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TRADING UP

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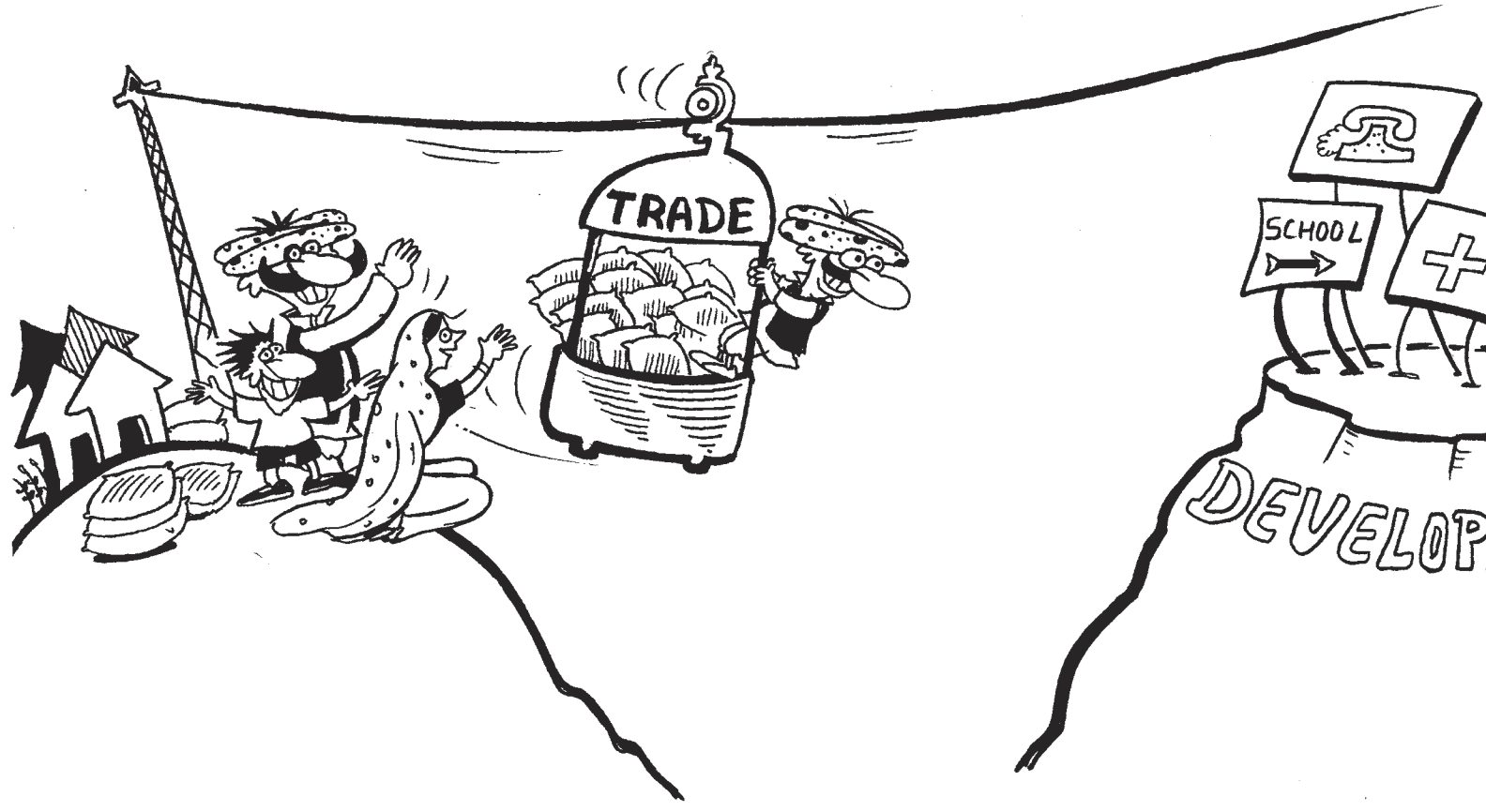

Trading for Development

Inside

Editorial

Trading for Development

Half of the world's population lives on less than US $ 2 a day and one-fourth on less than US $ 1 a day. The past decades have witnessed decline in relative poverty though the absolute numbers below poverty line has increased. One of the important policy tools to reduce poverty is aid. Notwithstanding the significance of aid, it can only play a modest role in poverty reduction. It is important to have a mechanism that develops the productive assets of people. In this regard an important policy tool is trade. Trade has enormous potential to lift millions of people out of poverty. According to an Oxfam study, an increase of 5 percent by developing countries in the share of world exports would generate US $ 350 billion. This is seven times as much as developing countries receive in aid. However, increasing integration of the global economy through international trade has also been accompanied by increasing disparity and inequality. Trade has not been able to live up to its potential of lifting people out of poverty. This is primarily because the present global architecture of trade rules lacks the development focus. The rules of the trade are rigged in favour of the rich countries and are detrimental to the interests of the poor.

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It is important to understand that trade on its own cannot result in poverty reduction. It needs to be rooted in appropriate policy framework at multilateral, regional and national levels to make a substantial dent on poverty. The controversy surrounding trade is not whether it is desirable, but about how the multilateral, regional and national trading regimes can operate in ways that support and foster development.

One of the populous regions of the world where the impact of trade is felt on livelihoods and millions of people is South Asia. South Asia has population growing at the rate of almost similar to that for low-income countries in general. About 21 percent of the world's working population lives in this region. South Asia is also home to nearly 40 percent of world's poor living on less than $ 1 a day. Given these realities, the Millennium Development Goals (MDGs) such as eradicating extreme poverty and hunger and developing a global partnership for development is not possible till the South Asian region grows and develops.

Today, in South Asia there exists a growing need to understand the linkages between trade and development and its implications on people at large. The Centre for Trade and Development (Centad) is an innovative, not-for-profit institution initiated and promoted and established by Oxfam GB in response to this need. It is dedicated to make markets work for the poor through policy oriented research and active engagement on trade and development with the policy-makers and other key stakeholders. The principal geographical focus of Centad will be South Asia.

Centad seeks to enhance the abilities of the government and other institutions to make economic globalisation work for the poor by providing access to accurate and timely information analysis, promoting better policies through research, facilitating informed public discourses and building formations of stakeholders for advocacy, on issues of trade and development. I am happy to note that Centad has already published two working papers and many more are in pipeline.

This magazine is a part of the advocacy and capacity building initiatives of Centad. *'Trading Up'* will demystify the issues around trade and development by providing cogent information on different themes related to trade and development.

The first issue of *'Trading Up'* focuses on the India's third Patent Amendment Bill and the G20 alliance. The patent bill has drawn a lot of public glare and apprehensions have been expressed about its impact on public health and availability of medicines to the poor not only in India but for the entire developing world. *'Trading Up'* attempts to elucidate further on these issues through an easy to understand approach. The focus on G20 is important in the wake of its increasingly important role in the ongoing negotiations in the WTO in arguably the most important area i.e. agriculture.

We hope that the readers will find the style simple and the content useful in comprehending aspects of the complex dynamics of trade and development. We would welcome comments on the structure and focus of the magazine. Letters to the editor and short commentaries will be published.

■ Dr. Samar Verma
Regional Policy Advisor
Oxfam GB

TRIPping on Drug Prices?

■ S.K.Verma

The Patents (Amendment) Act, 2005 has provided for product patent in all fields of technology, including drugs, pharmaceuticals and chemicals. It has also triggered fears that product patents in pharmaceuticals will spur drug prices, which will adversely affect the public health and most of the drugs would be out of the reach of common man.

As mandated by Article 65 of the TRIPS Agreement, India has recently adopted the Patents (Amendment) Act, 2005 (assented by the President on 4th April 2005), by further amending the Patents Act, 1970. The amended Act has provided for product patent in all fields of technology, including drugs, pharmaceuticals and chemicals. The Act has also dropped Chapter IVA on Exclusive Marketing Rights (EMRs) and mailbox applications, introduced as transitory measure in 1999 by amending the Patents Act, 1970, to comply with the TRIPS obligations under Article 70 (8) and (9). It has triggered fears that the introduction of product patents in pharmaceuticals will spur the drug prices, which will adversely affect the public health and most of the drugs would be out of the reach of common man.

Product Patents and Drug Prices

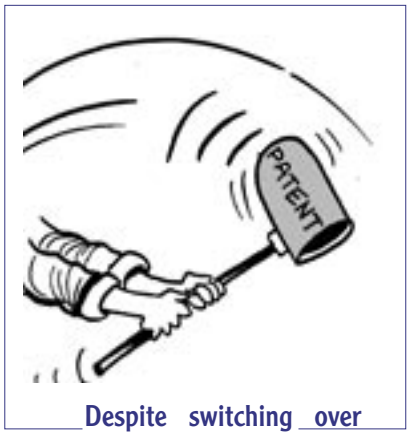
Before the adoption of Patents (Amendment) Act, 2005, drugs, pharmaceuticals and chemicals were subjected to process patents only and were protected for a shorter period (five years from the date of sealing of the patent). It was believed that by doing so, the prices could be kept at reasonable levels. Several studies have shown that patent protection is vastly more important to the pharmaceutical and chemical sectors than to other industrial sectors. This can be attributed to the ease, with which such products can be reversed-engineered. Patent claims to such products are easier to define and consequently infringement is easier to control by patents.

Given that India is a country where a large proportion of the population lives below the poverty line, the availability of medicines at reasonable prices has almost been of utmost importance to policy-makers. However, no serious attempts were made to estimate the quantum of the price-rise and welfare effects on the pharmaceutical sector, once the product patents are introduced. Studies conducted abroad, nevertheless, have thrown interesting issues and put definite numbers on the price changes and consequent welfare losses in India.

A study conducted in the USA in 2003 by a team of economists, based on empirical data on prices and market shares, has concluded that in the absence of any price regulation or compulsory licenses, the total losses to the Indian economy would be greater than the sales of all systemic (oral or injected) antibiotics (which form up to 17 percent of the retail drug sales) in 2000.[1] It has been pointed out that while the prices of patented drugs would definitely rise post-1 January 2005, prices of cheaper off-patent drugs in the same class too would increase when consumers opt for them and availability of drugs would also become an issue. Normally, for customers who cannot access a domestic brand of a drug substitute, there would be another brand. So far, they have been shuttling between the domestic brands because there are more local brands and more Indian companies than foreign. Once product

[1] Available at www.colombia.edu/~sc301/pharmaceutical-patents-2004-01.pdf

patent comes into existence, there will not be any copying (through process patent), and thus there will be loss of flexibility. It is also notable that the foreign firms may not be in a position to cater to the needs of the whole country as the supply may not meet the demand or they would be holding it back to earn high profits by creating artificial scarcity.



Despite switching over to product patent, all products, including those under patent elsewhere, which are currently manufactured and marketed in India will continue to be available in generic form.

Other studies, however, have shown that whatever the effect the introduction of product patents may have on prices, the proportion of the total pharmaceutical market affected is not likely to be more than 11 percent (rest is catered by generics and other forms of medicines). This is of course assuming, in the absence of evidence to the contrary, that a change into the product patent alone will not, in the short run, dramatically change this proportion. The overall picture that emerges by calculating the weighted mean change in prices is a price rise of 52 percent for the entire group of patented drugs, if these drugs are subjected to product patents. The highest changes, excluding acyclovir where elasticity is small, would be in ciprofloxacin and ranitidine, as both these drugs are important in their respective therapeutic groups. In India, price rise is expected above 60 percent in their case. However, where substitutes are available, or where there are existing monopolies, there may not be any price rise at all. It is concluded from these studies that, with the introduction of product patents, the maximum mean change in prices for the entire drug segment would be about 50 percent and only 40 percent of the patentable drug market (which translates to about 4 percent to the total pharmaceutical market) would experience a significant price rise. This is a substantial increase, and high monopolistic prices and the inability of producing new drugs by the domestic industry are expected to be experienced immediately. The newly amended Act has tried to ensure the availability of drugs through the following measures:

- Despite switching over to product patent, all products, including those under patent elsewhere, which are currently manufactured and marketed in India will continue to be available in generic form. The amended Act provides that in the case of mailbox applications, filed before 1 January, 2005 (and after 1 January 1995), the right to a patentee in respect of applications shall accrue from the date of grant of the patent and after a patent is granted, the patent holder shall be entitled to receive reasonable royalty from such enterprises which have made significant investment in producing and marketing the concerned product prior to 1 January 2005 and continue to manufacture the product, on the date of grant of the patent. No infringement proceedings shall be instituted against such enterprises (sec. 11 A).

- Parallel imports of cheap or generic drugs have been allowed by amending section 107A (b), (added in 2002) which provided imports with the authorisation of the patentee to sell or distribute the product in the local market. Now imports are allowed if the importer is 'duly authorised under the law".

- "Ever-greening" of a patent is not allowed, i.e., granting patents for relatively trivial changes. The amended Act provides patents only for new chemical entities. A new form of a known substance, which does not result in the enhancement of the known efficacy of that substance, shall not be eligible for patent (sec. 3(d)).

- Scope of patenability has been narrowed down by redefining the term "inventive step" (sec. 2(ja)) and new definitions of "new invention" and "pharmaceutical substances" have been added. The Act, however, does not provide any definition of "biotechnological invention" and "microorganism".

But these measures may not contain the drug prices or meet scarcity or non-availability of drugs. In such a situation, the liberal grant of compulsory licenses along with a strict regime of price-control may be the appropriate steps to be looked into.

India's Readiness to Control Drug Prices and its Compatibility with TRIPS

The amended Act has inserted a new section 92A, primarily to give effect to theTRIPS Council's Decision of August 2003,

adopted in furtherance of Paragraph 6 of the Doha Declaration, 2001, enabling the grant of compulsory licence for export of medicines to countries with insufficient or no manufacturing capacity, to meet emergent public health situations. This section has no relevance for the domestic market, for which other provisions of the Act in Chapter XVI (Ss. 82-94) will be relevant. In cases of extreme urgency or in case of public non-commercial use, compulsory licenses can be issued on notification by the Central Government. The Controller, while granting the compulsory licence has to ensure that the manufactured patented articles shall be available to the public at the lowest prices. As not many persons would be interested in compulsory licenses because of their non-exclusivity and limited duration, to give incentive to a licensee, the Act provides that even when compulsory licence is granted for pre-dominant purpose of supply in Indian market, the licensee may export the patented product as also when licence is granted to remedy a practice determined to be anti-competitive (sec. 90(1)(vii) and (viii)). The compulsory licenses may not be adequate to meet national health emergencies if the drug concerned is new. It would take at least 36-48 months, because the production of a new generic drug requires investment in plant and machinery, as well as bio-equivalence tests and regulatory approval.

For drugs produced outside India, the Government has to depend on overseas data and cost figures. It is feared that product patent regime might result in making the DPCO redundant as it deals mainly with bulk drug formulations.

In order to control prices, there already exists the Drugs (Prices Control) Order, 1995, (DPCO). The Order was passed to curb exorbitant profits in drug transactions and to make drugs available to a common man at affordable prices. Under the Order, the prices of drugs are fixed as per the formula: Retail Price (R.P.) = [Material Cost (M.C.) + Conversion Cost (C.C.) + Cost of Packaging Material (P.M.) + Packaging Charges (P.C.)] x [(1+ Maximum Allowable Post Manufacturing Expenses (MAPE)/100)]+ Excise Duty (E.D.) (sec. 7). However, for drugs produced outside India, the Government has to depend on overseas data and cost figures. It is feared that product patent regime might result in making the DPCO redundant as it deals mainly with bulk drug formulations. Under the Order, the Government is empowered to fix or revise the price of a bulk drug or formulation (sec. 11). Retail price once fixed cannot be changed without the prior approval of the Government. Every dealer or retailer has to display the price list as furnished by the manufacturer or importer at a conspicuous place in its premises. Besides, displaying the price clearly on the label of the container the sale of split quantity of a drug can be charged at a pro-rata price + 5 percent thereof.

Doubts have been expressed, however, about the compatibility of price control mechanism with the TRIPS Agreement. TheTRIPS does not have any explicit provision on the issue. On the contrary, it provides that the protection and enforcement of Intellectual Property Rights (IPRs) should be "in a manner conducive to social and economic welfare, and to a balance of rights and obligations" (Art. 7). The Members are allowed, while formulating or amending their laws and regulations, adopt measures necessary to protect public health and nutrition, and to promote the public interest in sectors of vital importance to their socio-economic and technological development (Art. 8.). These measures may include drug price control as well, and thus their legality cannot be challenged. Control of drug prices by the governments is common even in some of the developed countries, viz., Japan, Spain and Portugal, where compulsory licenses are liberally granted to meet the healthcare needs, including keeping a check on prices. Nevertheless, an effective regulatory body to monitor the prices must be constituted. In the matter of issuing compulsory licenses, a transparent and speedy method needs to be evolved.

Control of drug prices by the governments is common even in some of the developed countries, viz., Japan, Spain and Portugal, where compulsory licenses are liberally granted to meet the healthcare needs, including keeping a check on prices. Nevertheless, an effective regulatory body to monitor the prices must be constituted.

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Patents: Many Battles Ahead

James Love Speaks to Centad

Centad: How is the international community looking at the recent Indian Patent Law amendment? Has India's adoption of the product patent regime been a setback to the global campaign of improving the accessibility of medicines to the poor?

James: The initial reaction, looking mostly at the Ordinance that was proposed by the government, was extremely negative. The proposal included a number of provisions that were quite restrictive. The law that was actually passed by the parliament addressed some of these issues, particularly the narrowing of the grounds for patentability, which will reduce ever greening of patents, and the mandatory compulsory license on all mailbox patents that apply to products now being manufactured in India. This will give India a lot of experience with setting remuneration for patents on medicines. Also, according to Article 92 of the Indian law, India can easily issue compulsory licenses on new products, if it wants to. Today, the concern is not so much about the Indian law, but the political will in India to use the compulsory licensing provisions.

Centad: India has emerged as a big exporter of generic medicines to many small countries, especially in Africa and has helped them to fight epidemics and diseases at considerably less cost. Will the switchover to the product patent regime hamper this ability of India, once product patented medicines start entering the Indian market?

James: In the short run, nothing will change. But over time, it will depend upon the willingness of the government to protect its own poor. Novartis says it considers the Indian market to be 50 million people. The government will have to do something to protect the interest of the rest of the population who will not be able to afford medicines sold as a monopoly.

Centad: Will the provision of producing for export under the compulsory licensing regime, as provided in the new patent law, take care of this concern?

James: The Parliament fixed the problems with the export provision. For drugs now in the market, they will be about available for export. The big question will be the new drugs that are not yet manufactured in India. If India protects its own poor, the poor in other countries will also benefit. If India does not protect its poor, other countries will have to look elsewhere for suppliers. India is not the only country that is facing a test of political will. Brazil is yet to issue a compulsory license. Thailand is timid. China has not issued compulsory licenses. There are many countries that are unwilling to use the TRIPS flexibilities. At least India is starting with a large number of compulsory licenses on Mailbox patents, thanks to the amendments.

Centad: Do you envisage the possibility of big multinational pharma companies using the new Indian patent regime towards establishing strong monopoly power in one of the biggest pharmaceutical markets to the detriment of the poor of the world?

James: Of course, that is what the big pharma companies want. They not only want to charge high prices in India, a country they think of as potentially rivaling Canada or the UK as a market, but they want to eliminate India as a source of supply for cheap generics. The future will depend upon the strength of the Indian social movement. Will the poor in India persuade their own government to protect their interests?

Centad: How can civil society organisations focus their campaigns for improving the accessibility of medicines to the poor of the world in the context of the growing reality of product patenting of medicines under TRIPS?

James: The global battles have gone well. The local battles are largely ahead of us. In recent years, Brazil has threatened but not actually issued a compulsory license on a drug patent. China was pressured by the European Union and the USA to forgo compulsory licenses on drug patents in 2003. Thailand needs to move ahead. No member of the Bangui Agreement in West Africa has issued legal compulsory licenses yet. If these countries want cheap sustainable sources of generic medicines, they will have to face up to the need for a transparent and legal framework for generic medicines. One solution may be the creation of a global patent pool for essential medicines. The local social movement could pressure governments to issue compulsory licenses on patent owners who do not voluntary license to the pool, and the global social movements could directly pressure patent owners to license to the pool. By making it a big global project, it might be easier to obtain local action and buy-in.

■ James Love is Director of Consumer Project on Technology (CPTech), Washington DC, United States.
http://www.cptech.org

Patently in National Interests?

■ Robin Koshy

If the product patent regime leads to an era where even Indian domestic firms move on to more lucrative segments of the markets, then the repercussions on public health in the developing world could be catastrophic.

In 1977, Donald Smith and his father, Frank Smith, of Orlando, Florida secured the US Patent No. 4,022,227 for a hairstyle that would enable 'patients' with partial baldness to cover their pate by growing hair longer on the sides and combing it over. While the prevalence of this patently unflattering 'combover' style precedes the Smiths' patent, its popularity has remained unabated to this day.The Smiths have, however, failed to garner even a dime through royalty, despite the sanction of the law. An Ig-Nobel Prize for absurd and improbable research in 2004, with no monetary benefits, is the biggest reward they have yet got for their thought.

Not all frivolous patents go unrewarded. When such patents are in the realm of medicines and have a public health implication, then the reward for the patent holder can be at considerable costs to the larger public good. India has been the key protagonist of a long-drawn-out drama, to set in place a national patent regime that provides incentives for research and development (R&D), prevents abuse of patents and protects public interests (public health in particular) while meeting its international obligations under the Trade Related Intellectual Property Rights (TRIPS) Agreement. A stage show, that has had global and national audiences and actors comprising civil society groups, national and multinational pharmaceutical firms, least developed, developing and developed country governments; economists, lawyers and lawmakers.

From a simplistic and narrow pharmaceutical perspective, instituting a patent regime that is compliant with the TRIPS Agreement, required repealing the controversial feature of the Indian Patents Act 1970 that enabled process patents whereby domestic firms could develop generic copies of patented drugs by following a different manufacturing process.This needed to be replaced with a system that allowed product patents with 20-year validity for pharmaceutical products. Successive amendments of the Act in 1999 and 2002, an Ordinance in 2004 and the recent Amendment Bill in March 2005 have all been key milestones on the route to compliance. While campaigners for access to cheaper medicines express disappointment at amendments that exceed the requirements of the TRIPS Agreement, coalition equations and rediscovery of 'national interests' by political parties paved way for a final bill that was not as excessive as it could have been.

Several questions abound about the efficacy and impact of the new law. Is it all good and does it reflect a consensus of national interests, as the government believes? Will it be able to ensure affordable drugs and treatment in a country where the per capita health expenditure was as low as US$ 22 in 1998? Will the current Bill improve access to more effective treatments and drugs for diseases prevalent in India? Can the domestic industry cope with the opportunities and challenges that will arise?

Some Good, Mostly Bad?

Indeed, there are many broad positives in the new bill. Pre-grant opposition that would enable a member of public to challenge a patent application before it is granted has been restored.The process of issuing a compulsory licence (CL), that will enable the government to authorise a third party to produce a patented drug in the event of a national emergency (for example, a plague epidemic) has been sped up. Further, exports to countries

with inadequate manufacturing capacities are also permitted under CL. The bill also provides a measure of immunity to producers of generic versions of drugs that have application pending in the mailbox, from excessive royalty demands and litigation.

However, considerable ambiguities that could dilute the gains persist. Firstly, what can be patented (scope of patentability) under Section 2 of the Bill that accepts 'inventive step' as a feature that involves technological advance, economic significance or both, opens up possibilities for pharmaceutical firms to file patents for marginal improvements on known molecules or by merely citing economic potential. Not specifying pharmaceutical substance as a new 'chemical' entity could allow formulations, isomers and other incrementally modified drugs to be considered as new inventions. If one views the 8926 mailbox applications for patents that the Indian Patent Office received during 1999-2004 against the 274 new chemical entities that the US Federal Drug Administration approved during 1995-2004, it would be naive to conclude that we are in the midst of a pharmaceutical revolution. Evergreening of patents to extend monopoly rights by citing trivial advances, therefore, still remains a possibility.

Secondly, while the Bill allows for public and interested parties to oppose patents before they are granted, it is unclear whether challengers to patent applications will have access to all relevant information. What is clear, however, is that the controller of patents has the final say and contestants will have no room for appeal at the pre-grant stage.

Thirdly, producers of generic versions of new drugs in the mailbox can continue to produce them even after grant of patent, if they were producing them before 1 January 2005. These generic manufacturers who have made 'significant investment' will however, have to pay a 'reasonable royalty'. The subjectivity over 'significant investment' and 'reasonable royalty' opens them for interpretation. Besides, where a web of patents (patent thickets) covers a single pharmaceutical product, the prohibitive cumulative royalty that the generic producer might end up paying could make drugs frightfully expensive.

Fourthly, the Bill stipulates that applications for CL will be considered only three years after the grant of a patent. When better drugs that can save lives exist, the issuance of compulsory licences to ensure availability and affordability should have been weighed by public health concerns, albeit with justifiable royalties to the patent holders.

The Bill assigns considerable discretionary powers to the office of the Controller of Patents in framing rules and in deciding on pre-grant opposition. While such powers might enable faster decision-making process, it is worth debating whether the Patents Office has the requisite management, technical and infrastructural capacity to face up to the challenges that the new Bill brings.

A Consensus through Consultations?

Nevertheless, civil society organisations (CSOs), public health campaigners and the domestic pharmaceutical firms have been celebrating the minor gains that moderated the final Bill significantly from the December 2004 Ordinance. In all fairness, the turn of events that swayed the governments to incorporate some of the TRIPS flexibilities was perhaps more a fallout of realpolitik and political realignments than a willingness on the government's part to listen to civil society and public opinion. This is disconcerting. For one, in a democracy, defining and protecting national interest is not the sole preserve of the government. For all the competence that the government machinery might embody, public sentiments, even if India were insular to the pleas of other developing countries dependent on it for cheap generic drugs, needs to be respected.

Besides, popular opinion was not predominantly in favour of India reneging on its commitments, but to operate within the flexibilities that the TRIPS Agreement and Doha Declaration allowed to ensure access to cheaper medicines and drugs. In a country where public health expenditure was 0.9 percent of the GDP in 2002 (WDR 2004), 97 percent of the private expenditure on health is out of the pockets of patients (WHO, 1998), and less than 50 percent of the population have access to essential drugs or have been immunised (WHO, 1998), public health concerns need to be accommodated sufficiently while defining national interests.

Cheaper Drugs, Better Drugs?

Will the prices of drugs and healthcare rise? Kamal Nath, Union Minister for Commerce and Industry, has tried to allay fears of galloping drug prices by pointing out that 97 percent of the drugs are off patent and none of the drugs on the Essential Medicines List are on patents. Estimates of the value of drugs that would get into the product patent regime vary from US$140 million based on the Minister's figures to US$ 700 million according to the Pharmaceutical Research and Manufacturers Association of America (PhRMA). How much of these estimated values get transferred to the end-customer as a mark-up on price and by when, remains to be seen. India will have to plan ahead to establish a credible and comprehensive mechanism to monitor and enforce affordability

and accessibility of essential medicines, once they come under patents. Canada's Patented Medicines Prices Review Board that exclusively monitors the prices of patented drugs provides a model for emulation.

Will the current Bill improve access to treatment and R&D for new drugs in a largely poor nation with a high incidence of tropical and communicable diseases? Reverse engineering facilitated by the Indian Patents Act 1970 helped create a strong domestic pharmaceutical industry with the capability to develop cheaper generic versions of patented drugs. As a consequence the share of domestic pharmaceutical firms in India increased from 32 percent in 1968 to 77 percent in 2003 (UNCTAD, 2004). Although India accounts for only 1.5 percent of the global pharmaceutical market of US$ 480 billion, it accounts for an estimated 20 percent of the global consumption (Goldman Sachs, 2004). The difference in value and volume would indicate that Indian firms service the high volume–low priced segment of the market.

Domestic Industry to the Fore?

Can the domestic industry shift from being primarily a producer of cheap generics to a developer of proprietary drugs, new drug delivery systems and new chemical entities? India has several advantages. It has 64 United States Federal Drug Authority approved producing plants, the most outside the US. It has cheaper, yet highly skilled labour, low clinical trial and fixed asset costs. (UNCTAD, 2004) Indian firms, such as Ranbaxy and Dr. Reddy's are committed to increasing their R&D expenditure to 10 percent of their revenues from around 7 percent today (Economist, Sept 2003).

However, these advantages have to be put in perspective. Pfizer's global R&D expenditure of US$ 7.1 billion is roughly the size of the entire Indian pharmaceutical industry's domestic and export market. It is estimated that the industry spends up to US$800 million to bring a new molecule to the market (DFID Report "The Effect of Changing Intellectual Property on Pharmaceutical Industry Prospects in India and China", 2004). Even if money can buy more in India, drug development costs are astronomical. Which is perhaps why domestic firms, namely, Ranbaxy, licenses new discoveries to multinational firms for trial and development (Economist, September 2003). So long as this remains a viable strategy, R&D of these companies might focus on drugs that are relevant to the market of the multinational partner. Observers point out that even if R&D expenditure by Indian firms go up, it is likely to focus on areas where they can make quick money – diseases more prevalent in rich countries, such as cancer and diabetes. In 1999, only 16 percent of the R&D expenditure in India was spent on infectious and parasitic diseases prevalent here (DFID, 2004). Product patents will be beneficial to India if it leads to research and development for the supply of new drugs relevant to its disease profile.

For this to happen, Indian firms will have to buck the current trend and invest more in diseases such as AIDS, dengue, malaria and tuberculosis. Current figures are heavily skewed against poor man's diseases. The Commission on Intellectual Property Rights reported in 2002 that firms tend to spend on drugs that have a market potential of around $1 billion per annum or more, which is not often the scenario for drugs meant for developing country markets. Of the 1223 drugs introduced between 1975 and 1996, only 13 were aimed at tropical diseases. Only US$ 400 million of the US$70 billion spent on health research was spent on research on AIDS and malaria in 1998 (Sudip Chaudhari, 2003).

If the product patent regime leads to an era where even Indian domestic firms move on to more lucrative segments of the markets, then the repercussions on public health in the developing world could be catastrophic. Public policy initiatives to address this market failure have to be strengthened. Public-private partnerships, public investment in R&D, providing incentives to private firms for research could be some of the strategies. Bold approaches are also called for. The Institute for OneWorld Health, a US based not-for-profit pharmaceutical company follows an interesting model. It gets owners to donate intellectual property on drugs for diseases with huge public health impact but no market potential (for example, diarrhoea, which kills 2m people a year in developing countries), raises funds from donors and gets researchers to contribute their expertise, mostly for free.

Defining National Interests...

The US Special 301 Report of 2004 states rather unabashedly that the United States will advance its national interests in guaranteeing a higher degree of intellectual property protection through a variety of mechanisms including the negotiation of free trade arrangements and the use of Generalised System of Preferences. If the Indian government were ever to articulate its national interests in such a manner, it would be welcome to see it defining the accessibility and availability of drugs to millions of poor in India and elsewhere as one of the key guiding principles while administering the new patent regime. A patent regime that ensures access to new drugs for diseases prevalent here at affordable prices. And keeps innovative hairstyles and frivolous patents out.

■ Robin Koshy is Programme Officer with Centad. Views are personal. He can be contacted at robin.koshy@centad.org.

G20: The Road Ahead

Celine Charveriat Speaks to Centad

Centad: Today, the G20 has acquired a position in the multilateral trade negotiations that is much stronger than other existing or past coalitions. What makes the G20 different?

Celine: One distinctive feature of the G20 is that this alliance includes the political and economic heavyweights from the developing world. These key countries, especially Brazil, South Africa, India and China have forged an alliance at the highest political level that goes beyond the remit of the World Trade Organisation (WTO). They also seem to share a grand vision, which is to change the "geography of trade" and reduce the dependence of the South on the North.

Centad: The countries in the G20 are of varied nature and have different priorities. For instance, Brazil's interest in agriculture is diametrically different from that of India. How has the G20 been able to remain a cohesive unit in spite of these differences? Are there any apparent fissures that developed countries will try to exploit?

Celine: Any alliance which includes such a large range of members, from middle income agricultural exporters to net food importing least developing countries, is bound to have tensions, which will increase as agricultural talks proceed and details of market access commitments become more specific. But the G20 seems well aware of the need for continued unity to oppose a common front to the continuation of export dumping by developed countries. It is a matter of political necessity if they want to achieve any results in this area.

Centad: Some people argue that the G20 continues to speak in generic terms on different facets of agriculture, in particular, on market access issues of tariff reduction and special safeguard mechanism. Even the New Delhi Declaration does not say anything new. There is a wide divergence between the G20 members on these issues. Do you reckon that the G20 is avoiding the specificities of contentious issues to prevent the possibility of any rift between the countries in the G20?

Celine: There is a time for everything. At this stage of the market access negotiations, which are still blocked by AVEs, the G20 can easily hide its contradictions. But it is crucial that the alliance works on its internal dilemmas on market access so that the G20 can make joint technical proposals on market access when the time comes.

Centad: G20 has predominantly focused on agriculture. However there are indications that the G20 may also focus on issues such as Non Agricultural Market Access (NAMA) and Services. Will expanding the agenda of the G20 weaken the group and its existing position on Agriculture?

Celine: The G20 confirmed in New Delhi that it would not seek to achieve common positions on other issues. A larger mandate would have made it even more difficult if not impossible to reach consensus. However, the G20 is considering progress in other areas to guide its approach to the agricultural negotiations, which will be crucial to its success this year, as big trade offs will occur between agriculture, industry and services negotiations.

Centad: What role will political factors play in deciding the future of the G20? How will the strengthening trilateral axis between India, Brazil and South Africa (IBSA) and the political equations between Brazil and the US affect the G20?

Celine: Political factors will continue to play an important role, as well as progress in other areas such as the reform of the Security Council. What happens to regional integration in the Americas, and most specifically the Free Trade Area of the-Americas (FTAA), will also affect Brazil's strategy. How much and how this will affect the G20 still remains to be seen.

Centad: What should be the agenda of the G20 in the coming days in order to make the ongoing round of negotiations a truly development round?

Celine: To prevent another decade of dumping, the G20 should continue to push for effective reductions in trade domestic support, promote the rapid implementation of the cotton and sugar panels, and oppose any new renegotiation of the blue box by the United States. It should also ensure that market access commitments of developing countries are limited and flexible so that they do not threaten rural livelihoods and food security.

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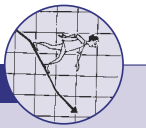
Key Agricultural Indicators of the G20 Countries, 2001

Compiled by the Centad Team

Country	Total GDP (US $ billion)	Agricultural GDP (US $ billion)	Agricultural GDP as a percent of Total GDP	Total Population (million)	Agricultural Population (million)	Agricultural Population as a percent of total population	Total Exports (US $ million)	Agricultural Exports (US $ million)	Agricultural Exports as a percent of total exports	Agri Imports (US $ million)	Agricultural Balance (US $ million)
Argentina	269	13	4.8	37	4	10.8	26,610	10,989	41.2	1,210	9,779
Bolivia	8	1	12.5	9	4	44.4	1284.8	400	31.1	234	166
Brazil	503	47	9.3	173	27	15.6	58,223	16,060	27.5	3,209	12,851
Chile	66	6	9	15	2	13.3	17,661.4	3,169	17.9	1,063	2,106
Guatemala	20	5	25	12	6	50	2,466	1,294	52.4	806	488
Paraguay	7	1	14.2	6	2	33.3	1,174	772	65.7	295	477
Philippines	71	11	15.4	77	30	47.1	32,664	1,444	4.4	2,429	-985
South Africa	113	4	3.5	44	6	13.6	28,996.7	2,255	7.7	1,217	1,039
Thailand	115	12	10.4	64	31	48.4	63,190	7,423	11.7	2,923	4,500
Indonesia	141	24	17	215	93	43.2	56,320.9	4,368	7.7	4,085	283
China	1,159	177	15.2	1,292	853	66	581,134.6	12,993	2.2	16,393	-3,401
India	477	120	25.1	1,025	545	53.1	44,292.9	5,282	11.9	4,062	1,220
Pakistan	59	15	25.4	145	73	50.3	9,238	1,020	11	1,519	-500
Nigeria	43	15	34.8	117	38	32.4	17,261	324	1.8	1,455	-1,132
Cuba	26	2	7.6	11	2	18.1	1,660.6	753	45.3	738	15
Zimbabwe	9	2	22.2	13	8	61.5	2,000	897	44.8	71	825
Mexico	618	27	4.3	100	23	23	83,000	7,631	9.1	10,830	-3,199
Egypt	98	17	17.3	69	25	36.2	7,068.2	628	8.8	3,222	-2,594
Tanzania	9	4	44.4	36	28	77.7	776.4	410	52	311	99
Venezuela	125	6	4.8	25	2	8	27,409	314	1.1	1,900	-1,585
G20	3936	509	12.9	3485	1802	51.7	1,062,432	78,426	7.3	57,972	20,952

Source:
1. G20 - Statistics, http://www.g-20.mre.gov.br/conteudo/statistics_01.pdf (Visited on 10 March 2005),
2. Compendium of food and agricultural indicators-2004 at http://www.fao.org/es/ess/compendium2004/list.asp (Visited on 10 March 2005)
3. Centad's calculations



Fair Trade: For Better or Worse?

■ Robin Koshy

In 2003, the United States exported 3.8 million tonnes of rice, making it the third largest exporter in the world, trailing only behind Thailand and Vietnam. This is despite the fact that it costs twice as much in the US to grow rice than it does in the other two countries. Such sterling export performance has been aided by the US$ 1.3 billion (72 percent of the total cost) that the American rice farmers got as subsidies in 2003! (Oxfam Briefing Paper 72 : Kicking Down the Door, 2005)

Not all countries can afford to bankroll their way to a comparative advantage in trade, especially when there is none. Certainly, not the developing countries. The dictum of classical economic theory where trade specialisation takes place according to comparative advantages is out of operation in a trading architecture riddled by trade distorting domestic support and high tariff boundaries. Will free trade that removes these distortions especially in developed countries, restore comparative advantages of developing countries in agricultural commodities, increase their export earnings, boost wages of their unskilled labour and stimulate economic growth in general?

Arvind Panagariya of Columbia University, thinks otherwise. His conclusions are born out of the fact that most of the least developed countries (LDCs) are net importers of agricultural commodities – 45 of the 49 LDCs import more food than they export. In his paper, 'Agricultural Liberalisation and the Developing Countries: Debunking the Fallacies' (2004), he contents that if subsidies are removed, the net importers will end up paying more for food. This loss will not be offset, unless they can become sufficiently large net exporters. Cut in rich country subsidies will therefore benefit only big agricultural exporters such as Brazil and Argentina, while most LDCs will be worse off than they were before. Although his arguments are not backed by substantive empirical analyses, some other studies estimate that larger countries will benefit, while smaller countries in the same regions will suffer (for example India will benefit, while the rest of South Asia will lose out). If poor countries emerge as net losers, it could stem their enthusiasm for the Doha Development Agenda and jeopardise liberalisation of trade in future.

Therefore, he argues that the poorest nations are better off with high domestic subsidies in developed countries so long as they get preferential access, while larger developing country exporters are kept out by high tariffs. He cites the European Union's Everything but Arms (EBA) initiative (or more precisely, Everything but Arms, Bananas, Rice and Sugar initiative!), that gives duty and quota free access for LDCS to sell at the high prices prevalent in the EU markets.

William Cline of the Centre for Global Development draws diametrically different conclusions about the impact of trade liberalisation on the basis of his empirical analysis and economic modeling in his book 'Trade Policy and Global Poverty' (2004). He argues that liberalisation of agricultural markets is the most important way to reduce global poverty as three-fourth of the world's poor (living on less than US$2 a day) are in rural areas. Rural poor are more likely to be dependent on farming and any increase in export opportunities will increase their income. The gains of the rural poor will outweigh the losses of the urban poor and there will also be a redistribution of income from cities to villages. Cline estimates that global free trade could increase agricultural prices by 10 percent, hike real wages of unskilled labour in developing countries by 5 percent and boost global economic welfare of developing countries by $90 billion annually. This, he estimates could pull 200 million people out of poverty, or 650 million people, if one factors in capital investment and a longer term period of 10-20 years. Welfare gains are highest from liberalisation of agriculture, followed by textiles and apparels.

The US$90 billion that developing countries could gain will dwarf the US$ 50 billion that developing countries receive as aid. Yet another argument, in favour of freer and fairer trade over aid and preferences. Interestingly, this corroborates Oxfam's calculation in its trade report in 2002 (Rigged Rules, Double Standards) that put the loss to developing countries due to rich country trade restrictions at US100 billion a year. Cline cites evidence that only a sixth of the world's poor live in the net food importing countries and estimates that over 130 million people could be pulled out of poverty in India and China alone. If this were put in the perspective of the global target of halving poverty by 2015, it would reflect significant advances in the two biggest battlefields. Here, one of Pangariya's arguments merits consideration – trade

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Demystifying TRIPS and Public Health

■ Centad Team

Is the agreement on Trade Related Aspects of Intellectual Property Rights (TRIPS) within the World Trade Organisation (WTO) in conflict with public health concerns?

Yes, the TRIPS Agreement is in conflict with public health concerns such as accessibility to medicines. The fundamental idea behind the TRIPS Agreement is that the inventors should be allowed to patent rights in order to foster research and development. People would be encouraged to innovate and invent only if they are assured of protection in terms of having the exclusive right over the invented product or process. This gives the patent holder a monopoly right to reap benefits of his intellectual property. However, such a right over a medicine or a drug may lead to a situation where the patent holder sets the price at such high levels that the medicine is out of the reach of common people. Hence, the conflict between TRIPS Agreement and public health concerns.

What are the flexibilities in the TRIPS Agreement to take care of the public health concerns?

The TRIPS Agreement provides some flexibilities to take care of the public health concerns. The Agreement allows member countries of the WTO to permit non-patent holders to manufacture patented drugs and medicines (compulsory license). It also allows governments to manufacture patented drugs or medicines for public non-commercial purposes without the approval of the patent holder (government use). However, the Agreement states that certain conditions need to be fulfilled while issuing compulsory licenses to safeguard the interests of the patent holder. For instance, an effort must have been made to obtain a voluntary license on reasonable commercial terms. Or, the patent holder should be paid adequate remuneration in each case taking into account the economic value of the license.

About TRIPS Agreement

TRIPS Agreement establishes minimum level of protection that each member country in the WTO has to give to the intellectual property of fellow WTO member countries. The areas covered by the TRIPS Agreement are – Copyright and related rights, Trademarks, including service marks, Geographical Indications, Industrial Designs, Patents, Layout-designs (topographies) of Integrated Circuits, Undisclosed Information, including Trade Secrets.

The Agreement recognises the right of countries to take measures against anti-competitive practices. In cases of anti-competitive practices, the agreement provides more flexible conditions to grant compulsory licenses such as relaxing the condition of paying adequate remuneration.

Do these flexibilities imply that any conflict between the rights of the patent holder under the TRIPS Agreement and public health concerns can be resolved amicably?

In spite of the flexibilities given in the agreement, there are concerns about the conflict that could arise while interpreting the rights of the patent holder and public health concerns. The Doha Declaration on TRIPS and Public Health, adopted at the WTO's Fourth Ministerial Conference in Doha on 14 November 2001, endeavoured to bring about clarity on this issue. This declaration was a major step towards resolving the conflict between TRIPS and Public Health. Following were the important features of the declaration:

- The TRIPS Agreement does not and should not stand in the way of member countries from taking measures to protect public health.
- The TRIPS Agreement must be implemented and interpreted in a manner that supports public health. Hence, any conflict between public health and the rights of the patent holder while interpreting the TRIPS Agreement should be settled in favour of the former.
- Each country is free to determine the grounds on which compulsory licenses can be issued. Any emergency kind of situation is not the prerequisite for issuing compulsory license. Further, on parallel imports, it states that a country's practices in parallel imports cannot be challenged in the dispute settlement system of the WTO.

However, it is important to remember that compulsory licenses come at a price. When a country issues a compulsory license it has to pay 'adequate remuneration' to the patent holder. The Agreement does not specify what 'adequate remuneration' means.

How are the public health concerns of the Least Developed Countries (LDCs) addressed in the TRIPS Agreement?

The TRIPS Agreement addresses the public health concerns of LDCs by providing longer transition periods to comply with the

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TRIPS and Public Health Jargon

■ Centad Team

Patent

An exclusive right to bar competitors from manufacturing, using, marketing, selling or importing a product invention or an inventive process for a fixed period of time, say, 20 years. For a patent to be granted, the invention must be new, non-obvious and have industrial application. Patent rights are territorial and are generally granted on a national basis. The rationale for patents arises out of the need of the inventor to recoup the costs sunk in research and development (R&D). It also provides incentives for R&D in future.

Patents can be of two types – Product Patent and Process Patent. A product patent grants exclusive rights relating to a product that involve a non-obvious inventive step, whereas, a process patent grants exclusive rights to the means of manufacturing a product.

Generics

A drug that is a bio-equivalent of an original drug that is either on or off patents. It contains the same active ingredient and hence interchangeable with the originator product. United Stated Food and Drug Administration (USFDA), for example, requires a generic drug to be the same as a branded drug in dosage, safety, strength, quality, mode of working, mode of consumption and usage.

Mailbox

After the TRIPS Agreement came into force 1 January 1995, developing countries like India were allowed a 10-year interim period to establish a national patent regime compliant with the TRIPS Agreement. Since India did not historically have a product patent regime for pharmaceutical products, an interim holding cell for product patent application in this field was received. Therefore, a mailbox was set up under the first amendment of the Indian Patents Act in 1999, at the Indian Patent Office to receive these applications for pharmaceutical product patents. This mailbox was opened after India became TRIPS compliant on 1 January 2005 through the Patent Ordinance issued by the government in December 2005.

Data Exclusivity

Data exclusivity is a measure that prevents the Patent Office (regulatory agency) from using the data in a pharmaceutical innovator's patent registration file for a specific period of time, to assess an application from a generic competitor seeking approval to sell a similar, competing drug.

When a generic application for a drug is made, the Patent Office can eliminate unnecessary animal and human trials of the drug, as it would already have been done for the innovator's drug. The regulators can instead evaluate the application against the data in the innovator's registration file. If a data exclusivity clause is in place, then this evaluation can be done only after the period of data exclusivity is over. If the data exclusivity is for say, five years, then it guarantees the innovator company exclusive control of the market for about eight years as it could take up to three years more for that generic producers to register and market a generic version. Data exclusivity is not data protection as the patent holders files are anyway protected by copyright laws and are never released by the Patent Office to third parties.

Pre-grant and Post-grant Opposition

The Right of a member of public or an interested party to oppose the grant of a patent while it is being processed by the Patent Office. The third Patent Amendment Bill in India has restored pre-grant opposition, although there is no right to appeal at this stage. Pre-grant opposition is useful in weeding out frivolous patents, although the challenger might not have access to adequate information.

Post-grant Opposition grants a similar right to oppose a patent after it has been granted. At the post-grant stage, complete information on the patented product is available, making the challenge more informed. Right of appeal is available at the post-grant stage, although delay in judicial processes can result in a patent holder enjoying a wrongful monopoly. India now has both pre-grant and post-grant opposition.

Compulsory Licence

A compulsory license is a licence granted by the government to use patents and other types of intellectual property to intervene in the market in the event of a market failure – i.e. patented products not being available in right quantities or at affordable prices or in the case of a national emergency (say, a plague epidemic).

Evergreening of Patents

A strategy adopted by pharmaceutical companies to take advantages of loopholes in the definition of what can be patented (scope of patentability) to obtain separate patents for multiple attributes of a single product or by citing marginal improvements in the original product. If the scope of patentability does not specify that patents will be granted only for 'new chemical entity' then pharmaceutical firms can file patent applications for incremental improvements and thereby

extend the exclusivity guarantied by the patent for another 20 years. If a new use of a known drug is also a criteria for grant of patent (say, if aspirin, a medicine for headache can also control high blood pressure), then a patent can be secured for this new application. Evergreening extends the period of exclusivity guaranteed by patent to the drug, thereby blocking out the entry of cheaper generic alternatives into the market.

Patent Thickets

A scenario where several patents cover a single pharmaceutical product. These patents can be for the individual chemical entities that go into the product and could be held by different pharmaceutical firms. A competitor wanting to produce a generic version of the drug will have to negotiate individually with each firm and pay royalty for each entity. The cumulative royalties of all the patents (royalty stacking) will significantly add to the price of the generic drug.

Exclusive Marketing Rights

Issuance of exclusive marketing rights is a transitory arrangement in countries that did not have product patents for pharmaceutical products at the time of the TRIPS Agreement. Suppose, a firm is granted a patent and marketing approval for a pharmaceutical product in a WTO member country, say United States. Then it can be granted the sole authority to sell that product in another country, say India, for a period of five years, provided it gets marketing approval in India as well.

Parallel Imports

Import of a patented drug sold cheaper in another country, without the approval of the patent holder in the domestic country.

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Fair Trade...

liberalisation has adjustment costs that could impact smaller and poorer countries more. Hence, compensation programmes need to be designed smartly to factor these costs in and prevent these countries from being disenchanted.

However, to cite these adaptation pangs and static losses to net food importing countries as reasons enough to preserve status quo and debunk trade liberalisation where it is needed most, is strange. As strange as the American comparative advantage in rice. Moreover, it cannot be ignored that many LDCs are net food importers today due to pressures from beyond their borders. Rice imports to Haiti, an LDC, increased by 150 percent between 1994 and 2003 after the International Monetary Fund forced it to cut rice tariffs from 35 percent to 3 percent. Ironically, three out of four plates of rice consumed in Haiti today come from the US, much to the impoverishment of Haitian rice farmers.

Panagariya, A., 'Agricultural Liberalisation and the Developing Countries: Debunking the Fallacies'.

Cline, W., 'Trade Policy and Global Poverty' , Centre for Global Development, 2004

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Demystifying TRIPS...

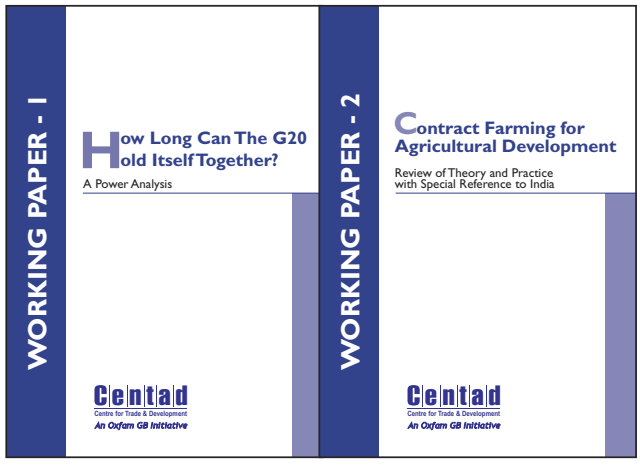
Agreement. The Agreement provides a time period of 10 years from the date of application of agreement to LDCs to apply the provisions of the Agreement. Further, LDCs do not have to comply with provisions related to patenting of pharmaceutical products till 1 January 2016.

LDCs rely on big developing countries (Brazil, India etc.) to meet their domestic demand for generic drugs. However, as these countries switch over to a product patent regime for pharmaceutical products, the imports of these cheap generics can be affected. The 30 August 2003 decision of the General Council of the WTO was addressed towards finding a solution to the problems of availability of cheap generics in these countries and other developing countries that have insufficient or no manufacturing capabilities in pharmaceutical sector. Such countries could notify the TRIPS Council of its intention to use the compulsory licensing regime as an importer. Once such a notification has been made, any country that possesses the manufacturing capability could issue a compulsory license for exports to the notified country.

Do national patent legislations of member countries of the WTO have a role in the debate surrounding TRIPS and public health?

The role of national patent legislation of different countries is very important. Countries in their national patent legislations should make use of the flexibilities given in the TRIPS Agreement and frame their laws in such a manner that gives precedence to public health concerns over the rights of individual patent holder. The Doha declaration clearly states that the TRIPS Agreement is to be implemented and interpreted in a manner that supports public health. National legislations of individual countries should not provide for 'TRIPS plus' obligations (obligations that go beyond the requirements of the TRIPS Agreement) such as granting of compulsory license contingent to an emergency or disallowing the grant of compulsory license within first three years from the date of grant of patent.

About Centad



Established by Oxfam GB, the Centre for Trade and Development is a not-for-profit organisation that seeks to strengthen the ability of governments and communities to make trade and globalisation work for development through policy research, advocacy, and promotion of informed public debates.

The last five to six decades have witnessed an unprecedented growth of global interdependence created by the explosive flow of goods, services, people, capital and ideas across borders. Reduction of barriers, advances in technology and implementation of radical ideas have catalysed this global integration of markets, and mobility of capital and information.

For developing nations to harness the opportunities that trade presents, they need to go beyond debates of whether globalisation can be reversed and whether trade is necessary. More importantly, they need the capacity to protect their interests in multilateral trade engagements, provide logical policy suggestions and build a wide network of stakeholders for dialogue and advocacy.

However, glaring gaps exist in terms of access to relevant information, policy advice based on sound research and the presence of a wide segment of stakeholders who understand trade and can engage in a meaningful dialogue. While the establishment of the World Trade Organisation (WTO) has galvanised civil society action and debates on trade, there is still a need to demystify the arguments around the current processes of trade and development.

For these gaps to be addressed, there is a need to connect and enrich high-level policy research, negotiations and advocacy with experiences of people and their organisations at the grassroots. Centad will attempt to address these gaps by:

- Developing a comprehensive knowledge centre on policy issues related to trade and development and building networks with other such centres across the world.
- Providing well-researched and cogently argued policy advice to governments on the linkages between trade and development.
- Creating a platform for CSOs to share, debate and advocate on relevant and emerging issues of trade and development.
- Building the capacities of CSOs, private sector, trade unions, media, parliamentarians to understand and articulate debates around trade and development.
- Educating the public to demystify the debates around trade and development.

Key Activities

1. Undertake policy-oriented research on trade and development.
2. Publish policy papers and briefing documents.
3. Establish a contributory Trade and Development Report for South Asia.
4. Organise seminars and fora for sharing knowledge and advocating on key policy issues.
5. Engage with policy-makers to advocate and lobby for change at national as well as global levels.
6. Develop a comprehensive, interactive website.

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