rights conferred by a patent, provided that such exceptions do not unreasonably conflict with a normal exploitation of the patent and do not unreasonably prejudice the legitimate interests of the patent owner, taking account of the legitimate interests of third parties.” Available at http://www.wto.org/english/docs_e/legal_e/27-trips_04c_e.htm accessed 21.4.10
market of the Member authorizing such use”. ¹¹ This makes it difficult for countries to use compulsory licensing to produce and export drugs to countries that lack manufacturing capacity or to meet public health needs in another country. If it had been agreed that developing nations could use Article 30 in this way, then Article 31 would have provided a ready-made solution that would be very easy to use without any additional conditions or procedures being adopted. But the USA and the EU rejected this simple solution.

The Ministerial Conference adopted the Doha Declaration on the TRIPS Agreement and Public Health, recognizing the flexibilities within TRIPS and the rights of member governments to use these in public health emergencies. The Doha Declaration had two key features. First, it affirmed that “[E]ach Member has the right to grant compulsory licences and the freedom to determine the grounds upon which such licences are granted”. Secondly, the Doha Declaration ‘resolved’ the above dilemma with Paragraph 6, which recognized that countries “with insufficient or no manufacturing capacities in the pharmaceutical sector could face difficulties in making effective use of compulsory licensing under the TRIPS Agreement” and instructed the WTO Membership to find “an expeditious solution to this problem ... before the end of 2002”. ¹²

But solutions could not be found so easily because of differing opinions between North and South on the use of TRIPS by governments and the interpretation of TRIPS provisions in cases of public health emergencies.

After further negotiations the Waiver decision was arrived at in August 2003. The Waiver Decision envisaged a complex regime and the procedure was so complicated that countries were actually discouraged from using this solution.

Developing nations wanted the solution to be applied broadly to both diseases and treatments. The USA disagreed with this broad coverage but, as developing countries remained firm, their view prevailed. However as questions were raised about Thailand using compulsory licensing for a drug for heart disease it is likely that the issue of broad coverage of diseases and treatments might continue to be questioned.

Countries other than LDCs have to issue a notification of intent to use the system as importing countries. Many countries have in fact notified that they intend to use this system as importers only in a limited way or not at all. Although more than 30 members of the WTO can avail of this, under the LDC category so far only one country (Rwanda) has used this. The general notification of intent can be issued by using a standard form developed by the World Bank. But this does not serve any great purpose other than increasing the transaction cost, as this is a mere formality. An analysis of the system’s use by Rwanda shows that it is cumbersome and that the 2003 decision is a flawed

---

¹¹ TRIPS Article 31, Other Use Without Authorization of the Right Holder (f)
http://www.wto.org/english/docs_e/legal_e/27-trips_04c_e.htm accessed 21.4.10
¹² http://www.wto.org/english/thewto_e/minist_e/min01_e/mindecl_trips_e.pdf accessed 21.4.10
model. Rather what is required is reformation of the IPR system to address public health needs.13

Insufficient or No Capacity to produce drugs: Another condition to being able to import medicines under this scheme is that the importing country has to be a LDC or a country that has insufficient or no manufacturing capacity. But once it has developed sufficient capacity it is expected not to use this system.

Exporting Country obligations: The exporting country has an obligation to issue a compulsory license. Only the authorized manufacturer should export the medicines, and only in the necessary quantities. The product should be clearly identified and the licensee should post these details on a website as well as informing the TRIPS Council on the issue of the license, its conditions, the quantities of medicines likely to be produced and their destination. The condition that only the amounts needed to satisfy the needs of the importing country or licensee should be exported is in itself an obstacle as it precludes production in bulk in anticipation of demand.

This system has not been useful and making it a part of TRIPS by inserting Article 31bis14 will not be of much help. An easier solution would have been found had the developed countries agreed to the proposal of the developing countries. Given the asymmetry in TRIPS between the powers of the patent holder and the state, the better solution would be to interpret provisions in such a way that public health gets precedence over IP rights. Developed nations have not hesitated to use compulsory licensing or threats by governments to ensure that adequate supplies are made available to them on favourable terms. But when the same techniques are used by countries like Brazil and Thailand they are frowned upon amid claims that those governments are robbing the patent holders.

Thus we are in a peculiar situation as some of the provisions of TRIPS are yet to be tested fully and even the provisions on issuing compulsory licensing have been contested. TRIPS also restricts the scope for countries to use anti-competitive measures.15 Although there are flexibilities in TRIPS, using them is not easy. Either countries lack the capacity to use them or the flexibilities are not sufficient to safeguard public interests, particularly regarding access to drugs. In addition bi-lateral/Free Trade Agreements further restrict the use of flexibilities through TRIPS-plus provisions.16 According to one commentator:

“TRIPS can be interpreted and – more importantly – implemented in a manner which offers an amount of policy space for domestic regulation of public interests equivalent to GATT and GATS. Achieving this primarily calls on

---

13 See Rimmer (2008) for an analysis of the use by Rwanda and the effort by Canada. Rimmer contends that codification of this ‘solution’ is not an appropriate model as it is too flawed to be any real use.


15 Correa (2005)

16 TRIPS-plus refers to the pursuit of stricter levels of pharmaceutical IP protection than required by the TRIPS Agreement or the Doha Declaration e.g. via trade agreements, in particular with the US and in accession agreements to the WTO. See ‘t Hoen (2009) especially pp69-84.
national implementation legislation (as well as technical assistance provided in this regard) to make use of the discretion available and also places an obligation on WTO Panels and the Appellate Body to take the relevant treaty objectives seriously. Given the rather disappointing TRIPS jurisprudence of Panels so far, one might nevertheless be better off with a comprehensive public interest exception integrated into TRIPS – for example by simply removing the consistency test in Art.8:1 TRIPS”.

Developing country members have expressed the view that the Paragraph 6 solution has not been an effective one. Here too the North-South divide is evident. Amending TRIPS to make it more flexible is not an easy task, but making changes in the Paragraph 6 solution to make it more flexible might be possible with much difficulty and protracted negotiation. But the reality is that things are not moving fast in the TRIPS Council on many issues and the stalemate shows no sign of moving further. India and China have together taken consistent positions on these issues, particularly on the use of compulsory licensing by developing countries and LDCs.

The use of compulsory licensing by Thailand illustrates how a government can use this as a part of public health policy to enhance access to drugs. Thailand has used compulsory licensing more than once, despite threats and pressure from the USA against such use. Thailand has used this to provide medicines to treat cancer and heart disease as well as HIV/AIDS. Its government’s authorization of use was limited to use under public health insurance and this was in tune with Article 51 of the Thailand Patents Act which authorised the right to use any patent for carrying out “any service for public consumption”. Although many countries may not be providing universal health access in the same way as Thailand, they could still use compulsory licensing to enable more access to drugs, including essential drugs.

The implications of these developments for access to medicines in developing nations and LDCs are not positive. As we will point out elsewhere, these developments coupled with TRIPS-plus norms in bi-laterals and Free Trade Agreements (FTAs) threaten the meagre policy space available under TRIPS for using the provisions of TRIPS to enhance access to drugs.

WHO

At the 1996 World Health Assembly concerns were expressed about the consequences of globalizing IPR standards for access to drugs. WHO was asked to publish a guide on the implementation of TRIPS in order to minimize the negative impacts of higher levels of patent protection on access to drugs. In 2004 the Commission on Intellectual Property Rights, Innovation and Public Health (CIPIH) was established. It submitted a report in

---

17 Ruse – Khan (2009)
19 See Oh (2009) for details.
The Commission stressed the need to look at the bigger picture given that as incentives IPRs form part of the incentives for innovation. It took the view that in some markets IPRs may not be an effective incentive and that there was a need for other incentives and for financial mechanisms to be put in place as well as for collaboration among stakeholders. It acknowledged that access to innovations was important in public health and that current efforts to promote innovations were welcome but not sufficient. The Commission noted the controversies over IPRs and access to medicines and suggested that WHO should develop an Action Plan to enhance access and innovation. The Commission underscored the need to increase the funding for finding cures for neglected diseases and stressed the need for enhanced funding for innovations on a sustainable basis. The Commission thus recognised the need to think beyond the current IPR regime and the need to find innovative solutions for enhancing access and affordability and new drugs for Type II and Type III diseases.

The Commission’s report was discussed at the World Health Assembly and the WHO formed Working Groups to take this issue further and to study the proposals and recommendations of CIPIH. While countries welcomed the recommendations made by CIPIH, WHO could not immediately take up any new initiatives to facilitate and enhance further R&D of neglected diseases. At the World Health Assembly in 2009 an ambitious action plan spread over five years was adopted. It is estimated to cost $150 billion over five years for implementation. Various mechanisms have been proposed to address the problems; identified as ‘push’ and ‘pull’ mechanisms these advocate various solutions ranging from Advance Market Commitments to priority vouchers.

An Expert Working Group on research and development financing for neglected diseases has almost completed its work and its report is expected soon. In the meantime some studies have been done as part of the process initiated by WHO. While WHO has been sensitive to these issues and is striving to support initiatives, it lacks the mandate to take up any or some of these proposals for implementation. A comparative review undertaken for the Expert Working Group pointed out the merits and shortcomings of the 90 proposals under consideration. It observed that: “These fundraising mechanisms, depending on the choice of proposals within them, could raise an additional $US 4.6 billion per annum by 2015 for health R&D for the developing world”.

On the other hand a study done for WHO proposes setting up a Global Health Research and Innovation Fund (GHRIF) and estimates that a funding allocation of between USD $3 billion and USD $15 billion is needed per annum.

---

22 See RIS (2009) for a brief discussion.
23 Health Policy Division (2009)
24 Feletto, M., Maltin S.A. (2009)
Although estimates of actual spending on R&D for neglected diseases vary, a recent study shows that India and Brazil are among the top spenders, although their R&D spending is much less than similar funds provided by Private Foundations in developed nations.\(^{25}\) As more studies and evaluation are to be done, it is too early to come to any definite conclusions on the outcome of the processes at WHO. However what is becoming clear is that raising resources for enhancing health R&D or for the development of new drugs which are needed most by developing nations and LDCs will be the major challenge rather than the lack of workable proposals. For developing nations and LDCs the outcome of the processes at WHO is important, but it is not likely to result in any new major funding commitments, either to WHO or to programs like the Special Programme for Research and Training in Tropical Diseases (better known as TDR). Some proposals are likely to be taken up for testing and implementation but at this stage it is not clear as to whether WHO itself would do this or whether these will be done jointly with some governments and/or interested UN agencies.

Developing nations have stepped up their funding on research on neglected diseases although their funding alone is not adequate to meet the needs. According to a recent study India and Brazil are among the major spenders in research on neglected diseases. But given the disparity among developing nations and the impact of the global economic crisis on most of them, one cannot expect that their funding will go up drastically in the short term. This means that developing nations should explore opportunities for collaborative research, identify priorities and derive the most from the limited funding. They can rely on funding from other sources, including Private Foundations, but they should be cautious about Private Foundations setting the agenda or direction of research.

An issue that should engage the attention of developing nations is enhancing the capacity to produce drugs and assuring quality control in drug manufacture. Many countries do not have dynamic generic industries and their national innovation systems are not able to absorb technology and improve upon it. There is much scope for South-South cooperation in this. Another potential option is to enhance the capacity to produce quality generics in LDCs which can use the time-frame given in TRIPS to delay the introduction of product patenting in drugs. But time is running out and unless steps are taken within a year or two, they will not be able to make the best use of the flexibility in TRIPS.

In addition to the above areas, developing nations face three challenges: 1) They will have to resist the pressure in negotiations over FTAs and bilaterals on TRIPS-plus provisions 2) They need to be aware of the newer efforts on harmonization and enforcement and 3) They need to develop the capacity to use the flexibilities in TRIPS, particularly the option of compulsory licensing, and use creatively the policy space available in implementing TRIPS and in enforcing IPRs.

While the first two tasks need coordinated action at various levels, including regional and global, the third task needs more South-South co-operation and developing nations should seek the assistance from international agencies like UNCTAD, UNDP and WHO.

\(^{25}\) “Two developing countries were among the top 5 government funders of neglected disease R&D in 2008, Brazil with an investment of $36.8m (2.0%) and India ($32.5m, 1.7%).” Moran M. et.al. (2009)
in fulfilling it. By now developing nations have had almost a decade of experience with TRIPS and harmonization under TRIPS. They should use this experience in such a way that in future they are able to strike a better balance between IPR as an incentive and access to technology and public policy objectives. This calls for understanding the nuances of TRIPS and using the Dispute Settlement Understanding (DSU) of WTO wherever necessary to thwart attempts to impose rules and regulations not warranted under TRIPS.

Here too, developing nations can learn a lot from the experience of India and China in implementing TRIPS. In particular regarding the provisions on compulsory licensing, Section 3(d) of the Indian Patents Act and (although not relevant in the context of drugs) the copyright law of China.

Thus while all stake-holders are aware of the issues and the acute need to increase funding, an increase in funding commitments from developed nations cannot be expected in the near future. Developing nations can mobilize their own resources and work with Private Foundations to increase the flow of funds. It should be stressed that developing nations should go for a “walking with two legs” strategy so that they do not end up in a “one step forward, two steps back” situation in the name of implementing TRIPS.

The G77/China group and the Africa Group have taken more or less the same positions in fora like WTO, WHO and in WIPO (particularly on the WIPO Development Agenda). Efforts should be made to foster more South-South co-operation in capacity building and the transfer of technology in the pharmaceutical sector. Another important step can be increasing the trade in pharmaceutical products and raw materials among developing countries and LDCs, both in terms of volume and value. Thus “walking with two legs” will help developing nations react sufficiently and in a timely manner as well as take proactive steps. In this China and India can play an important role by working together and by working with other countries in tandem.

Developing countries can use WHO as a forum to pursue their interests and express their concerns and as in the case of sharing virus samples, they can use it to demonstrate that they cannot always be expected to be the silent donors of samples without a stake in the development and sharing of vaccines. Developing countries can seek the help of WHO in capacity building, including using TRIPS flexibilities in their respective national regimes, increasing the capacity to produce essential drugs and in formulating public health policies. The stand taken by developing countries in the sharing of virus samples and in invoking the principles of Access and Benefit Sharing indicates that they are not willing to end up as donors and consumers who pay a high price on account of IPRs and monopolies/oligopolies in the pharmaceutical sector. It is significant that all developing countries including India and China supported the position taken by Indonesia on the virus sharing issue.

It is likely that by the time of the next World Health Assembly in May 2010 a clearer picture on the financing of R&D for the health needs of developing countries might emerge.
To conclude, developments in WTO and WHO are important even if no breakthroughs can be expected. It is important to stick to the positions taken in these fora as well as to resist new pressures and new demands from developed countries. It is worth pointing out here that India and China have taken almost similar/identical positions on issues in both WTO and WHO.

Recent Developments in WTO

The stalemate in the WTO talks continues and the Doha Round is nowhere near completion. While talks in the WTO are important, countries are not keen to continue the talks and bring the Round to completion. There are many factors at work in this. The global economic crisis has shown that there are limits to unregulated globalization and countries have to protect their societies and economies from downturns and crises before thinking of further liberalization and deregulation. Countries have realized that while protectionism may look bad in theory, they have to resort to it as and when needed to safeguard national interests and employment. Since the USA and Europe are yet to recover from the crisis and reach a stage of faster growth they are not keen to join the negotiations with more offers on trade liberalization and reduction in subsidies. The inward-looking economic policies being pursued by the USA and the pressures from lobbies not to liberalize further in some sectors has dampened the interest in further liberalization under the auspices of Doha.

To sum up, the Doha Round is not becoming irrelevant but its importance in the short term has declined. Unless there is an economic recovery and countries are willing to offer better terms in negotiations, the stalemate is likely to continue. But irrespective of this it is essential that the need for a development-friendly outcome is borne in mind when talks resume and that the issues raised by developing countries on rule-making and diminishing policy space on account of implementing WTO Agreements are addressed in a fair manner.

But this does not mean that the developed nations are not seeking to raise the norms for IPR protection. Here too what we are witnessing is an attack on many fronts including ‘forum shopping’. Despite the fact that the WTO is the right forum in which to operate, they are trying to do certain things outside it due to the fact that any revision in TRIPS is not easy. On the other hand creating new organizations and more coordinated efforts that build upon what has been achieved by TRIPS is possible outside WTO. One such strategy is making Free Trade Agreements or bi-lateral agreements with developing countries, individually or as regional blocs. The proliferation of bi-lateral/regional trade agreements/Free Trade Agreements with developed countries including the EU has been

---

26 See RIS (2007) for analysis of the proposals in the Doha Round and the responses from developing countries.
a significant feature of the global trading system in the last 15 years. While most of these agreements are signed with the objective of liberalizing and better facilitating trade among/between countries their long-term impact on domestic policy making and on adhering to WTO agreements is not clear. Whether they undermine the WTO trade regime or simply complement it with agreements that encourage more inter-regional trade is a matter of contention. But what is certain is that the scope of these FTAs and bi-laterals often go beyond what is covered by WTO Agreements. In that sense they are mostly Plus commitments and not abrogation, partially or fully, of the commitments under WTO. According to two scholars:

“Perhaps even more important than the sheer quantity of trade agreements is the scope of their coverage. While the 19th century and early 20th century bilateral agreements were often narrowly focused on reducing tariffs, the more recent ones contain obligations that are wide-ranging and controversial, from investment provisions to intellectual property rights affecting access to medicines to protections for labour/human rights and the environment. While the full impact that these agreements will have on domestic policy-making is uncertain, it is clear that a number of agreements are going beyond the coverage of the WTO as well as the regional and bilateral agreements negotiated prior to 1999 and reaching a new level of international policy-making.”

What is important for the access to medicines debate is that the TRIPS-plus norms and other policies that target government programs on health spending, including purchasing agreements and reimbursement schemes are not restricted to developing countries alone. The Australia–United States Free Trade Agreement is an example of this. Studies show that this Agreement goes beyond obligations under TRIPS in the granting of IPRs and enforcement and thereby limits the policy space to use TRIPS.

These provisions affect access to medicines and force nations to give up some options. They restrict the right to prohibit evergreening of patents or to use compulsory licensing or to avoid extending IPR protection to test data. Studies show that such provisions are found in almost all the FTAs/bi-laterals with the USA/EU or both. Often these provisions have been contested and as a result there has been some softening of TRIPS-plus norms in some circumstances. Nevertheless, the implications for access to drugs are ominous because they block or reduce the available options. This has serious implications for access to second/third generation drugs for HIV/AIDS and for drugs for which generics are not available, or if they are available where they cannot be imported or obtained using compulsory licensing due to adherence to conditions imposed in bi-laterals/FTAs.

---

28 See Mitchell, A.D., Voon, T. (2009) for an analysis of TRIPS-plus provisions. There are other studies on this Agreement which come to similar conclusions. For reasons of space they are not discussed here.
Conclusion

The current scenario with respect to access to drugs or increased funding for research for drugs for neglected diseases raises questions about the shortcomings and limitations of the current IPR regime under TRIPS. Unfortunately this is compounded by other developments/factors that limit the policy space of governments to seek further strengthening of TRIPS. The debates in the WTO on IPR issues relating to access to drugs have not resulted in effective solutions as demonstrated by the response to the Paragraph 6 solution. Under the auspices of the WHO, several studies have been completed. Based on these, areas for further action have been identified. However uncertainties about raising the resources to implement the plans that would address access and innovation issues persist. In the absence of a long-term commitment and support from the member countries the WHO itself may not be able to do much on these issues.

References


