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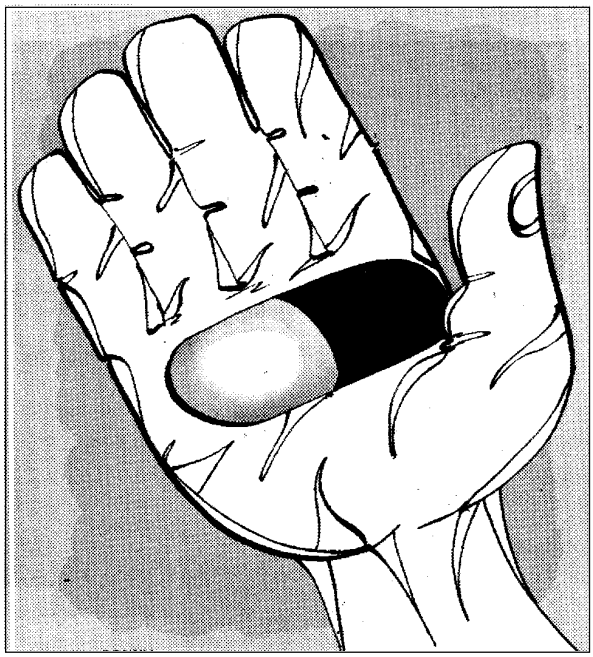
**Research Report**

# TRIPs and Public Health: Ways Forward for South Asia



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# TRIPs and Public Health: Ways Forward for South Asia

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# TRIPs and Public Health: Ways Forward for South Asia

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# PREFACE

Trade Related Intellectual Property Rights (TRIPs) has always been one of the most contentious issues in the WTO. A multilateral agreement was signed at the end of the Uruguay Round despite the reluctance by many developing countries such as India, Brazil etc. The growing significance of intellectual property rights (IPRs) is posing policymakers with difficult questions regarding the precise limits of state authority in respect of public health governance structures against the background of global private networks.

Many studies have been undertaken on the political economy of the WTO and Trade Related Intellectual Property Rights (TRIPs). Are developing countries nothing more than mere facilitators for the global network of private interests? Or do governments have to re-define the way they have traditionally conceived their public health role and the mechanisms through which they are realised? These are some of the pressing issues that policymakers face in developing countries today when addressing critical public health problems.

"The argument for intellectual property protection is that it costs money to invent knowledge and that the widespread diffusion of knowledge once secured is also desirable. We have here the economist's trade-off that more intellectual property protection means more knowledge, but it also reduces diffusion. The social optimum lies somewhere in the middle, as often", says Prof. Bhagwati, a noted trade theorist.

According to the Commission on Intellectual Property Rights (CIPR) new study "Integrating Intellectual Property Rights and Development Policy", the global expansion of IPR was unlikely to generate significant benefits for most developing countries. It is most likely to impose high costs such as highly priced medicines and seeds, making poverty reduction more difficult. In addition, it would also increase cost of access to many products and technologies, diminishing the degree of competition worldwide for many products and services.

Poor countries have been suffering at the hands of the patent holders ever since the TRIPs agreement came into being. Increasing realisation of this fact resulted in signing of a separate declaration on TRIPs Agreement and Public Health at Doha. The declaration acknowledges the primacy of the member countries' right to protect public health and promote access to medicines for all. The declaration was but a pyrrhic victory for developing countries.

The author of this paper has tried to utilise the available documentary research to answer one specific question: what genuine choices do policymakers in South Asian developing countries now have, following the link between the trade regime and pharmaceuticals. It is the central contention that the flexibilities within TRIPs provide the best guarantee for addressing some of the adverse consequences for public health management in the light of growing significance of IPRs to the pharmaceutical industry.

The paper begins with a brief overview of the key features of the corporate business model of pharmaceuticals. The establishment of complementary market structures and industrial policies are part of the process through which industrialised countries in particular have oriented their domestic and foreign economic policies towards exploiting the knowledge economy. At the same time this paper provides some insights into the challenges faced by governments in South Asian countries.

The aim here is to anchor the present discussion of public health and the impact of TRIPs in the socio-cultural environment of this region. There is a critical need for greater research and documented studies regarding the public health infrastructure in these countries. Even the limited studies on public health governance in India tend to provide a limited overview of the multiple effects of globalisation and it is unclear the extent to which there is a clear political commitment towards adopting pro-poor policies with regard to reducing the barriers to access in essential medicines.

This paper has been written before the current imbroglio on TRIPs and Public Health, which resulted after the US insisted on very limited coverage of number of diseases under the window of compulsory licensing and the power of poor countries to import them if they did not have a domestic manufacturing capacity.

**Jaipur**
**April 2003**

**Pradeep S Mehta**
**Secretary General**

# *SECTION I*
# THE NATURE OF THE PROBLEM IN PUBLIC HEALTH: SOME PRELIMINARY THOUGHTS

Global public health governance is very much in the public spotlight.[1] This is largely the result of high profile actions by the US government and multinational companies to assert their dominance and competitive advantage in the pharmaceutical industry.[2] For example, the United States Trade Representative (USTR) was instrumental in exerting international and bilateral pressures on Brazil, Thailand and South Africa to adopt stringent intellectual property standards.

Brazil, for example, was hauled to the dispute settlement machinery in the World Trade Organization (WTO).[3] This action was a response to the decision of the Brazilian government to increase supplies of its generic medicines to address the AIDS/HIV epidemic. Brazil was handed to the dispute settlement body in the WTO because of its decision to increase supplies of generic medicines to address the AIDS/HIV epidemic. The USTR led initiative was prompted by PhrMa concern that this practice would lead to a serious erosion of its profits from sale of its blockbuster drugs, which were currently on patent.

***Brazil was handed to the dispute settlement body in the WTO because of its decision to increase supplies of generic medicines to address the AIDS/HIV epidemic. The USTR led initiative was prompted by PhrMa concern that this practice would lead to a serious erosion of its profits from sale of its blockbuster drugs, which were currently on patent.***

Last year the concerted efforts by multinational pharmaceutical companies to prevent the South African government from accessing viable alternative supply systems floundered in the domestic court.[4] Two years ago Glaxo and SmithKline (GSK) threatened CIPLA with a lawsuit. It was alleged that the Indian pharmaceutical corporation was supplying the South African government with generic supplies of products, which were manufactured in breach of GSK's patents.

Each of these events is suggestive of a growing trend where the emerging private networks of commercial interests are now encroaching on the traditional measures employed to address the critical needs in public health. Access to essential medicines can be affected by a number of factors. The asymmetries in information regarding health needs, government procurement policies, implementation of national drug policies, inadequate public health infrastructure, national wealth and barriers raised by IPRs, individually and cumulatively pose challenges to public health governance.

Public health management involves addressing the multiple effects of the above factors and due consideration needs to be given to adopting measures in other forums like policymaking in housing, environment, food and health safety, sanitation and education. The TRIPs debate and the concerns about access raise one set of problems. This agreement draws in public health into the global trade regime by emphasising the norms and values of the dominant supply model of OECD countries. This model attempts to solve one logistical problem, i.e., to make available to all governments a sustainable and affordable supply system.

The efforts to establish linkage between the trade regime and the orthodox model of public health (which is based on a set of voluntary rules at international level and government's standard setting role) resulted in policymakers intensifying tensions amongst Member States in the WTO. It is, therefore, meaningful to examine the corporate pharmaceutical supply chain and to evaluate the extent to which the patent system and the industrial policies impede access to medicines. The paper also focuses on the constraints imposed by TRIPs in enabling developing countries to access alternative supply systems to ensure access to affordable medicines.

| **Comments** |
| --- |
| 1. Public health governance ceases to be purely a domestic issue.<br><br>2. Access to essential medicines can be affected by a multiple set of factors, which increases challenges for public health governance.<br><br>3. Developing countries need to understand the dynamics of the OECD pharmaceutical business model so that its policymakers will be better able to formulate policy proposals based on an appreciation of the necessary trade-offs this process entails. |

## *SECTION II*
# THE OECD CORPORATE PHARMACEUTICAL MODEL AND PUBLIC HEALTH

Policymakers are now discovering that by requiring Member States to implement TRIPs obligations, the WTO is posing, to both developing and developed countries, a set of questions previously unexplored in international trade law. We can preface this point with four brief points, which seem to be marginalised in debates on TRIPs.

First, that public health is a concept, informed by political and economic considerations. Policymaking in public health has generally been accorded lower priority than other national issues like defence, trade, telecommunications and services. It would be more accurate to say that pro-poor health policies have generally been marginalised as a priority issue when compared with other demands made on national governments. Broadly speaking, there is a consensus amongst most governments that capitalism and the market mechanism best guarantee economic prosperity. Public health goals have largely been measured in terms of economic prosperity of the nation as a whole and in turn, to shift the responsibility for health security on the individual.

***Policymaking in public health has generally been accorded lower priority than other national issues like defence, trade, telecommunications and services. It would be more accurate to say that pro-poor health policies have generally been marginalised as a priority issue when compared with other demands made on national governments.***

Globalisation exposes some of the shortcomings of adopting this approach to public health management. Interestingly, it is the pharmaceutical industry and multinational corporations that are becoming the subject of anger and disillusionment. However, there is nothing new as the history of public health reforms in the UK reminds us of similar occurrences during the post Industrial Revolution era. That said, a feature we now discover in the contemporary era, particularly in advanced democracies, is the prevalence and intensity of opposition in domestic politics as well as increasing participation by non-governmental organisations in subjecting public health policymaking to greater scrutiny.

Secondly, despite the political rhetoric, with increasing pressures on public resources, there has been a clear policy shift, irrespective of political affinities, in replacing welfarism and collectivism with individual responsibility. Public choice theorists argue that governments, in formulating their national policies, are motivated less by concerns about those who constitute a minority in the electoral register and more about appealing to the majority, who tend to comprise the working and affluent classes in society. Given this, the issue of access to medicine affects a small minority in the population. Therefore, it is not surprising that calls for a more socially responsible approach to public health are usually made by charitable and non-profit making organisations like Oxfam, ActionAid and MSF.

***The issue of access to medicine affects a small minority in the population. Therefore, it is not surprising that calls for a more socially responsible approach to public health are usually made by charitable and non-profit making organisations like Oxfam, ActionAid and MSF.***

Thirdly, governments have largely delegated their responsibilities for research, development and distribution to the private sector. Indeed, public health management is largely directed towards maintaining the integrity of the

corporate supply chain in ensuring its viability. This is important since the interposition of the price mechanism defines the primary avenue through which medicines are now accessed.

Fourthly, it cannot be emphasised sufficiently that public health management requires government investment and commitment, if the *causes* of the current problems are to be addressed.

It would be appropriate to begin by providing an account of the corporate pharmaceutical model since the present focus of the TRIPs Council and the Doha Declaration revolves around some of its adverse implications for public health governance in developing countries. This supply system is constructed around market norms and values. The corporate mode is a commercial medium designed to make available new medicines to the State in exchange for health goods being characterised as private goods. The premise behind this characterisation is instrumental in condoning one of the primary objects of the corporate vehicle, which is to make a profit.

***The corporate mode is a commercial medium designed to make available new medicines to the State in exchange for health goods being characterised as private goods. The premise behind this characterisation is instrumental in condoning one of the primary objects of the corporate vehicle, which is to make a profit.***

Whilst dominance and control over the supply chain can be achieved through contractual and licensing arrangements, it does not resolve the problem of 'free riders'. Since technology enables the intangible value to be replicated at well below the marginal cost, the viability of the business model is dependent on capturing knowledge in the public domain. The patent system reflects the trade-off that is made in enabling the pharmaceutical industry to avail itself of this private rights system.

Before examining this system in more detail and its implications for pharmaceuticals, we can briefly summarise some of the key outcomes of situating health as a public good in the private sector:

First, the view that the market and the private sector are creators of wealth resulting in an increase in prosperity is reflected in the emphasis by OECD countries on the economic aspects of deregulation and privatisation of the pharmaceutical sector.

Second, the obligations on the government to discharge their role as a custodian of public health is now limited to facilitating the process of establishing a sustainable and affordable supply system. The role of governments in investing in the development of new drugs is not entirely clear.

***Privatisation and deregulation policies adopted by OECD industrial economies during the 1970s significantly contributed to the ability of the private sector to maximise the potential of the knowledge economy in the pharmaceutical sector. At the same time, considerable structural adjustments were made to ensure that universities and their research departments provided a critical mass of skilled workforce.***

Privatisation and deregulation policies adopted by OECD industrial economies during the 1970s significantly contributed to the ability of the private sector to maximise the potential of the knowledge economy in the pharmaceutical sector. The leading countries like the US, Japan, the UK, Germany and Switzerland invested heavily in the knowledge industry. It is estimated that investment in the knowledge economy by OECD countries, between 1972 and 1991, rose from 1.80 percent of GDP to 2.25 percent of GDP.[5]

At the same time, considerable structural adjustments were made to ensure that universities and their research departments provided a critical mass of skilled workforce and partnerships with the pharmaceutical industry were established.[6] Universities in the US, for example, permitted their researchers to direct their research towards capturing the value in knowledge rather than regard collaborative research and knowledge creation as an end in itself. The pharmaceutical industry has asserted, however, that the patent system and

market norms have directly contributed to its ability to develop and market new medicines.[7] Some doubt the causality between the market and the patent system.

In a report issued by the United Nations Development Programme (UNDP), it is suggested that considerable public assistance and investment have accelerated the process whereby R&D in pharmaceuticals has been successfully converted into medicines made available in the market.[8] For example, government assistance and involvement by educational institutions have been noted in the development of at least 70 percent of new medicines brought into the market.

***Public taxation, tax credits and subsidies on R&D have been employed by OECD countries to assist the pharmaceutical industries at various stages of the R&D process. It is said that some $106mn were made available during 1983 and 1993 through the tax credit system of public taxation.***

Public taxation, tax credits and subsidies on R&D have been employed by OECD countries to assist the pharmaceutical industries at various stages of the R&D process.[9] The US government provided financial backing to the pharmaceutical sector for undertaking R&D into some of the key diseases.[10] It is said that some $106mn were made available during 1983 and 1993 through the tax credit system of public taxation.

Third, by characterising medicines as private goods, the governance structure set in place by governments makes no allowance for the concept of essential medicines. Access to essential medicines is determined by the same norms as those which apply to all consumables. The government's role is restricted to formulating and implementing public health policies and ensuring that the integrity of the supply chain is not compromised by self-seeking conduct. Control of the supply chain is, however, left with the pharmaceutical industry. Medicines have to be purchased, as would be the case with any private goods. The only difference being that given the particular characteristics of the health goods, it can only be accessed through prescription or direct purchase over the counter from certified health providers.

Fourth, the cognate of the minimal role of the government is that the primary responsibility for development, manufacture, distribution and sale is left with private sector.

**Comments**

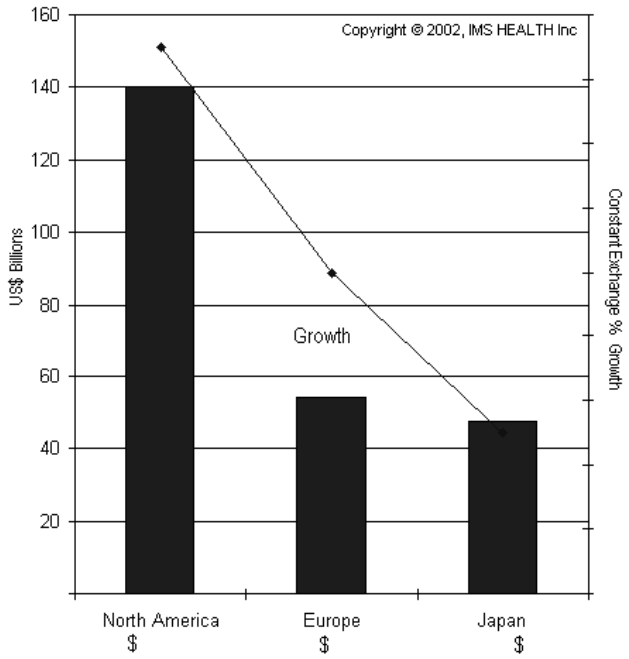
1. Market structures and industrial policies complementing the corporate pharmaceutical model involve a trade-off. Right holders of patents are now capable of asserting proprietary interests over the goods and intangible value. In return of a brief monopoly over the use of the invention the State is provided access to the relevant information and a legitimate expectation of an affordable and sustainable supply system being made available.

2. Since medicines are now characterised as private goods, access to health goods and the medicines produced are determined by market forces and the price mechanism. The market does not discriminate between ordinary medicines and those, which are necessary to avert fatalities and other adverse health consequences.

3. Without considerable public investment by OECD industrial countries the pharmaceutical industry would not have been able to develop and introduce many of the drugs.

It is claimed that the economies of scale and control over the supply chain are critical to ensuring the viability of the corporate pharmaceutical model. The use of the private sector to supply health goods has also led to the emergence of a lucrative industry. Global sales have now reached an estimated US$1.3tn.[11]

**Figure 1: Regional Breakdown of Sales in US $ Billions (12 months to January 2002)**




*Source:* IMS Health's Drug Monitor, 2002

Central to the viability of the corporate pharmaceutical model in developing new medicines is the patent system. The importance attached by the industry to this property regime is illustrated by the fact that transnational corporations like Merck, Pfizer, Glaxo-Welcome and Bristol Myers, not only own the majority of the patents but they are now the key actors in the global pharmaceutical industry. The only South Asian developing country which has any viable industry is India, having ranked 17th.

***Merck, Pfizer, Glaxo-Welcome and Bristol Myers, not only own the majority of the patents but they are now the key actors in the global pharmaceutical industry. The only South Asian developing country which has any viable industry is India, having ranked 17th.***

The relationship between competitive advantage and dominance in the supply chain on the one hand, and the patent system on the other can be elaborated further. The patent system is the creation of political patronage. The availability of this private rights system is based on the premise that without appropriate incentive systems and control over the knowledge created during R&D a sustainable and affordable system of medicines would not be made available by the private sector. For example, the pharmaceutical sector unlike other sectors is resource intensive and time consuming. It is generally understood that the discovery to market phase can at times take up to 6.5 years and results in some cases, the R&D cost of US$300mn.[12] Doubts have been expressed whether high costs have been the result of extensive marketing and advertising incurred.[13] This is contradicted by the pharmaceutical industry who claim that the high prices charged for its medicines reflect the costs of R&D.

| Table 1: Selected Exporters of Medicinal and Pharmaceutical Products in the World | | | | | |
|---|---|---|---|---|---|
| **Countries** | **1994** | **1995** | **1996** | **1997** | **1998** |
| Germany | 8739.1 | 10268.3 | 10711.8 | 11655 | 14036.7 |
| United Kingdom | 6080 | 7720 | 8320.1 | 8940.2 | 9666.6 |
| Switzerland | 6324.9 | 7589.8 | 8411.2 | 8208.5 | 9854.4 |
| USA | 6184.5 | 6554 | 7330.1 | 8230.5 | 9660.8 |
| France | 5415.4 | 6864.4 | 7244.7 | 7900.8 | 9314.5 |
| Belgium | 3333.1 | 4120.6 | 4301.6 | 4885.5 | 5481.8 |
| Italy | 2759.3 | 3630 | 4299.3 | 4430.3 | 4897.8 |
| Netherlands | 2780.7 | 3973.8 | 3437.9 | 3770.6 | 3519.6 |
| Sweden | 2467.5 | 2546.2 | 2943 | 3057.6 | 3567.5 |
| Ireland | 1847.6 | 2105.8 | 2782.8 | 3356.7 | 4745.4 |
| Denmark | 1615.1 | 2160.8 | 2214.6 | 2272.4 | 2213.3 |
| Japan | 1547.9 | 1843.7 | 1889.4 | 1952.4 | 1915.1 |
| China | 1185.3 | 1582 | 1516.1 | 1536.2 | 1692.3 |
| Spain | 1061.2 | 1164.9 | 1414 | 1516.9 | 1702.6 |
| Austria | 1054 | 1333.7 | 1374.5 | 1324.9 | 1343.1 |
| Hong Kong, SAR | 832.9 | 975.3 | 1020.1 | 967.5 | 882.4 |
| India | 585.8 | 724.2 | 814 | 947.2 | 901.1 |
| Canada | 504.7 | 611.1 | 683.4 | 957.7 | 1052.1 |
| Australia | 534.3 | 618.8 | 737.7 | 784.5 | 768.6 |
| Singapore | 494.8 | 601.2 | 616.2 | 616.6 | 592 |
| Mexico | 296.7 | 399.4 | 552.4 | 636.8 | 715.9 |
| Slovenia | 283.1 | 318.8 | 357.7 | 402 | 387.8 |
| Israel | 276.4 | 255.3 | 334.3 | 416.7 | 396.6 |
| Hungary | 249.4 | 276.6 | 281.4 | 357.3 | 311.6 |
| Korea, Republic of | 218.5 | 259.4 | 279.5 | 289.8 | 292.3 |
| Poland | 200.1 | 223.8 | 256 | 294.6 | 196.7 |
| Norway | 190 | 210.1 | 225.4 | 217.9 | 224.2 |
| Finland | 192.1 | 214.4 | 204.9 | 214.5 | 231.4 |
| Argentina | 111.9 | 140.9 | 198.8 | 282.3 | 298 |
| Czech Republic | 150.3 | 185.6 | 218.1 | 213.7 | 210.1 |
| Brazil | 132.8 | 167.6 | 189.1 | 217.3 | 248.1 |
| *Source: International Trade Statistics Yearbook 1998*, United Nations | | | | | |

Observers, however, argue that the high R&D costs do not constitute actual expenditures but reflect the costs of borrowing and factoring failures and R&D where patent applications have been unsuccessful.[14] A better way of approaching the relationship between the patent system and the dominance of the OECD corporate model lies in understanding the importance of standard setting and its implications for competition and the creation of alternative supply systems.

With advances in science, multinational corporations have invested in skilled personnel and sophisticated technology to undertake research in genetic engineering, sequencing and other techniques like growth hormones and interferon. The patent system enables investment in this process of knowledge creation. A condition precedent to the grant of the patent is that the invention is new, involves an inventive step and is capable of industrial application.[15] Depending on the tradition and specific needs identified by the government and judicial roles these criteria are left deliberately open ended so that the standards are 'technology neutral' and do not curb proper development of technology.[16]

***If the underlying policy is to promote technological advance and new therapeutic drugs, it will be in the public interest to have a broad definition of each of the requirements for patentability. The reverse holds true if it is felt that a patent might inhibit further R&D or curb legitimate competition.***

If the underlying policy is to promote technological advance and new therapeutic drugs, it will be in the public interest to have a broad definition of each of the requirements for patentability. The reverse holds true if it is felt that a patent might inhibit further R&D or curb legitimate competition. The standard setting for patentability is important since it can have important implications for competition from generic drugs manufacturers. The effect of a successful application is that they result in the creation of patent enclosures over the pool of knowledge in the public domain. Patents are granted in respect of the compounds or active ingredients in a product or the process through which new therapeutic uses are discovered.

Given that the pharmaceutical industry is lucrative and that the essence of the market is to increase competition, it is common for multinational corporations to register patent applications for a wide range of compounds, therapeutic uses, polymorphs and processes. From a strategic point of view, the application for a patent is seen as a useful technique to dissuade competition from foreign and local industries. The grant of a patent creates a presumption of validity unless contrary evidence is made available by those seeking its revocation.

Another feature about the nature and scope of the patent system is that governments tend not to provide prescriptive standards. It may be the case that in those countries where a premium is placed on encouraging inventions, there may be a willingness to embed greater flexibility in the patent system. The flexibility of the criteria of patentability makes it malleable to fit into any particular political or social mould.[17] For example, under the UK Patents Act, 1977, an invention to be patentable must be 'new'.

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It is, however, the case that it is rare for new compounds of chemicals to be found. That said, patents have been granted where the claims covered a new use for compounds in an existing product. One example of this would be the use of a particular combination of compounds, which is currently used in a drug as an antihistaminic, for a non-obvious purpose. Equally, patent offices are particularly vigilant in ensuring that patent applications are not granted as a matter of routine. One way of ensuring those only legitimate inventions are granted a monopoly. It is also required that applications describing the claims should be submitted in a precise manner. This is important since the claim defines the scope of the patentee's monopoly.

Product by process claims are particularly notorious in that the product is ultimately characterised by the structure or composition, which leads to its development. As a general rule the European Patent Office has been willing to grant product by process patents if it is shown that the pharmaceutical drug is new and inventive. The patentability of inventions and examination of the

applications require a skilled workforce versed in the practice of sifting through the documents.

In addition to this, the ability of the patent system to fulfill the public interest goals is dependent on government funding of a judicial and administrative system. Their importance lies in ensuring that legitimate competition is not stifled. The effect of a patent is that it vests in its right holders commercial rights of excludability in respect of the data captured by the instrument as well as the use of the product or process. The duration of the patent monopoly is usually determined by reference to the date of filing of the application. In most legislation, this monopoly period is 20 years. The patent system enables the right holders to preserve imperfect market conditions to recoup their investment by enabling them to charge prices above the marginal cost and maximise the economic value of the knowledge captured by the patent.

***The ability of the patent system to fulfill the public interest goals is dependent on government funding of a judicial and administrative system. Their importance lies in ensuring that legitimate competition is not stifled.***

Given that knowledge management is an important part in maximising the commercial value of a patent, it might be useful to briefly outline some of the techniques employed by the corporate pharmaceutical model. It is difficult to state conclusively whether the patent system stifles future research and development.[18] National patent legislation permits with limits access to the data captured by the patent for the purpose of further research. One argument would be that critical processes and products, which are subject of patent protection, might prevent competitors from undertaking derivative R&D.

Compound extraction is a common technique employed. These are mainly known compounds. If it is extracted or developed by a known method but put to a new use, patent protection may be available for that specific purpose. An example of this is the extraction of a known compound from *neem*, (ie azadirachtin) by a well-known process. Its subsequent use, which is not obvious to the person skilled in the field for curing cancer, will be deemed to satisfy the threshold of patentability.

To maximise the commercial potential of the knowledge covered by a patent, pharmaceutical companies have increasingly turned to maximising the underlying technologies in the patents which are due to expire. It is a common occurrence that multinational corporations have made applications for derivative patents to extend their monopoly beyond the statutory period. In this respect where such practices have been successful, it is possible to argue that the use of patents in this manner may stifle the transfer of knowledge and technology, which is the normal occurrence when the patent expires.

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One example of this is the case of the blockbuster drug for ulcers – Zantac. The patent for Zantac was owned by Glaxo Wellcome. One of the generic manufacturers in North America – Novopharm – announced plans to commence manufacture of a generic version of Zantac. A lawsuit was filed by Glaxo, and on appeal against the US Federal Court decision, argued that this generic version could not be produced without infringing their second patent.

Another strategy used by the industry is to alter the composition of the compounds in the drug so that it can be marketed as a superior drug or de-classify particular drugs, with the approval of the health authority or any other government body so that they could be made available over the counter or repackage their delivery and distribution systems.

This poses two access issues. First, the high prices charged may prevent those least able to access the market from purchasing the medicines directly or limit the supplies that can be acquired owing to limited government resources. Second, as described above, patent enclosures may be employed strategically to prevent data from being made freely available for commercial exploitation without prior authorisation. Together these two factors raise a broader question of whether, in accessing essential medicines, governments should be permitted to develop alternative supply systems.

***Pubic health objectives can not be operationalised purely through making new and effective drugs available. A number of OECD countries adopt health rationing as a necessary health management instrument. Other measures include registration requirements, pricing, controls on introducing new drugs in the market and reimbursement.***

How do OECD industrial countries address the problems of access to essential medicines, if they are relevant at all? This is a difficult question, since pubic health objectives can be operationalised not purely through making new and effective drugs available. A number of OECD countries adopt health rationing as a necessary health management instrument.[19] Other measures include registration requirements, pricing, controls on introducing new drugs in the market and reimbursement. The table below provides a summary of the use of healthcare rationing by public health authorities.

**Table 2: Healthcare Rationing**

| **Rationing Device** | **Countries by example** |
|---|---|
| Employment status or income level | USA |
| Waiting lists for treatment<br>Price controls for medicines | UK, Canada |
| Reference Pricing | Western Europe (14), Central Eastern Europe (3), Middle East (4), Asia, Pacific (5), Canada, Pakistan |
| Mandatory government-imposed price cuts | Spain, France, Japan, Italy |
| Control on price increases | Argentina (public sector), |
| Global medicines budget | Canada (provinces) |
| Benefit caps on medicines | Germany, Netherlands |
| Physician incentives programmes | Some US state Medicaid programmes |
| Restrictive formularies for medicines | Australia, Netherlands |
| Profit controls | Canada, Japan, US MCOs |
| Fourth Hurdle – Cost-Effectiveness Measure | UK, Spain Western Europe (5), Australia, Japan |
| *Source:* CMR, 2000 | |

Decision making in public health can also involve improving the lifestyles of individuals and education programmes to ensure that they do not become susceptible to disease. Also, government expenditure in public health may be directed towards improving sanitation, housing and the environment, all of which have 'knock-on' effects on the health security of the community.

OECD countries have captured much of the economic gains from globalisation. Increase in national wealth has seen a commensurate rise in investment in public health infrastructure.[20] Access to essential medicines is facilitated in most of the OECD countries through some form of public or private health insurance.[21] Finally, much of the public health debate in TRIPs is concerned with those in the community who are least able to access the market system.

***OECD countries have captured much of the economic gains from globalisation. Increase in national wealth has seen a commensurate rise in investment in public health infrastructure. Access to essential medicines is facilitated in most of the OECD countries through some form of public or private health insurance.***

In OECD countries, increased economic prosperity has led to a significant decrease in the levels of poverty and the types of epidemics and diseases, which are labelled as 'poverty-related illnesses'. The per capita income of individuals in OECD industrialised countries, it is worth recalling, is between $22,000 and $32,000.

Against this background, which provides a plausible explanation for the absence of public health crises and concerns about access to essential medicines, one cannot overlook the built-in checks and balances to ensure that public health goals are not subverted. For example, to counter-balance the property rights model there are equally extensive regulatory frameworks that deal with anti-trust and compulsory licensing issues.

As recent as September 2001, a US class action suit was initiated against the multinational GlaxoSmithKline, alleging that the multinational failed to inform doctors in the UK and the US that its bestselling anti-depressant drugs were addictive and resulted in withdrawal systems when patients stop taking them. The FTC has recently commenced an investigation into allegations that three of the leading pharmaceutical companies in the US falsely listed patents in the Administration's Orange Book to stave off competition from generic competitors.[22]

***It is noticeable that access issues are relatively less of a problem where the democratic process facilitates greater accountability and compel governments to balance the interests of industry and those of the community least able to afford access.***

Governments in OECD countries have resorted to measures like price controls on prescription drugs and the use of generics or non-branded medicines.[23] For example, in Canada strategies are being devised to reduce the public health bill without causing adverse political consequences.[24] The Ontario government is said to pay $2bn for prescription drugs, which exceeds those paid by private insurers. In addition to this, the activities of opposition parties, pressure groups and non-governmental organisations are now providing much needed transparency by way of focusing on the activities of both governments and the pharmaceutical industry. It is noticeable that access issues are relatively less of a problem where the democratic process facilitates greater accountability and compel governments to balance the interests of industry and those of the community least able to afford access.

| Comments |
| --- |
| 1. The dominance and competitive advantage enjoyed by multinational corporations from OECD countries would not have been possible without extensive support from the member governments.<br><br>2. The emergence of privatised networks in OECD countries is the result of adopting market structures and industrial policies, which marginalise the role of the government.<br><br>3. The pharmaceutical industry has a commercial not a philanthropic mandate. Governments in OECD countries acknowledge this. At the same time checks and balances are placed to ensure that abuses do not subvert the role of the government in promoting health security.<br><br>4. Access problems are minimised if the democratic process is allowed to function in its normal mode.<br><br>5. Standard setting in the patentability of pharmaceutical industry is critical to determining the level of competition and the pool of knowledge that is at the disposal of competitors. |

## *SECTION III*
# GLOBALISATION, TRIPs AND SOUTH ASIAN DEVELOPING COUNTRIES

The emergence of global privatised networks and access regimes in healthcare products is part of the process by which capitalism is now redefining the global landscape, traditionally dominated by sovereign nation states. The mobility of capital and the emergence of global financial networks coupled with the pervasive nature of the industrial policies adopted in economies like the US and the EC have an immediate significance in developing countries as they attempt to manage their domestic affairs effectively.

The emergence of new regulatory forums at both regional and international levels as venues for formulating and implementing 'voluntary' strategies for cooperation between countries is underscored by intense competition amongst nation states to entrench their global dominance. Standard setting has now been transformed into a form of regulatory arbitrage where institutions like the WTO and its agreements become mechanisms through which lucrative rent transfers can be captured by reducing pluralism in industrial policies, standards and market structures. The convergence of the interests of the multinational corporations in search for newer markets and their political sponsors has an added economic dimension. Cross-border licensing fees and royalties from IPRs, for example, amount to 91 percent of the market share.[25] It is estimated that in 2000, US companies earned an estimated $38bn from licensing fees.

***Standard setting has now been transformed into a form of regulatory arbitrage where institutions like the WTO and its agreements become mechanisms through which lucrative rent transfers can be captured by reducing pluralism in industrial policies, standards and market structures.***

It would be a mistake to isolate the multiple effects of globalisation on national public health governance. Institutions like the World Bank and the IMF link the grant of substantial aid and liquid loans to developing countries adopting a programme of structural reform and market discipline. In World Development Report 2003, calls have been made for these countries to adopt structural adjustment programmes.[26] In a previous report, the World Bank was particularly critical of policymakers who defer to the protectionist industries and rent-seeking groups in their countries. For example, the report draws attention to the[27] '[e]xperience between 1990 and 1999, which, it says, illustrates the general rule stated as follows:

*"Over that decade the number of people living in developing countries on less than $1 a day fell from 1.3 billion to 1.2 billion, and the proportion of people living in extreme poverty fell from 29 percent to 23 percent. Most of these gains were made in the two fastest growing regions – East Asia and Pacific and South Asia.*

In Europe and Central Asia, which experienced painful economic contraction over much of the period, both the number and the proportion of people living on less than $1 a day increased. In Sub-Saharan Africa and the Middle East and North Africa the poverty rate declined slightly, but not fast enough to reduce the number of people living in extreme poverty. And in Latin America and the Caribbean, where average growth has been slow, poverty reduction has also slowed down."

Loan obligations and structural adjustment measures imposed as conditions for grants also impose costs, notably in the form of interest repayments and policy change. It is arguable whether any significant and effective use is made of these financial packages to eradicate poverty-related illnesses and increase access to essential medicines. More importantly, the repayment obligations are likely to reduce resources available for any projected state expenditure on public utilities and programmes. The activities of all these institutions now can be said to supplant the WHO in determining the question of promoting public health governance in a global marketplace. Joseph Stiglitz captures the impact of the interpenetration of globalisation on developing countries and leaves us to hypothesise its impact on global public health governance:[28]

*'Globalisation is powerfully driven by international corporations, which move not only capital and goods across borders but also technology. Globalisation has also led to renewed attention to long established international* intergovernmental *institutions … . Many, perhaps most, of these aspects of globalisation have been welcomed everywhere. No one wants to see their child die, when knowledge and medicines are available somewhere else in the world. It is the more narrowly defined economic aspects of globalisation that have been the subject of controversy, and the international institutions that have written the rules, which mandate or push things like liberalisation of capital markets….'*

| **Comments** |
| --- |
| Public health governance in the global environment cannot be dissociated from the policies of the governments in adopting free market principles. Consequently, there is an unavoidable shift in autonomy over standard setting away from governments towards international institutions like the WTO, World Bank and the IMF. TRIPs is a form of regulatory arbitrage where countries like the US, EC, Canada, Australia and Japan have imposed their standards at the global level. |

***TRIPs makes explicit a very old problem of delegation and, arguably, neglect by governments of public health. In the context of TRIPs we need to understand how the interaction of its provisions with the corporate business model potentially creates a formidable instrument for OECD industrial countries and multinational corporations.***

TRIPs makes explicit a very old problem of delegation and, arguably, neglect by governments of public health. The immediate question that this paper addresses is, in the light of the dominance of corporate pharmaceutical model, how do we make this model viable in addressing the public health needs of South Asian developing countries in particular.[29]

In the context of TRIPs we need to understand how the interaction of its provisions with the corporate business model potentially creates a formidable instrument for OECD industrial countries and multinational corporations. This Agreement came into force on 1 January 2000.[30] Carlos Correa suggests that though TRIPs does mark an important change in governance structures in public health, its significance should not be overstated.[31] This is true since Member States are under no obligation to set in place systems of property protection that OECD industrial countries have in place. The only requirement is that some measure of protection is made available for 'any inventions, whether products or processes, in all fields of technology'. That said, the previous reference to the growing consensus amongst all governments about the dominant role of capitalism and their recognition of the pivotal role of the corporate pharmaceutical model are too important to ignore and still leaves unresolved the question of creating a viable supply system or framework for

developing countries with critical public health problems. A description will be provided of the key features of the TRIPS agreement as they affect access to essential medicines.

**Standard Setting**

Article 27:1 obligates all Member States to enact measures, which provide protection for pharmaceutical patents on products or processes. The monopoly period will be 20 years from the date of filing of the patent application.

**Comments**

1. South Asian countries, subject to the provisions for transition under Articles 66 and 67, will either have to set in place an entirely new patent system or modify those currently in place to ensure compliance with TRIPs.

2. It will not be open to developing countries to insulate product and process patents in pharmaceuticals, since discrimination on the grounds that they are essential medicines is prohibited (see, for examples, Articles 3 and 4). In the absence of any grounds for refusing the grant of a patent, Article 28 vests in pharmaceutical companies who are the primary owners of intellectual property, the right to require developing countries to obtain prior authorisation before making, using, offering for sale, selling or importing patented products.[32]

3. India and Pakistan, for example, will have to extend a patent monopoly for 20 years. In the case of the former, pharmaceutical patents will now be available as both product and process patents. Article 28:2, for example, also affirm that patent owners enjoy the contractual rights to assign, or transfer by succession, a patent and to conclude licensing contracts.

4. Member States retain some residual discretion. For example, Article 27:2 provides that:

   *'[m]embers* may *exclude from patentability inventions, the prevention within their territory of the commercial exploitation of which is necessary to protect* ordre public *or morality, including to protect human, animal or plant life or health or to avoid serious prejudice to the environment, provided that such exclusion is not made merely because the exploitation is prohibited by their law'.*

**Public Health**

Whilst Member States retain autonomy over their management of public health and the measures for implementing their policies, its scope is ambiguous. Article 8 requires that any measures adopted to alleviate public health concerns or promote public interests in this sphere are consistent with the provisions in TRIPs.

**Parallel Imports**

TRIPs does not expressly prohibit parallel importing. Developing countries during the pre-TRIPs era have utilised parallel importing as a tool of economic strategy. As India did not provide product patent protection for pharmaceutical products, until the enactment of the present Patents (Second Amendment) Act, 1999, domestic manufacturers like Cipla and Ranbaxy marketed generic

versions to other countries without obtaining consent from the original patent owners. This had a number of benefits like depressing prices by stimulating competition with substitute patents, facilitating transfer of technology by permitting reverse engineering, assisting in capacity building and exploiting economies of scale by exporting generics to other developing countries.

| Comments |
|---|
| 1. Even though Article 6 is unequivocal in stating that the WTO dispute settlement body will not have the competence to adjudicate on the issue of exhaustion of patent rights, some circumspection is required.<br><br>2. It is conceivable that, as between two Member States with TRIPs compliant legislation, it would be argued that parallel imports are discriminatory against a foreign multinational located in the importing country. Furthermore, it is likely that PhRMA might resist parallel imports because they erode their rights of excludability under Article 28 and possibly Article 27(1). It could be queried whether Article 8 might be relied upon, if evidence is forthcoming to show that this measure is intended to address public health concerns. |

**Compulsory Licensing**

Compulsory licenses have been seen as an important safeguard against abuses of monopoly and unfair competition. This is likely to be an area of future controversy and uncertainty as to the final outcome. Developing countries are provided for in Article 31 along with the broadest possible scope of measures to address problems of affordability due to high prices of essential medicines. Article 31 permits a government or health authority to issue a license for production without the consent of the patent owner. This is likely to be resisted by patent owners as the creation of an alternative supply system would lead to a dampening of the prices charged and increase competition in the market.

| Comments |
|---|
| 1. Article 31 does not stipulate the grounds, which permit the Member States to use a patent without the authorisation of the right holder. That said, it outlines a set of procedures when this process is relied upon by the Member States.<br><br>2. There is a built-in mechanism that requires any such authorisation to be preceded by legitimate negotiations and attempts made to have acquired a voluntary license.<br><br>3. Before Article 31 is relied upon Member States must have resources to ensure that right holders are reasonably compensated.<br><br>4. The elaborate process outlined in Article 31, which includes the creation of mechanisms for judicial review and documentation, is likely to result in protracted negotiations. Paragraphs (b) and (f) can however be dispensed with if there is evidence of anti-competitive practices. Article 31(k) however, requires that this be first preceded by a decision reached through an administrative or judicial process.<br><br>5. The process for obtaining a compulsory license is measurably accelerated where there is a national emergency or other circumstances of extreme urgency.<br><br>6. Use by the person authorised under Article 31 is non-exclusive and non-assignable. This is important since it permits right holders to continue to market their products and also when the terms of the issue cease to be relevant, subsequent use may be revoked.<br><br>7. Any such use shall be authorised predominantly for the supply of the domestic market of the Member authorising such use. |

**Table 3: Articles in TRIPs Most Relevant for Access to Pharmaceuticals Products**
**(*Note: A number of articles contain further specific conditions, exceptions and exemptions, which are spelled out in TRIPs or other referenced agreements*)**

| | |
|---|---|
| *Non-discrimination (Articles 3, 4, and 27)* | "National Treatment...Each Member shall accord to the nationals of other Members treatment no less favourable than that it accords to its own nationals with regard to the protection of intellectual property…"<br>"Most-Favoured-Nation Treatment…With regard to the protection of intellectual property, any advantage, favour, privilege or immunity granted by a Member to the nationals of any other country shall be accorded immediately and unconditionally to the nationals of all other Members…"<br>"[P]atents shall be available and patent rights enjoyable without discrimination as to the place of invention, the field of technology and whether products are imported or locally produced." |
| *Parallel importation ("exhaustion of patent rights") (Article 6)* | "Exhaustion…For the purposes of dispute settlement under this Agreement, subject to the provisions of Articles 3 [National Treatment] and 4 [Most-Favoured-Nation Treatment], nothing in this Agreement shall be used to address the issue of the exhaustion of intellectual property rights." |
| *Objectives of TRIPs (Article 7)* | "Objectives…The protection and enforcement of intellectual property rights should contribute to the promotion of technological innovation and to the transfer and dissemination of technology, to the mutual advantage of producers and users of technological knowledge and in a manner conducive to social and economic welfare, and to a balance of rights and obligations." |
| *Protection of public health (Article 8)* | "Principles…Members may, in 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, provided that such measures are consistent with the provisions of this Agreement." |
| *Process and product patents (Article 27)* | "Patentable Subject Matter…patents shall be available for any inventions, whether products or processes, in all fields of technology, provided that they are new, involve an inventive step and are capable of industrial application." |
| *Subject matter which may be excluded from patentability (Article 27)* | "Patentable Subject Matter…Members may exclude from patentability inventions...necessary to protect ordre public or morality, including to protect human, animal or plant life or health…"<br>"Members may also exclude from patentability:<br>(a) diagnostic, therapeutic and surgical methods for the treatment of humans or animals;<br>(b) plants and animals other than micro-organisms, and essentially biological processes for the production of plants or animals other than non-biological and microbiological processes." |
| *Limited exceptions, including "Bolar" provisions (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." |
| *Compulsory licensing (Article 31)* | "Other Use Without Authorisation of the Right Holder...Where the law of a Member allows for other use of the subject matter of a patent without the authorisation of the right holder, including use by the government or third parties authorised by the government, the following provisions shall be respected. |

*Contd...*

| | |
|---|---|
| | authorisation ... shall be considered on its individual merits;<br>such use may only be permitted if, prior to such use, the proposed user has made effort to obtain authorisation from the right holder on reasonable commercial terms and conditions and that such effort have not been successful with a reasonable period of time. This required may be waived ... in the case of a national emergency or other circumstances of extreme urgency or in cases of public non-commercial [governmental] use.... [Notice is required.]<br>the scope and duration of such use shall be limited to the purpose for which it was authorised ...;<br>such use shall be non-exclusive;<br>such use shall be non-assignable ...;<br>any such use shall be authorised predominantly for the supply of the domestic market ...;<br>authorisation for such use shall be liable, subject to adequate protection of the legitimate interests of the persons so authorized, to be terminated if and when the circumstances which led to it cease to exist and are unlikely to recur [with provisions for review] ...;<br>the right holder shall be paid adequate remuneration in the circumstances of each case, taking into account the economic value of the authorisation;<br>the legal validity of any decision relating to the authorization of such use shall be subject to judicial review or other independent review by a distinct higher authority in that Member;<br>any decision relating to the remuneration provided in respect of such use shall be subject to judicial review or other independent review ...;<br>Members are not obligated to apply ... subparagraphs (b) and (f) where such use is permitted to remedy a practice determined after judicial or administrative process to be anti-competitive [and may take account of anti-competitive practices in setting compensation] .... |
| *20-year minimum term of protection (Article 33)* | "Term of Protection…The term of protection available shall not end before the expiration of a period of twenty years counted from the filing date." |
| *Data protection and Exclusivity (Article 39)* | "Protection of undisclosed information…In the course of ensuring effective protection against unfair competition…Members shall protect undisclosed information…and data submitted to governments or governmental agencies…" |
| *Transitional Periods (Articles 65 and 66)* | TRIPs provides a period of transition during which countries are required to conform their national legislation and practices to its requirement. The latest dates for WTO Members were/are: 1996 for developed countries; January 1, 2000, for developing countries (as a general rule); January 1, 2005, for developing countries who had not introduced patents before joining the WTO; and January 1, 2006, for least-developed countries. TRIPs specifically acknowledges the economic, financial, administrative and technological constraints of the least-developed countries and therefore provides for possible extension of the transitional period. |
| *Transfer of technology and technical cooperation (Articles 66 and 67)* | "Developed country Members shall provide incentives to enterprises and institutions in their territories for the purpose of promoting and encouraging technology transfer to least-developed country Members in order to enable them to create a sound and viable technological base…[and] shall provide, on request and on mutually agreed terms and conditions, technical and financial cooperation in favour of developing and least-developed country Members." |
| *Review (Article 71:1)* | "The Council for TRIPs shall review the implementation of this Agreement after the expiration of the transitional period referred to in paragraph 2 of Article 65. The Council shall, having regard to the experience gained in its implementation, review it two years after that date, and at identical intervals thereafter. The Council may also undertake reviews in the light of any relevant new developments which might warrant modification or amendment of this Agreement." |
| *Source:* Brook Baker (2002) | |

With the exception of India, there is some ambivalence regarding the extent of the costs involved in both orientating existing market structures and social welfare in developing countries. Countries like Nepal, Bangladesh and Sri Lanka do not have a sound intellectual property infrastructure. The idea that the TRIPs agreement has built in mechanisms to provide its policymakers with some leeway assumes that these countries are at the same level of development or have critical mass of skills and technological infrastructure.

***Countries like Nepal, Bangladesh and Sri Lanka do not have a sound intellectual property infrastructure. The idea that the TRIPs agreement has built in mechanisms to provide its policymakers with some leeway assumes that these countries are at the same level of development or have critical mass of skills and technological infrastructure.***

It is difficult to see at this juncture what countries like Nepal or Bangladesh are likely to gain in terms of transfer of technology or capacity building. Indeed, the establishment of supportive market structures and industrial policies in reality is likely to favour OECD developing countries. Capacity building assumes that there is a highly skilled and literate human resource base. Even if that is available, it will take time before the benefits are realised as the table below suggests that considerable investment is required before the critical mass of skills is reached.

**Table 4: The State of Pharmaceutical Industry in South Asia**

| **Stage of Development** | **Country** |
|---|---|
| *Sophisticated vertically integrated pharmaceutical industry with a significant research base* | NIL |
| *Possessing innovative capabilities. Ability to copy new chemical entities by a process of reverse engineering* | India |
| *Ability to produce therapeutic ingredients / raw materials from:* | Bangladesh and Pakistan |
| *Chemical intermediates, Fermentation and Plant sources* | |
| *Formulating dosage forms from imported raw materials* | Nepal and Sri Lanka |
| *No pharmaceutical industry* | Nil |
| *Source:* Balakrishnan (2000) | |

| **Comments** |
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| Countries like Bangladesh, Sri Lanka and Nepal, in particular, will need to undertake a feasibility study to determine whether adopting the looser standards will be in their best interests. For example, in the case of Nepal and Sri Lanka the trade-off between increasing FDI and higher intellectual property standards needs to be examined closely. This is in contrast with the position in India, where falling FDI can be arrested by developing their patent legislation with the aim of encouraging foreign multinationals to locate their industries in India and/or enter into joint ventures with local manufacturers. |

*In one study it was observed that patent protection would result in negative welfare and price effects. Price, it is claimed, is expected to increase by 5 to 67 percent. In addition to making some life saving drugs, unaffordable welfare losses are expected to be in region between $162mn to $1,261mn.*

A more immediate concern that emerges from the implementation of TRIPs is the effect of the influx of foreign medicines and high prices will have on the ability of governments to resource public health needs. In one study it was observed that patent protection would result in negative welfare and price effects.[33] Price, it is claimed, is expected to increase by 5 to 67 percent. In addition to making some life saving drugs, unaffordable welfare losses are expected to be in region between $162mn to $1,261mn.[34] If one puts this in the broader context of international trade diversion of foreign exchange revenue, it is estimated in the range of around $101mn to $839mn.[35] As the table below amply illustrates, developing countries with no viable pharmaceutical industry are likely to find that their options in accessing generic supplies produced in breach of patent rights curtailed.

**Table 5: Pharmaceutical Production Consumption, Imports and Exports in South Asia**

| | Production as percentage of world total | | Consumption per capita USD | Percentage share of | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| | | | | Production to consumption | | Imports to consumption | | Exports production | |
| | 1975 | 1990 | 1990 | 1975 | 1989 | 1975 | 1989 | 1975 | 1989 |
| Bangladesh | 0.1 | 0.07 | 1.1 | 89.9 | 83.8 | 10.4 | 16.3 | 0.3 | 0.2 |
| India | 0.93 | 1.29 | 2.2 | 96.9 | 104.3 | 6.5 | 5.4 | 3.5 | 9.4 |
| Pakistan | 0.14 | 0.33 | 5.1 | 80.9 | 79.1 | 20.5 | 21.6 | 1.8 | 0.9 |
| Sri Lanka | - | - | 1.8 | 25.8 | 16.7 | 74.4 | 84.1 | 0.8 | 4.5 |
| Total | 2.2 | 2.7 | | | | | | | |

*Source:* UNIDO – The Worlds Pharmaceutical Industries; An International Perspective on Innovation, Competition and Policy by Robert Balance, James Pogany and Helmet Forsteiner, 1992

**Comments**

India has one of the lowest drug prices and it is largely the product of price controls and absence of product patent protection. It is difficult to be definitive about the impact on prices and welfare losses. Greater competition from foreign imports, particularly where the pharmaceuticals are substitutes, might lead to lowering of prices. Alternatively, domestic prices might rise to reflect the prices charged in imported pharmaceuticals.

*Poverty is endemic and is often a key determinant of access, which in turn raises wider issues of the levels of government funding of public health and more importantly ensuring the effective implementation of their national drug policies.*

The debate on TRIPs and the implications of linking IPRs with goods must be considered against the demographics of the crises in this region. Poverty is endemic and is often a key determinant of access, which in turn raises wider issues of the levels of government funding of public health and more importantly ensuring the effective implementation of their national drug policies. The South and South East Asian region have at least 50 percent of the world's poor. Poverty increases the risk of poor health. For example, those who are deprived of basic amenities like housing, sanitation and water are likely to have their exposure and vulnerability increased. This susceptibility is underscored by poorly resourced public health infrastructures and the lack of national health insurance.

It is expected that in countries where the annual average income is $296, infant mortality rates are likely to be around 10 percent of live births. In high-income countries, however, where an income of $27,730 is taken as the annual average, the mortality rates are 0.6 percent.[36] The high death rates according to the report issued by the World Health Organization shows that the poor in both low-income and middle-income countries fall prey to infectious diseases like HIV/AIDS, malaria, tuberculosis and childhood infectious diseases.[37]

***The costs of addressing the public health needs through pubic insurance in the absence of established private sector insurance cannot be emphasised sufficiently. It is well known that apart from HIV/AIDS other diseases like malaria, tuberculosis, cancer and cardiovascular respiratory problems continue to stretch the under resourced health care and administration system in developing countries.***

Non-communicable diseases like diabetes, cardiovascular diseases, and cancers are equally problematic. The costs of addressing the public health needs through pubic insurance in the absence of established private sector insurance cannot be emphasised sufficiently. India, for example, has the world's second-largest population and over 400,000 cases of cancer registered annually.[38] It is well known that apart from HIV/AIDS other diseases like malaria, tuberculosis, cancer and cardiovascular respiratory problems continue to stretch the under resourced health care and administration system in developing countries.[39] Reduced prices of essential medicines and access to data to produce cheaper alternatives are critical to any pro-poor national health policies.

**Table 6: Selected Key Indicators in South Asia**

| Developing Asian Country | Population in million 1999 | Infant Mortality Rate 1998 | Maternal Mortality Rate 1990-1998 | Under 5 Mortality 1998 | Prevalence of Malnutrition % of children under age 5 1992 – 1998 | Population below national poverty line % Latest available | Population below $1 a day % Latest available | Per Capita GNP US$ 1999 | Ratio of the incomes of the poorest 10% to the richest 10% | Health expenditure as a % of GDP | | External debt as a % of GNP 1998 | Number of Scientists and Engineers in R & D per million population 1987–1997 |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | | | | | | | | | | Public 1990–1998 | Private 1998 | | |
| Bangladesh | 128 | 73 | 440 | 96 | 56 | 35.6 | 29.1 | 370 | 1:7 | 1.6 | 1.9 | 22 | 52 |
| India | 998 | 70 | 410 | 83 | 53 | 35.0 | 44.2 | 450 | 1:10 | 0.6 | 4.2 | 20 | 149 |
| Nepal | 23 | 77 | 540 | 107 | 57 | 42.0 | 37.7 | 220 | 1:9 | 1.3 | 4.2 | 31 | n.a |
| Pakistan | 135 | 91 | n.a. | 120 | 38 | 34.0 | 31.0 | 470 | 1:8 | 0.9 | 3.1 | 41 | 72 |
| Sri Lanka | 19 | 16 | 60 | 18 | 38 | 35.3 | 6.6 | 820 | 1:8 | 1.4 | 1.7 | 41 | 91 |

*Source:* K Balakrishnan, 2002

**Comments**

It is beyond the scope of the paper to examine the procurement policies employed by government, the prevalence discounted pricing and the effective implementation of national drug policies. There is particular need for greater investment by government and targeting of foreign aid on those diseases prevalent in poor communities.

# *SECTION IV*
# CONCLUSIONS AND POLICY RECOMMENDATIONS

This study focused on one question: what genuine choices do policymakers in South Asian countries now have following the link between the trade regime and pharmaceuticals. It attempted to answer this question by focusing on the business model of pharmaceuticals. It proceeded to describe how even though all economies subscribe to the view of capitalism as a means of ordering societies, OECD countries in particular have obtained a crucial headstart. Though we seem to understand some of the basic rules of how economic prosperity and social welfare can be increased, it would be foolish to think that we have fully grasped the multiple effects of globalisation and the pervasive nature of private networks, their logic and norms. This is a particular problem when faced with the present impasse on how best governments in developing countries can best discharge their obligations towards those least able to afford life saving medicines and treatments.

The study has provided a partial response to the way some of the problems can be overcome through judicious interpretation of the flexibilities in the TRIPs agreement. Clearly, much empirical work is needed to document the extent to which the economies that we have considered in South Asia are adversely affected and the extent to which the promises in the preamble in TRIPs are realised in tangible terms. This paper concludes that it is too easy to demonize the WTO. Multinational corporations and TRIPs lead to a mischaracterisation of the real challenge of finding an alternative system in which medicines neglected by the market are developed and also takes measures to ensure that essential medicines are not subject to market mechanism. One could end with this poser: if we did not have TRIPs, would the communities in South Asian countries, who are least able to access the market of life saving drugs find their governments ever more responsive to their needs? The ambivalence here does not defeat the limited goal of this study, which is to provide a foundation for the contention mentioned at the outset.

***Multinational corporations and TRIPs lead to a mischaracterisation of the real challenge of finding an alternative system in which medicines neglected by the market are developed and also takes measures to ensure that essential medicines are not subject to market mechanism.***

**Specific Recommendations**

*Standard Setting*

The impact of TRIPs in terms of the economic and social costs of establishing patent systems should not be underestimated. Inadequate systems for the processing of patent applications, examination of patent specifications and claims and supervision of the exercise of patent rights can increase barriers to access. That said, since TRIPs is not prescriptive in terms of patentability, it is imperative that further studies are undertaken while enacting TRIPs compliant legislation. Some circumspection is warranted in relying on WIPO IP models, which are largely based on OECD industrial policies and market dynamics.

| Recommendations |
|---|
| 1. Invest in training and recruitment of skilled personnel. |
| 2. Increase dialogue and partnership programs with Export Promotion Organisations. |
| 3. Factor costs of running the patent system into the application fees. |
| 4. Empirical studies to be undertaken to customise the patent legislation to reflect the level of the skilled workforce, the dependence on foreign export earnings and the necessary trade-offs. |

*Compulsory Licensing and Export/Import Restrictions*

***TRIPs does not address a situation where their issuer have no viable domestic industry. The requirement that the products manufactured under compulsory license must be supplied predominantly to the domestic market renders the value of the provision illusory.***

Article 31(f) only enables the issuance of compulsory licenses for domestic production. Apart from the question of whether developing countries will have sufficient resources to provide reasonable compensation to the patent owner, TRIPs does not address a situation where their issuer have no viable domestic industry. The requirement that the products manufactured under compulsory license must be supplied predominantly to the domestic market renders the value of the provision illusory. Equally, countries like India, which have the domestic capacity, may be reluctant to supply least developed countries since the latter does not possess markets, which enable the former to derive the necessary economies of scale to make the production viable.

| Recommendations |
|---|
| 1. Ensure that the patent legislation contains TRIPs compliant compulsory licensing provisions. TRIPs does not provide an exhaustive set of grounds for the issue of compulsory licenses. It is imperative that developing countries draw on the Preamble in TRIPs and articulate the specific grounds where governments may issue compulsory licenses. An overhaul of National Drug Policies and documentation of targeted diseases and sectors, which can benefit from issuing of compulsory licenses or use of Article 30. |
| 2. Amend Article 31(f) and adopt the framework suggested by the African Group which has been made available to the TRIPs Council. |
| 3. Establish a fixed system for compensation based on developing country's resources. |
| 4. See Doha Declaration, which attempts to resolve the problem of countries with little or no viable domestic industry. |

*Parallel Imports*

Countries are not prevented by TRIPs from setting up provisions on exhaustion. One way of overcoming the barriers to essential medicines caused by high prices and the oligopolistic structure of the pharmaceutical industry is to increase competition. It is important that complementary legislation is found in all developing countries.

| Recommendations |
|---|
| 1. Need to make explicit in national legislation that rights of excludability do not extend to importation of drugs, which have been made available in the global market. |
| 2. Article 6 does not need to be amended, since by implication it leaves the issue of exhaustion of patent rights to national governments. |

*Technology Transfer*

Article 7 specifically states that the protection and enforcement of IPRs should contribute to the promotion of technological innovation and to the transfer and dissemination of technology. It is unclear whether this is more than an aspiration since the provision envisages that this transfer must be to the mutual advantage of producers and users of technological knowledge and in a manner conducive to social and economic welfare, and to a balance of rights and obligations.

| **Recommendations** |
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| 1. Developing countries need to engage in consensus building to ensure greater transparency. |
| 2. Identify possible technological impediments |
| 3. Urge OECD industrial countries to provide multinational corporations with market incentives to encourage joint ventures and collaborations with domestic industries in developing countries. This is particularly important to address the lack of R&D in developing medicines and treatments commonly found in South Asia like malaria, diarrhoea, pneumonia, tuberculosis. Less than 0.2 of the $56bn spend on R&D globally is targeted towards this end of spectrum. |
| 4. See Doha Declaration, which seems to imply that this is a TRIPs obligation. |

*Single Package Deal*

A premise of the TRIPs agreement is that all countries have the capacity and levels of development to maximise the potential of the knowledge economy. All developing countries need to have in place TRIPs compliant legislation by the end of 2005. The paper has shown that this is an unrealistic expectation.

| **Recommendations** |
|---|
| 1. There is a need for developing countries to undertake a review of their infrastructures to ascertain what constitutes a realistic target period. |
| 2. The Doha Declaration waives the requirement for least developed countries like Nepal and Bangladesh. TRIPs compliant legislation need only be introduced in 2016. There is a possible argument that countries like India, Sri Lanka and Pakistan should also be given flexible transition periods given the levels of poverty that we find in these countries. |
| 3. Transition periods should be seen as an important tool provided by TRIPs and should be fully utilised. |

# *APPENDIX A*
# DOHA MINISTERIAL DECLARATION ON TRIPs AND PUBLIC HEALTH

The Ministerial Declaration on TRIPs and Public Health issued at the 4th WTO Ministerial Conference in Doha, Qatar represents the latest phase in efforts to address some of the legal and policy issues accompanying the implementation and enforcement of patent rights in the global market of pharmaceuticals. India and Pakistan have recently enacted TRIPs compliant legislation. It is expected that Bangladesh and Sri Lanka will follow suit. Nepal, with the assistance of WIPO will have the relevant legislation in place.

Member States during Doha agreed that there was a need for a coordinated effort, which included the WTO, to enable developing countries address the public health needs. That said, it will be the height of naivety to ignore the fragility of the consensus since OECD countries and PhRMA will not readily relinquish their interests in maintaining an effective property protection system. That said in a special discussion on patent rights and access to medicines developing countries embarked on a coordinated strategy and presented arguments before the TRIPs Council of the need for the entire WTO community to demonstrate their share of the responsibility for the public health problems in developing countries. With these brief points in mind we can now turn to the key provisions in the Doha Declaration to ascertain whether a consensus is beginning to emerge that economic imperatives should not trump humanitarian concerns.

| *KEY PROVISIONS OF THE DOHA DECLARATION* | *COMMENTS* |
|---|---|
| Paragraph 1:<br>"We recognise the gravity of the public health problems afflicting many developing and least-developed countries, especially those resulting from HIV/AIDS, tuberculosis, malaria and other epidemics." | This is a reflection of one of the consequences of the linkage between public health governance and trade. It marks an important stage in the evolution of the international trade regime where the WTO now provides a strategic lead in global public health governance. |
| Paragraph 2:<br>"We stress the need for the WTO Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPs Agreement) to be part of the wider national and international action to address these problems." | The WHO and the World Bank have been particularly supportive of the efforts of the WTO. The important point here, and which is often glossed over, is that global public health governance is not purely a trade issue but one which requires greater coordination amongst all international organisations and stakeholders. The use of this vocabulary is significant. |
| Paragraph 3:<br>"We recognise that intellectual property protection is important for the development of new medicines. We also recognise the concerns about its effects on prices." | This is first indication that the exercise of patent rights may lead to increases in prices. Concerns about prices need to be balanced with the overall need for a sustainable supply system. |
| Paragraph 4:<br>"the TRIPs Agreement does not and should not prevent Members from taking measures to protect public health. Accordingly, while reiterating our commitment to the TRIPs Agreement, we affirm that the Agreement can and should be interpreted and implemented in a manner supportive of WTO Members' right to protect public health and, in particular, to promote access to medicines for all." | This paragraph would seem to add nothing new to an obvious feature in public health management. Culture, tradition and history have long characterised the State as the political and moral custodian of the community's health security. The concluding sentence can be interpreted as rejecting any suggestion that TRIPs obstructs public health initiatives. This stage setting is important, not least that it circumscribes the policy prescriptions that are specifically identified in the remainder of the memoranda. |

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| *KEY PROVISIONS OF THE DOHA DECLARATION* | *COMMENTS* |
|---|---|
| Paragraph 5:<br>"Accordingly and in the light of paragraph 4 above, while maintaining our commitments in the TRIPs Agreement, we recognise that these flexibilities include:<br>(a) In applying the customary rules of interpretation of public international law, each provision of the TRIPs Agreement shall be read in the light of the object and purpose of the Agreement as expressed, in particular, in its objectives and principles.<br>(b) Each Member has the right to grant compulsory licences and the freedom to determine the grounds upon which such licences are granted.<br>(c) Each Member has the right to determine what constitutes a national emergency or other circumstances of extreme urgency, it being understood that public health crises, including those relating to HIV/AIDS, tuberculosis, malaria and other epidemics, can represent a national emergency or other circumstances of extreme urgency.<br>(d) The effect of the provisions in the TRIPs Agreement that are relevant to the exhaustion of intellectual property rights is to leave each Member free to establish its own regime for such exhaustion without challenge, subject to the MFN and national treatment provisions of Articles 3 and 4." | Paragraph 5 enumerates some familiar features of the TRIPs Agreement. Members can for example, determine the grounds under which compulsory licenses can be granted. Its reach in both quantitative and qualitative terms is important since it purports to point to the way the flexibilities in TRIPs can be best maximised to correspond with the pubic health needs in developing countries. For instance, public health crisis is not to be viewed restrictively.<br><br>Paragraph 5(c) accepts that Members should have the right not only to determine what constitutes 'national emergency' but may adopt measures to alleviate crises in 'circumstances of extreme urgency'. This is not to be limited to diseases like HIV/AIDS, tuberculosis and malaria but can cover any other epidemic that visits a particular community. The reference to expediency is important. Procedural or administrative frameworks lack the lightness of touch where time is of the essence to ensure that medicines can be made available to avert potential fatalities.<br><br>Finally, paragraph 5(d) makes available to Members another policy instrument. Members can now manage their public health by constructing their own regime on exhaustion of intellectual property rights. This is however said to be subject to Articles 3 and 4. |
| Paragraph 6:<br>"We recognise that WTO Members with insufficient or no manufacturing capacities in the pharmaceutical sector could face difficulties in making effective use of compulsory licensing under the TRIPs Agreement. We instruct the Council for TRIPs to find an expeditious solution to this problem and to report to the General Council before the end of 2002." | Paragraph 6 is solely concerned with increasing the utility of compulsory licenses as a policy tool in overcoming some of the barriers to access. At present two problems are particularly prominent: (i) capacity; (ii) design. It has been shown that countries like Bangladesh, Sri Lanka, Pakistan and Nepal are perhaps least well equipped to maximise the potential of this instrument as they are sorely lacking in human and institutional infrastructure. Article 31 as presently constituted has not anticipated the consequences for these countries in implementing TRIPs. In the absence of this option and as the costs of patented medicines increasing, access is likely to be insurmountable.<br><br>The second 'design' issue arises from the condition that the issue of compulsory licenses under Article 31(f) compulsory licenses, is a response to overcoming domestic health needs. It is true of course, |

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| *KEY PROVISIONS OF THE DOHA DECLARATION* | *COMMENTS* |
|---|---|
| | that TRIPs still permits imports of generic medicines from other countries so long as patent rules are not in force in these countries. Similarly, a country like India after implementation of TRIPs will not be permitted to export on patent medicines produced under a compulsory license to alleviate the public health needs in Bangladesh or Nepal. The effect of a rigid application of TRIPs is that genuine public health needs are foreclosed by purely geopolitical considerations. It was agreed in Doha that the TRIPs Council should formulate an expeditious solution before the end of 2002.<br><br>Paragraph 6 falls short of permitting countries with little or no capacity to engage in parallel imports; a corollary being that countries cannot unilaterally or with license export to such countries with public health crises. Finally, it should be noted that TRIPs is to be now interpreted in the light of customary rules of interpretation of public international law (paragraph 5(a)). When interpreting the particular provision the TRIPs Agreement shall be read in the light of the object and purpose of the Agreement as expressed, in particular, in its objectives and principles.<br><br>The requirement that least developed countries implement TRIPs compliant legislation is somewhat of a puzzle. Countries like Nepal and Bangladesh neither have a strong economic presence or basic institutional infrastructures that would have led to the competitive advantage of OECD countries being undermined. It could be argued that an embracing market liberalisation policy without addressing questions of capacity and human resources may prove to be counterproductive and consequently divert scarce resources from priority sectors. |
| Paragraph 7:<br>"We reaffirm the commitment of developed-country Members to provide incentives to their enterprises and institutions to promote and encourage technology transfer to least-developed country Members pursuant to Article 66.2. We also agree that the least-developed country Members will not be obliged, with respect to pharmaceutical products, to implement or apply Sections 5 and 7 of Part II of the TRIPs Agreement or to enforce rights provided for under these Sections until 1st January 2016, without prejudice to the right of least-developed country Members to seek other extensions of the transition periods as provided for in Article 66.1 of the TRIPs Agreement. We instruct the Council for TRIPs to take the necessary action to give effect to this pursuant to Article 66.1 of the TRIPs Agreement. | Indeed, in the absence of domestic manufacturing capacity imports become a critical means for increasing access to essential medicines. Given the poor economic prospects and the demands on public health services as a mechanism for access two immediate problems emerge. Production and R&D of 'developing countries' diseases are likely to be limited if not expensive. This is likely to create a market failure, which can only be addressed by increased government role in creating market incentives. The other would be the relative expense of acquiring on-patent medicines.<br><br>Paragraph 7 can be regarded as emphasising this rethinking about the place of least developing countries within this new international community. Members now restate their commitment to provide incentives to their enterprises and institutions to promote and encourage technology transfer to least-developed country Members pursuant to Article 66.2. More significantly, least-developed countries will not be obliged, with respect to pharmaceutical products, to implement or apply Sections 5 and 7 of Part II of the TRIPs Agreement or to enforce rights provided for under these Sections until 1st January 2016. This statement is however made without prejudice to the right of least-developed country Members to seek other extensions of the transition periods as provided for in Article 66.1 of the TRIPs Agreement. To this end, the TRIPs Council was instructed to take the necessary action to give effect to this pursuant to Article 66.1 of the TRIPs Agreement. |

We can conclude from this short précis of the Doha Declaration that the political compromise reflects in large part the negotiating efforts of developing countries underpinned by a firm base of support from scholars and non-governmental organisations in compelling the WTO to reorientate its narrow outlook of international economic relations. Rather than viewing the rule of law purely as means to achieving economic goals, the organisation is now being compelled to rethink how best civil society can be integrated in the decision making process. Whilst the clarification and enumeration is helpful, the discussion anticipates the real challenge lies in the coming months as the task of operationalising the key commitments begins.

A careful reading of the text suggests that policymakers, following the failure of the Seattle talks, were keen to forge a consensus as a strategy for working out a political solution. This explains the careful crafting of the text to ensure that both the interests of the patent owners and those of developing countries were accommodated.[40] With the exception of paragraph 6, the Doha Declaration does not add anything else. It emphasises both the flexibilities of TRIPs and the need for a global solution, which by implication will necessitate greater coordination between the NGO's, the World Bank, the IMF, and the institutions within the UN. Indeed, the Declaration avoids affirming that 'essential medicines' should constitute a genus of public goods.

**Comments**

1. It is unclear at this stage whether Article 31 will incorporate a new exception.[41] The protracted negotiations revolve around two questions. First, to permit governments like Bangladesh, Nepal, Sri Lanka and Pakistan, who have little or no domestic capacity can now issue a compulsory licence.

   Second, to enable countries like India, China or Brazil to export their pharmaceutical products to address the public health needs in other developing countries.[42] According to the EC the insertion of a textual provision provides:[43]

   'a straightforward, clear, legally secure, effective and permanent solution within an existing legal framework, i.e. Article 31 of the TRIPs Agreement.'

2. The OECD countries are not favourably disposed to the use of Article 30. The broad effect of their proposals would be to layer the access issue with procedural requirements, which can prove to be time consuming, costly and burdensome.

3. Policymakers have yet to consider the economies of scale issues when dealing with production for export to developing countries with small markets. Countries like Nepal, Bangladesh or Sri Lanka may have too small a domestic market to justify pharmaceutical industries. But, investment and expenditure are justified in other big developing countries for developing medicines for these markets.

4. The communication from the African Group merits serious examination.[44]

# *APPENDIX B*
# TRIPs COMPLIANT LEGISLATION

***Case Study of Patent Legislation in India and Pakistan***

| TRIPs FLEXIBILITIES | INDIA | PAKISTAN | COMMENTS |
|---|---|---|---|
| Patentability | S2(j) an invention covers "a new product or process involving an inventive step and capable of industrial application"<br><br>S2(ja) inventive step means a feature that makes the invention not obvious to a person skilled in the art. | S2(i) 'invention' includes any new and useful product including chemical products…and includes any new and useful improvement of any of them; 'process' means any process or manner of new manufacture of a product and includes a new use of a known process or product.<br><br>S10(1) provides that subject to sub-section (2), an invention shall be considered to be capable of industrial application if it can be made or used in any kind of industry. The industry shall be understood in its broadest sense. It shall cover, in particular, agriculture, handicraft, fishery and services<br>S7(2) adopts similar provisions in paragraph (b) | Pakistan's overly prescriptive approach goes beyond the minimal threshold required by TRIPs. For example, it would be easier to patent pharmaceutical patents on the grounds the claim showing 'any' new and 'useful product. Potentially discoveries will be brought within the scope of s2(i). The Indian legislation by contrast reserves in the Patent Office the residual discretion. |
| Exclusions | S3(b) "an invention the primary or intended use or commercial exploitation of which could be contrary to public order or morality or which causes serious prejudice to human, animal or plant life or health or to the environment"<br><br>S3(p) "an invention which, in effect, is traditional knowledge or which is an aggregation or duplication of known properties of traditionally known component or components" | | There is no reference in the Pakistan legislation to protect traditional knowledge. The Indian legislation arguably limits the scope in which biological organisms can be exploited. The mere fact that the traditional knowledge is not publicly known is insufficient. This is an attempt to avoid bio-piracy and ensures that traditional knowledge handed down to the indigenous community or |

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| TRIPs FLEXIBILITIES | INDIA | PAKISTAN | COMMENTS |
|---|---|---|---|
| | | | which has been developed are incapable of being captured by patents. |
| Parallel Imports | S107A now provides that (a) any act of making or using a patented invention within three years before the expiry of the terms of the patent by any person for the purpose of development and submission of information to any regulatory authority responsible for grant of marketing approval for the product of invention; (b) importation of patented products by any person from a person who is duly authorised by the patentee to sell or distribute the product, shall not [be] considered as an infringement of patent rights". | S30(5) provides that the rights of excludability do not extend to acts in respect of articles which have been put on the market by the owner of the patent or with his consent or acts done only for experimental purposes relating to a patented invention. | S30(5) is badly drafted and does not adequately define the reach of the exhaustion principle or the scope of the 'Bolar' provisions.<br>This can be contrasted with section 107A |
| Working of Patented Inventions | General Considerations to operationalise Chapter XVI S83(a) inventions to be "worked in India on a commercial scale and to the fullest extent that is reasonably practicable"<br>(b) "they are not granted merely to enable patentees to enjoy a monopoly for the importation of the patented article"<br>(c) that the protection and enforcement of patented rights contribute to the promotion of technological innovation.."<br>(d) "do not impede protection of public health and nutrition and should act as instrument to promote pubic interest.."<br>(e) "do not in any way prohibit Central Government in taking measures to protect public health"<br>(f) "the patent right is not abused…does not resort to | S59 provides for the issue of compulsory license if the patented invention is not exploited or is insufficiently exploited, by working the invention locally or by importing in Pakistan. The right holder may however avoid the issue of this non-voluntary license if he satisfies the Controller that circumstances exist which justify the non exploitation or insufficient exploitation of the patented invention in Pakistan. | It may be argued that such prescriptions are tantamount to discriminating against patents as a field of technology contrary to Article 27(1)<br>(i.e., pharmaceutical process or product patents). |

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| TRIPs FLEXIBILITIES | INDIA | PAKISTAN | COMMENTS |
|---|---|---|---|
| | practices which unreasonably restrain trade or adversely affect the international transfer of technology"<br>(g) "that patents are granted to make the benefit of the patented invention available at reasonably affordable prices to the public." | | |
| Compulsory Licenses | S84(1)(a) "that the reasonable requirements of the public with respect to the patented invention have not been satisfied"<br>(b) that the patented invention is not available to the public at a reasonably affordable price"<br>(c) "that the patented invention is not worked in the territory of India" | 58. (1) Subject to sub-section (2), where (i) the public interest, in particular, national security, nutrition, health or the development of other vital sectors of the national economy so requires; or<br>(ii) the Federal Government has determined that the manner of exploitation, by the owner of the patent or his licensee, is anti-competitive, and the Federal Government is satisfied that the exploitation of the invention in accordance with this sub-section would remedy such practices, the Federal Government may, even without the consent of the owner of the patent, decide that a Government agency or a third person designated By the Federal Government may exploit a patented invention. | It could be argued that this exceeds the limits imposed by Article 31 and furthermore any conditions are subject to the due process of mechanisms of judicial review, reasonable compensation, voluntary agreement etc.<br>It is not possible under TRIPs for pharmaceuticals manufactured under compulsory license to be exported to other countries where TRIPs legislation is already in place. |

| Comments |
| --- |
| India is the most proactive exponent in utilising the flexibilities. Countries like Bangladesh, Sri Lanka, Nepal and arguably Pakistan do not have the capacity or the critical human resources to exploit the economies of scale. The local working requirements will ensure a viable supply chain to be located within the region and will facilitate attempts to increase domestic capacity, human resource base and promote a culture conducive to exploiting the knowledge economy.<br><br>On a macro-economic level, this strategic use of the patent system should reduce reliance on foreign imports and will improve the country's balance of payment. Revenues saved in potential rent transfers can be invested into the pharmaceutical industry and increase the expenditure on improving the public health infrastructure. The strategic use of the patent system must be balanced against the opportunity cost of the likely impact on FDI, technology transfer and joint venture licensing arrangements.<br><br>It is difficult to see the extent to which in view of the limits under Article 31 what benefits countries other than India stand to gain from using compulsory licenses. One reason lies in the fact that the commercial production requires sufficient economies of scale to render the investment viable. |

# *APPENDIX C*
# A SUMMARY OF TRIPs ISSUES AND IMPLICATIONS FOR SOUTH ASIA

| TRIPs OBLIGATIONS | SOUTH ASIAN DEVELOPING COUNTRIES |
|---|---|
| Non Discrimination Policies | Pharmaceutical exports cannot be discriminated against by enacting protective legislation. In practical terms there will be an increase in foreign pharmaceutical products which will require governments in Bangladesh and Sri Lanka and Pakistan to assess the impact on welfare loss and the domestic industries which currently possess some manufacturing capability. It is unclear as to the extent to which the Indian generic industry will be significantly affected. There will invariably be some form of contraction in the industry as well as increase in the entry into joint ventures or licensing of domestic manufacturers. |
| Protection to be made available for product and process patents in pharmaceuticals | All countries must now set in place patent protection systems and legislation. This will impose considerable costs on countries like Nepal and Bangladesh who will need to have in place an entirely modern framework. Sri Lanka, which has previously adopted the WIPO model, may have to undertake minor modifications. India, however, has now to amend its legislation to ensure that process patents are protected. |
| The interface between Article 27(1) and Article 28(a) is at present unclear. | India which has a substantial generic industry may be significantly affected if it is unable to exploit the economies of scale in case parallel imports are prohibited under the agreement. This is the reverse of the 'local working' requirement where foreign multinationals located in developing countries may argue that parallel imports of cheaper versions of patented products produced locally are being discriminated against. |
| Standard Setting for Issuing of compulsory licenses. | Domestic legislation must enact the standards prescribed by Article 31(f), which restrict the issuance of compulsory license on the grounds stipulated in the section. The requirement that royalty payments are made presupposes that governments have adequate resources to fund the repayments. Also, there is an assumption that in producing the medicines under compulsory license, domestic manufacturers do not attach any importance to the economies of scale particularly where the domestic market is small or not viable. |
| TRIPs recognises that developing countries may not be able to comply with the obligations. Consequently, transition periods are made available. | Almost all the developing countries in South Asia have in place TRIPs compliant legislation with the exception of Nepal, which is presently being assisted by WIPO. |
| FDI and Technology Transfer | It remains to be seen, given the complexion of the corporate pharmaceutical model, whether these aspirations are likely to be operationalised. It must be questioned whether any credible benefit is to be gained in the case of Nepal and Bangladesh, in particular. |

# Endnotes

1. See Gary G. Yerkey and Daniel Pruzin, "United States Drops WTO Case Against Brazil Over HIV/AIDS Patent Law" WTO Reporter (June 26, 2001) and C Raghavan, 'US beats a (tactical) retreat over Brazil's patent law' (visited 7 February, 2002) http://www.twnside.org.sg/title/tactical.htm.

2 See Brazil – Measures Affecting Patent Protection WT/DS199/1, G/L/385, IP23 (Request for Consultations by the US, 8 June 2000) and Brazil-Measures Affecting Patent Protection WT/DS199/39 (Request for the Establishment of a Panel by the US, January 2001).

3 FM Abbott, 'The Doha Declaration on the TRIPS Agreement and Public Health: Lighting A Dark Corner at the WTO JIEL (2002) 5:2, 469 at 470-472. See however Phrma's response: 'PhrMa supports USTR on Brazil http://www.phrma.org/press/newsreleases//2001-06-25.238.phtml. (last visited, 6 February, 2002)

4 See a summary of the South African Medicines Act Court Case in http://www.tac.org.za/newsletter/ns010424.txt. See however Phrma's response: 'PhrMa supports USTR on Brazil http://www.phrma.org/press/newsreleases//2001-06-25.238.phtml. (last visited, 6 February, 2002)

5 Ibid.

6 It is said that in the US the resource base rose from 788,500 in 1965 to over 1.8million in 1989.

7 See FIM/IFPMA, *The Question of Patents: The Key Medical Progress and Industrial Development* (Geneva, 1998).

8 See generally UNDP, *Human Development Report* 1999

9 Ibid p 69. See also C Correa *Some Assumptions On Patent Law And Pharmaceutical R&D* Quaker, Occasional Paper 6. Available at www.quno.org.

10 See archives in http://www.cptech.org

11 See Fortune Magazine, "Fortune 500: Drug Industry Most Profitable Again" April 3, 2002.

12 See OECD, *Technology and the Economy* (1992). Also C Correa, 'Some Assumptions on Patent Law and Pharmaceutical R&D' Quaker Occasional Paper No 6, pp3-6.

13 C Correa, 'Some Assumptions on Patent Law and Pharmaceutical R&D' Quaker Occasional Paper No 6

14 Ibid p4

15 UK Patents Act 1977 section 1.

16 See J Schmookler, *Invention and Economic Growth,* (Harvard UP, 1986) Chapter 1

17 See Lord Hoffmann in *Biogen Inc v Medeva Plc* [1997] RPC 1 at p 34. Also section 2 Patents Act 1977

18 The following account is taken from A Gupta, 'Enigma of Intellectual Property Rights: How Long Shall We Miss the Opportunities?' Paper presented at the 49th Indian Pharmaceutical Congress in Trivandum 20 December 1997. Available at www.iprcommission.org.

19 S Taurel, 'Healthcare Policy in the Twenty-First Century: The Outlook for Innovation' CMR International Annual Lecture given to the Royal College of Physicians, London June 27, 2000.

20 V Fuhrmans and G Naik 'In Europe, Drug Makers Fight Against Mandatory Price Cuts' http://online.wsj.com/article/0,,SB102341006255711560 0,00.html?mod=Page%20One

21 See for example, Charles EM Normand and J Patrick Vaughan*, Europe Without Frontiers, Implications For Health* (England: J Wiley, 1993)

22 News, 'Regulators Investigate Patent Fraud Claims' 13 January 2002 *Legal Media Group* .The companies concerned were GlaxoSmithKline, Biovail and Bristol-Myers Squibb

23 See V Fuhrmans and G Naik 'In Europe, Drug Makers Fight Against Mandatory Price Cuts' http://online.wsj.com/article/0,,SB102341006255711560 0,00.html?mod=Page%20One. PhRMA is coming under increasing pressures in both the EU and the US. According to this feature in the Wall St Journal, the US legislature is pushing PhRMA to reduce its prices for Medicaid patients. In EU the governments have targeted a list of costly drugs and negotiated discounts. Also White Paper, *The New NHS: Modern, Dependable* (Cm 3807, 1997).

24 J Keon 'Fast generic relief for the cost of pharmaceuticals', The Globe and Mail, January 24, 2002

25 N Kumar, 'Intellectual Property Rights, Technology and Development: Experiences of Asian Developing Countries' at p11. This paper is part of a series of papers commissioned by the UK Commission for Intellectual Property Rights and can be found at http://www.iprcommission.org/documents/Kumar_study.doc.

26 See Press Release on August 21 'World Bank Urges More Balanced Approach to Global Development'

27 See World Bank, World Bank Development Indicators 2002 (last visited 6 May 2002) Available at: http://www.worldbank.org/data/wdi2002/economy.htm. On close reflection however the central premise informing these prescriptions can be problematized. The logic that poverty and public health problems are self-reinforcing and can be alleviated by developing countries embracing industrial policies and property protection systems is an over simplification. Apart from the recognition that public health management is complex it assumes too readily that the costs of such policies are overridden by prospective economic gains or that these countries have the capacity let alone the infrastructures to exploit the potential of intellectual capital. Though this may be a long-term objective the economic arguments fail to provide an answer to the question of how best the present health crises regarding access is to be overcome in the light of their varying levels of development.

28 J Stiglitz, *Globalisation and Its Discontents* (Penguin, 2002) p 10

29 P Danzon, "The Pharmaceutical Industry" in B Bouckaert & G de Geest, Encyclopedia of Law & Economics (Cheltenham: Edward Elgar, 2000) 1055, 1066.

30 See India – Patent Protection for Pharmaceutical and Agricultural Chemical Products, WT/DS50/R (Panel Report) and WT/DS50/AB/R (Appellate Body Report). The Agreement integrates the corresponding obligations assumed by the Member States in international conventions of the WIPO, the Berne Convention (ie Protection of Literary and Artistic Works and the Paris Convention for the Protection of Industrial Property. A number of principles are also set out in the Agreement to ensure that a universal set of rules will now govern the administrative and dispute resolution mechanisms for the enforcement of intellectual property rights in Member States. Where the resolution of intellectual property rights in the domestic jurisdiction proves to be inadequate or unsatisfactory TRIPS obligations are most likely to be enforced through the WTO's new conflict resolution administrative and judicial processes.

31 C Correa, *Integrating Public Health Concerns into Patent Legislation in Developing Countries* (South Centre, 2000) p 5

32 Under Art 28:1b a similar entrenchment of rights exists for process patents to prevent unauthorised acts exclusive to its owner.

33 Source: UNIDO – The Worlds Pharmaceutical Industries; An International Perspective on Innovation, Competition and Policy by Robert Balance, James Pogany and Helmet Forsteiner, 1992

34 J Keon, 'Fast generic relief for the cost of pharmaceuticals', The Globe and the Mail, Jan 24, 2002.

35 Source: UNIDO – The Worlds Pharmaceutical Industries; An International Perspective on Innovation, Competition and Policy by Robert Balance, James Pogany and Helmet Forsteiner, 1992

36 See Human Development Report 2001 Table 8 and CMH World Development Indicators from the World Bank, 2001 cited in WHO, *Macroeconomics and Health: Investing in Health for Economic Development* (Geneva: WHO, 2001) (visited 7 May 2002) < http://www3.who.int/whosis/cmh/cmh_report/e/htm/001-020/001-020.html

37 Ibid

38 "Fighting Cancer with Cesium: India" www.tcdcwide.net/tcdcweb/experiences/scitech/cases/st4indi.htm

39 G Felkner et al (eds) *The Pharmaceutical Industry in India and Hungary – Policies, Institutions and Technological Development* (World Bank, 1997). Also See P Trouiller (et al) 'Drug development for neglected diseases: a deficient market and a public-health policy failure' (2002) 359 Lancet 2188-94 (22 June). Available at http://www.thelancet.com/journal/vol359/iss9324/full/llan.359.9324.editorial_and_review.21486.1. The location of pharmaceutical industries in the commercial environment the authors argue has led to a distinct lack of emphasis on R&D in tropical diseases and tuberculosis. This conclusion is the result of analysing data from Medline and the databases of the US FDA and the European Agency for the Evaluation of Medicinal Products. The authors found that of the 1393 new chemical entities marketed between 1975 and 1999, R&D on diseases that are commonly found in poor communities were accorded low priority. The study showed that only 16 covered diseases of relevance to developing countries.

40 See Submission by the African Group, Barbados, Bolivia, Brazil, Cuba, Dominican Republic, Ecudor, Honduras, India, Indonesia, Jamaica, Pakistan, Paraguay, Philippines, Peru, Sri Lanka, Thailand and Venezuela. IP/C/W/296 (29 June 2001). Available at http://docsonline.wto.org/GEN_viewerwindow.asp?D:/DDFDOCUME../W296.DOC.HT
(Visited on 28 June 2002)

41 See P Geitner, EU Proposal to increase access to drugs for poor countries attacked by activists as 'impracticable' June 24 AP Business Writer. Available at: http://story.news.yahoo.com/news?tmpl=story&u=/ap/20020624/ap_wo_en_po/eu_wto_drug_patents_2.

42 IP/C/W/339 paragraph 4

43 Ibid paragraph 5

44 IP/C/W/351 24 June 2002

# CUTS' PUBLICATIONS
# TRADE, ECONOMICS AND ENVIRONMENT

**STUDIES**

1. **Policy shift in Indian Economy**
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