TRIPS and Access to Affordable Drugs

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It is a well-recognised fact that many modern medicines, largely discovered and developed by the pharmaceutical industry are in general unaffordable to the majority of patients in economically backward, developing countries. Since they constitute around 75 per cent of the world’s population, it is a matter of great concern for the future of healthcare itself, if for the majority of world’s population, access to medicines, which are patent protected, is denied. Problems of access to medicines are related to the problems of non-availability of disposable income among the population to meet their medical needs as well as the high and unaffordable prices of drugs.

The issue that is now being debated is the impact of the TRIPS Agreement on the availability and affordability of much needed medicines for the poorer populations of the world and if there is indeed a negative impact, what are the possible modalities to reduce that impact and make drugs cheaper for deserving populations and developing countries?

Between the flexibilities available in TRIPS Agreement and the Doha Declaration on Public Health, can Member Countries through appropriate legislative and administrative measures, safeguard the interests of their poor populations? Can governments in developing countries bring in appropriate legislations to ensure equitable access to medicines much like the Patient Protection and Affordable Care Act of Barack Obama approved by the US Congress in March 2010?

Keywords: TRIPS, affordable drugs, access to medicines, innovation, patent, compulsory licence

The grant of compulsory licence to the Indian company Natco Pharma to manufacture and market in India the anti-cancer drug, Nexavar, a drug patented by the German pharmaceutical company, Bayer, has attracted considerable attention and debates around the world. In the history of Indian patent law, this is the first major grant of such a licence, even though Indian Patent Law, 1970 which was in operation for 33 years (from 1972 till 2005) had not only provision for compulsory licences, but also for licences of right for pharmaceuticals. In this sense, this decision has been an epoch making event in the history of the industry. The implication of the grant of compulsory licences on the current system of intellectual property rights (IPR) protection as dictated under the Trade Related Aspects of Intellectual Property Rights (TRIPS) Agreement, affordable access to patented drugs and investments in innovation and new drug discovery and development need to be evaluated to guide future developments since there are a large number of patented drugs needed, primarily in developing countries which are not accessible to most of the patients who need them.

Problems of access to medicines are related to the problems of non-availability of disposable income among the population to meet their medical needs as well as the high and unaffordable prices of drugs. The elements responsible for the high prices of drugs are: (1) high costs of drug discovery and development, (2) low productivity in R&D activities, (3) inordinate delays and long gestation periods for development of drugs and their regulatory approvals, (4) heavy investments in marketing including promotion and distribution of drugs, (5) high rate of obsolescence of even established drugs due to unexpected adverse drug reactions and/or emergence of better drugs, (6) high investments needed for setting up manufacturing facilities particularly in new technology areas, and (7) high costs of investing in manufacturing and marketing of drugs. While these costs are real and need to be expended, the IPR protection system which grants ownership and exclusive rights for the drug to the patent holder, provides a platform for recovering these costs through drug sales.

IPRs and Innovation

Innovation is the lifeline for growth in industrial activity, more so in certain sectors such as the

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pharmaceutical industry. It leads to discovery of new and better products, profitable growth through them and further investments in R&D and in general economic and social benefits to society.

The question has often been raised about the role of IPR protection systems in developing, nurturing and encouraging an innovation culture. A framework for exploiting such innovation also needs to be in place if benefits from innovation are to result in economic growth and social benefits. Stakeholders who have invested in innovative pursuits also need to be rewarded through ensuring financial returns for their efforts. And yet, there are those who argue that IPR protection could, instead of encouraging innovation, indeed stifle the process by building fortresses around the innovation and preventing third parties from entering the area. This concern is based on the fact that IPRs are indeed monopolies guaranteeing exclusive rights to not only the product in question but also to the technology space it is part of. To that extent it is deemed that IPRs indeed can and do lead to anti-competitive practices. To break through such monopoly, valuable and often non-productive efforts and resources are required which lead to increasing costs to the ultimate beneficiaries. Stronger IPR protection therefore does not necessarily lead to more innovation, let alone cost-effective innovation.

**Access to Drugs**

Lack of access to much needed drugs\(^5\) may be due to high costs of drugs, low purchasing power or non-availability. Each one of these elements which result in poor access to drugs need to be analysed in detail before corrective steps are considered. Shortages in supply of drugs also affect a patient’s access to drugs. Such shortages may be due to unexpected rise in demand resulting from sudden incidence of epidemics, low production capacity or in rare cases companies reducing or terminating production due to market forces or Government imposed drug price controls. During the implementation of the first Drugs Prices Control Order in India in the early sixties, drugs categorised as essential drugs were given very low profit margins (mark up over manufacturing costs), with the result that many manufacturers stopped their production and supply.

**Costs of New Drug Discovery and Development**

Over the years the total costs of discovering a new drug molecule\(^6\) from synthetic, natural products or through biotechnology routes have escalated several fold with figures quoted at over US$ 2 billion for a single drug to reach the market. In spite of several new approaches to drug discovery, including rational design and application of systems biology, genomics and proteomics, the overall costs have not come down. The failure rate remains very high and drug withdrawals and bans, post-marketing have increased due to adverse drug reactions, safety issues and the emergence of better drugs. Thus, R&D in the pharmaceutical area remains the least productive of all activities in this sector in terms of investments and returns. The consequence is that the drug prices which are related to such high costs are unacceptably high, making them unaffordable to the majority of the world’s population.

To minimise the impact of such costs, during the last five decades, leading R&D based pharmaceutical companies targeted bulk of their research efforts at markets which had the potential to achieve blockbuster status (annual sale of a single brand > US$ 1 billion). This meant that research efforts were concentrated in areas which have high market needs and patients who could afford the latest version of drugs. The poor track record of this model is leading companies to genomic and proteomics (omics) based personalised medicines.

While the ‘omics’ model which relies on genomics and proteomics currently being actively followed by leading pharmaceutical companies, surely leads to better, more specific, effective and safer drugs, they are useful for limited number of patients and their prices are inordinately high. The average costs of treatment with each of the top ten biotechnology based drugs, many of them for chronic conditions, are around US$ 20,000 or more per month, clearly outside the reach of most patients, notably from the developing countries. The pricing model, while it is based on costs of R&D, production and marketing, is supported by the patent system by virtue of the exclusivity on the product guaranteed during the period of validity of the patent. Generic companies on the other hand have no R&D costs to recover and hence can and do offer the drugs at prices one fifth or even less than those for the patented versions making them more affordable.

**Reducing the Costs of Drug Discovery**

Apart from approaches adopted at the operational level for reducing the time required to complete the process of drug discovery, development and approvals, use of more rational R&D models,
development of new and better drug delivery systems and products of existing drugs, discovery of new indications for marketed drugs, improved production and marketing logistics are some of the new ideas which are being pursued in recent times.⁹

Open Source Drug Discovery

Among the approaches being increasingly mooted for more efficient R&D efforts are two recent developments initiated by some of the world bodies with the support of a few of the leading pharmaceutical companies. They are the use of the Open Source Drug Discovery (OSDD)⁹ approach and the development and use of patent pools. The Council of Scientific and Industrial Research (CSIR), India has taken the lead and has a major programme involving many global partners.

The primary objective of the OSDD model is to discover drugs through networking and bringing together all available data including on genomics and computational biology, technical and scientific skills and infrastructure of several groups from all over the world. It is hoped that this approach would lead to meaningful outcomes in terms of reduced costs and time frames than those expended for current models. However, it is obvious that OSDD can only stimulate and at best lead to earlier identification of a candidate molecule. The arduous task of drug development constituting 80 per cent of the financial and scientific and technical skill resources has still to be sourced from outside the programme. Unfortunately these resources are available largely with the R&D based pharmaceutical companies and their compulsions for active involvement will be guided by commercial considerations.

Patent Pools

While patents are indeed the lifeline of the pharmaceutical companies, it is a fact that over 90 per cent of patents granted by the various patent offices are never exploited through commercialization. The reasons are many. Apart from lack of adequate markets, often times patents are applied for and taken for protecting technology territories from third party entries and defending and building fortresses around successful products. Thus, a large number of innovations protected through patents but not exploited, remain on the shelves and eventually lapse without any attention being paid to them. The consequence is that very valuable and potentially useful innovations, which could have benefited patients, are never put to use. The concept of patent pools⁹ involves collective management of intellectual property to expand access to desired medical technologies and products. Patent pools are based on an agreement between two or more patent owners to pool those of their patents which are of no direct commercial interest to them and licence them to one of them or to a third party under pre-determined licensing terms for exploitation by the sponsor. It is also understood that patent owners are agreeable to have a collective management of the patent pool for more expeditious discovery and development of drugs.

Access to drugs also depends on availability in the concerned markets, often times depending on supply chain management including distribution. Many developing countries have very ineffective distribution systems in place, making drugs not easily accessible to populations dispersed across large geographical territories.

Parallel Imports

One of the strategies which has been debated in recent times is based on the implicit provision in the TRIPS Agreement on the issue of parallel imports as a means of reduced prices and increased access. Parallel imports¹⁰-¹² constitute import of a patented product from a market, where it has been launched by the patent holder or his licensee at prices lower than elsewhere. The question is whether under the principle of exhaustion of rights of the patent holder with the first launch of the product, are others free to import the same product without licence from the patent holder at prices at which the drugs are offered in that territory? Articles 6 and 39 of the TRIPS Agreement are deemed to indicate formal sanction for parallel imports. In other words, countries can import patented products from any country where the patent holder has marketed the product. If the national law establishes a national exhaustion of rights, then such exhaustion will be applicable only when the patented product is marketed in that country. On the other hand, if an international exhaustion of rights is invoked, the first launch of a patented product in any country will be equivalent to exhaustion of rights globally. In such a case, countries are free to import the patented product at the lowest prices at which they are available in any country. India has not taken a clear position on this issue and so far no parallel imports have taken place.
The Indian Patents Act, 1970

The Indian Patents Act of 1970 (ref. 13) which came into force in 1972, had several discriminatory clauses which disallowed product patents on medicines, food and agro products; reduced the validity from 14 years (for all sectors) to seven years from the date of filing or five years from the date of sealing of the patent whichever was shorter; included a provision for automatic licences of right in addition to compulsory licences for non-working of the patent in the country and put the onus of burden of proof in cases of infringement of process patents on the process patent holder. These terms virtually decimated the patent system as far as pharmaceutical patents were concerned and not surprisingly, practically all R&D based multinational companies (MNCs) stopped filing applications in India. The only applications filed in the patent offices were for processes and that too with little expectation of their exploitation through own use or through licensing to third parties. Such a highly diluted patent system in India enabled better access to medicines at more affordable prices. In the absence of provisions for grant of product patents, Indian companies were free to manufacture and market product patent-protected drugs as long as they did not infringe valid process patents. Aided by a strong chemical technology base, within years India developed strong capabilities to produce even the most sophisticated active pharmaceutical intermediates (APIs) or bulk drugs. Thus, from an industry perspective, India became a major supplier of APIs to both the developed and the developing countries. Even major MNCs used India as an outsourcing hub for their bulk drugs supply. India is today the 3rd largest country producing pharmaceuticals in volume terms and 8th in value terms.

The fact that India became a major force in the supply chain for pharmaceuticals is apparent from the fact that Indian exports today match the domestic consumption. Unlike in early days, India today supplies generics and bulk actives even to the innovator companies thereby establishing its credibility as a quality supplier. However, on the flip side, the dilution of the patent system which disallowed grant of product patents were deemed to have been major deterrents to investments in much needed drug discovery and development programmes, even by the large Indian companies. The impact of reduced interest in discovery programmes also affected the discovery of drugs for diseases of the poor; an area often neglected by the R&D based MNCs. At the same time, other developing countries which need them the most neither have the skills or resources to initiate R&D activities to discover and develop drugs for diseases of the poor. Thus the Indian industry got branded as a supplier of generic products with little contribution in the area of new drug discovery and development.

Pre – TRIPS Era

Prior to the signing of GATT in April 1994 and the setting up of WTO in 1995, countries of the world had different standards of protection of intellectual property in the pharmaceutical sector ranging from no protection through patents to restriction to process patents only. The period of validity of patent protection ranged from 7 years (India) to 17 years (USA), in addition to provisions for compulsory licences (most countries) and licences of right (India) under stipulated conditions. Countries of the developed world provided the highest levels of protection where innovations of products, processes and new utilities of existing products were subject to protection under the patent system. The legal systems prevailing in these countries also favoured the rights of the inventors over those of alleged infringers. The famous judgement (Diamond v Chakravarthy, 1980) in the case of protection of new microorganisms developed through the hybridoma technology, when the US Supreme court ruled that that the oil gobbling pseudomonas strain invented by Ananda Chakravarthy, is a highly cited case in point. By and large the US has been innovator friendly in the matter of grant of patents.

Post – TRIPS Era

The relevance of the inclusion of TRIPS as one of the key Agreements under the General Agreement on Tariffs and Trade (GATT) finalised at the end of the Uruguay Round of Trade talks itself has been questioned in many quarters ever since the establishment of WTO. The principal arguments in favour of TRIPS have been that IPR protection encourages innovation leading to new useful products, investments in their manufacture and marketing and consequently impacts trade and economic growth of nation states. While the majority of the founder members in WTO perhaps were not fully cognisant of the restrictive role that TRIPS could potentially play in their overall development in all these areas at the time of signing the Agreement, today most of the 153 members of the WTO are well positioned to
analyse the impact of TRIPS on their own growth in economic and non-economic terms including access to much needed drugs for their populations. TRIPS was also meant to bring in a globally harmonised IPR regime, free market access and most favoured nation (MFN) status among the members, across the border direct investments, technology transfer and in general a global trade order respected and implemented by member states through the WTO.

TRIPS Agreement

It is to be understood that TRIPS as agreed upon and administered by the WTO is a minimum purpose agreement and Members are free to provide more protection through their national legislation. There have been many attempts by some of the members, particularly from the developed countries to further strengthen the Agreement and provide higher levels of protection, by for example removing some of the safeguards and flexibilities offered under the present Agreement. There are others who argue that current provisions should be treated as the maximum available for the Members to exercise in order to ensure adequate enforcement of users’ rights as well.

Impact on Trade, Innovation and Economic Growth

The inclusion of TRIPS in the GATT Agreement which led to the evolution of WTO as the most important instrument for protection of intellectual pursuits was intended to promote multilateral trade in new products developed through innovation.

At the end of 16 years since the setting up of WTO, it is interesting to evaluate the impact of TRIPS on some of the growth parameters which were intended and promised, particularly in the less developed countries of the world. The fact that the least developed countries (LDCs) have so far not benefited and are still not ready to join the mainstream was well recognised at the Doha Summit in 2001. That was the reason for extending the time for implementation of the TRIPS Agreement by 5 years from 2011 for all LDCs. How effective has WTO been in dealing with regulation of trade among the member countries, monitoring implementation of the terms of the various agreements and providing a base for negotiated settlements on disputes between the members? After all, it is claimed that the members of WTO constitute 97 per cent of global trade and hence should indeed be the premier agency responsible for an effective, fair and equitable global trade order.

While global trade had increased multi-fold over the years from 1995, not necessarily due to the efforts of WTO (until recession hit global economies since 2008), there is still no evidence that foreign direct investments or levels of innovation has increased as a consequence of implementing better protection of IPR systems in developed or developing countries. However, what is clear is that lack of an effective IPR system would have affected investor confidence in enlarging the scope and resources allocation in innovation which is the life line for new products discovery and development. It has also not been possible to identify a direct relationship between IPR protection and economic growth as measured by common parameters such as per capita GNP or income distribution.

TRIPS and Healthcare

The statement by the then Director General of the United Nations, Kofi Annan in 2001, that ‘IPR protection is the key to bring forward new medicines, vaccines and diagnostics urgently needed for the health of the world’s poorest people’ was soon refuted when at the Inter-Ministerial Conference in Doha in 2001, representatives of the developing countries stated that IPR has stood in the way of access to drugs for the poor. It further held that ‘the TRIPS Council has to find a solution to the problems countries may face in making use of compulsory licences if they have too little or no pharmaceutical manufacturing capacity’ and authorised the General Council to take action by end 2002.

The conflict between TRIPS provisions and public health issues gathered momentum due to non-availability and non-affordability of drugs used in the treatment of HIV/AIDS in Latin American and African countries. In cases affecting this issue in South Africa and in Brazil, after major resistance from United States and to some extent from Europe, who took the matter to the Dispute Settlement Board of WTO, the ultimate winners were the affected developing countries. The disputes on this issue raised at the WTO by US were withdrawn in spite of pressure from R&D based pharmaceutical companies. In fact, the offer from some Indian companies, notably Cipla, to supply some of these drugs at one fifth to one tenth of the innovator’s prices put additional pressure on the US and European companies. US President Clinton in 2000, after many domestic debates announced a change in State policy through an executive order supporting compulsory
licences for HIV/AIDS drugs and technology for Sub Saharan Africa. The European Union and the WHO also endorsed the view that while implementing the provisions under TRIPS, the ill effects of TRIPS on availability and affordability of drugs should be a major consideration calling for appropriate action on the part of the producers and national governments. It was just as well, since if countries which are members of WTO took unilateral decisions to provide healthcare to their people even at the cost of going back on their obligations under TRIPS, the whole edifice of IPR protection systems would have collapsed.

**Doha Declaration and Access to Drugs**

The role of TRIPS to influence healthcare in developing countries was realised in its totality for the first time at the Inter-Ministerial Conference in Doha in 2001 (ref. 15). The resolution to initiate a fresh round of talks, the Doha Round, was a consequence of such a realisation.

Para 4 of the Doha Declaration not only confirmed the rights, but also the obligations of WTO members to interpret and implement the TRIPS Agreement in a manner supporting the protection of public health through access to needed drugs. In addition, it recommended the provision to export patented products to countries which lack technical strengths to utilise their compulsory licences. In addition, the LDCs lack the legal, legislative and administrative set up to fight for their rights even when compulsory licences have been granted.

A particularly interesting case would be the case of compulsory licences for anti-HIV/AIDS drugs providing the life line to millions of patients who have no access to much needed drugs at affordable costs. While the Doha Declaration (Para 6) of 2001, maintained that public health issues will supersede private interests protected through the patent system when it concerns life threatening diseases such as tuberculosis, malaria and HIV/AIDS; and compulsory licences could be issued under Article 31 of TRIPS, it was not until 30 August 2003 when an agreement was reached on the modalities of exercising these provisions by the TRIPS Council. Eight years later, there have been very few compulsory licences granted, even though there has been acute need for grant of compulsory licences to make drugs available at affordable prices to poor patients. The reason has been that the conditions imposed for the supply of drugs against compulsory licences granted to the importing country which has no technical ability to produce it themselves are so cumbersome, time consuming and restrictive that in practice they are difficult to implement. For example, the exporting country should obtain a licence to export the product, produce batches only for the required quantity which has to be specially labeled and colour coded for the purpose and stop production once that demand is met. The experience of Canadian and Indian companies to supply anti-HIV/AIDS drugs have been far from satisfactory, defeating the very purpose for which these provisions have been made in the first place. A few countries, most notably Thailand, Brazil have effectively implemented the compulsory licence system to cater to their domestic market.

**The Doha Round**

The Doha Round not only covers in its scope the implementation of already agreed upon terms for the proper functioning of the WTO, but also of many fresh ones. It covers among many issues concerning the developing and least developed countries, such as ensuring access to affordable healthcare, more particularly to patented drugs. While it is true that the patent system under TRIPS embodies monopoly, even if for a limited period for the inventor (patent holder), even TRIPS mandates that such a monopoly should never be used to create anti-competitive practices. At the same time, developing an equitable system of protecting the innovator’s interests and balancing them with those of the poor and needy is not an easy task. That is precisely what the Doha declaration on TRIPS and Public Health attempted to do. The Declaration emphasizes that TRIPS should not prevent members from acting to protect their national health issues. It affirms governments’ rights to enforce the flexibilities afforded by TRIPS in the form of compulsory licences, parallel imports and through national interventions including control on prices of drugs through appropriate legislations. Furthermore, as a result of several negotiations at the TRIPS Council, special provisions for utilisation of compulsory licences even by members who have no technological capability to implement them by associating with other members, have now been approved by the WTO. The patent holder, however, continues to own the patents and is entitled to receive commensurate compensation from the licensee. However, in spite of protracted negotiations on this issue and consensus on approaches, the final outcome is far from satisfactory. The procedure to be followed
to import under their licence or to produce the drugs using compulsory licences is much too cumbersome and bureaucratic to offer a practical and meaningful solution to the problem; so much so, during the last fifteen years, only one case has been successfully handled under these provisions to make patented drugs available to another country through manufacture and supply.

Compulsory Licences to Improve Access to Drugs

Compulsory licences for the exploitation of patented products under specified conditions and terms have been available in the Patent Acts of most countries including the developed countries long before TRIPS Agreement came into force. While many countries such as Brazil, South Africa, Eritrea, Mozambique, Zambia, Ghana, India, Indonesia, Malaysia of the developing world and Italy and Canada of the developed world have issued compulsory licences, mostly for HIV/AIDS drugs; the most effective use of compulsory licences has been in Thailand which under its generic medicines policy has implemented the maximum number. In 2006, 2007 and 2008, Thailand issued seven compulsory licences, two for HIV/AIDS, one for cardiovascular diseases and four for cancer. In many ways, the Thailand model which aims at increasing generic competition to reduce the prices of drugs and thereby improve access has been used by most of the other developing countries, albeit less effectively. Experience has shown that production and marketing of drugs under compulsory licences considerably reduces the prices of drugs and makes them more accessible and affordable provided the licensee has the technological capabilities to utilise the licences. The patent holders, US and European based pharmaceutical companies, vehemently complained against Thailand’s compulsory licence policies, but so far there have been no sanctions or penalties imposed by the respective Governments. The strategies adopted by the patent holders in such cases have been diverse. Some companies voluntarily reduced drug prices in those markets, some provided the drugs at concessional prices or in some cases free of cost and at the other extreme, some companies refused to register some of their new products in those countries.

The Indian Scene

Even though the Indian Patents Act, 1970 provided for compulsory licences for all patents and in addition automatic grant of licences as a matter of right in case of non-working of the granted patent, during the 35 years of its operation no effective compulsory licences were granted by the Indian Patent Office. This was partly due to the fact that as a result of the highly diluted patent system operative for the pharmaceutical sector, applications for patents were not being filed by the innovators in the Indian Patent Office during that period. In addition, since there was no provision for applying for product patents, generic producers were free to manufacture and market patented drugs as long as they were produced through processes not patented in India. With India’s strength in the area of chemical technology, Indian companies are producing through indigenously developed processes even the most sophisticated chemical molecules; in other words, Indian companies have the capacity to manufacture even the most complex synthetic molecules. Although India’s technology strengths in the fermentation area, including biotechnology products are still found wanting and are inferior to those of China, and China is a larger global supplier in the area of fine chemicals and intermediates; there is no doubt that in the area of APIs and drug formulations, the Indian industry is well ahead of most other countries and is a major supplier in the global market.

Statutory Price Controls

For the last five decades, India had some form of statutory price control on drugs to enable patients access drugs at the lowest possible prices. Such administrative actions have no relation to the TRIPS Agreement itself. Starting with categorization of drugs according to their essentiality and fixing maximum allowed margins under each category, the number of items under control have been progressively reduced over time. From a basket of drugs comprising 347, the number of drugs under control has come down to 76. No satisfactory answer to find an equitable solution to the problem of safeguarding patients’ interests without jeopardizing availability of drugs has yet been found. The National Pharmaceutical Pricing Authority and its stakeholders primarily from the pharmaceutical industry are currently discussing the latest report on this issue by the Pronob Sen Committee and the Ministerial and Parliamentary Committees constituted for this purpose.

Invoking Provisions under IPA, 2005

Two recent cases related to patents filed by R&D based global MNCs in India during the post-TRIPS era are illustrative of the nature of possible trends and
direction in which the TRIPS Agreement will be interpreted and implemented in India in coming days. Many of the flexibilities in the TRIPS Agreement would be exploited to overcome problems of exclusivity through patents standing in the way of making drugs more accessible and affordable.

The Gleevec Case

The Indian Patent Act, 2005 has restricted the scope of inventiveness to exclude inventions deemed to be trivial in character compared to prior art by introducing Section 3(d). This section is particularly applicable to pharmaceutical inventions and has been a bone of contention.

Article 27 of the TRIPS Agreement clearly mandates that ‘patents shall be available for any inventions whether for products or processes in all fields of technology provided they are new, involve an inventive step and are capable of industrial application – and in that context Section 3(d) would appear to be in violation of this provision since it dictates a discriminatory provision that ‘the mere discovery of a new form of a known substance which does not result in enhancement of the known efficacy (safety is not mentioned) of that substance – unless such known process results in a new product or employs at least one new reactant.’ However, the explanation which follows stipulates that derivatives of the known substance are not patentable unless ‘they differ significantly in properties with regard to efficacy.’ Assuming that there is an agreement on the interpretation of the term ‘significantly’, thereby eliminating possible subjective interpretations, this section does not preclude the grant of patents even for products derived from a known substance. The important question is how to arrive at the level of significance of a new invention vis-à-vis the state-of-the-art. The criticism that making incremental inventions and patenting them in the interests of getting a fresh lease of exclusivity, often referred to as ‘evergreening’ is strictly not tenable since the patent office is the examining authority and therefore has the powers to determine whether the new invention has inventive merits. A major legal battle has been going on between the Swiss company, Novartis and various groups including Indian companies and several advocacy groups on the issue of patentability of Imatinib (Gleevec) under Section 3(d) of the Indian Patents Act. While the current ruling is in favour of the plaintiffs, the final question as to whether the Indian position on Gleevec is compliant with the TRIPS Agreement is still to be decided in the Courts.

The Nexavar Case

The decision of the Controller General of Patents to grant compulsory licence to an Indian company for the manufacture and marketing of the anti-cancer drug Nexavar of the German MNC Bayer has aroused considerable interest in many countries and among international agencies.

The compulsory licence granted by the Controller General of Patents in India for the anti-cancer drug, Nexavar is applicable only for the Indian domestic market as stipulated in TRIPS under the original provisions. The rationale for the grant of compulsory licence for Nexavar was the inability of the patent holder to meet the demand and the extraordinarily high price of the Bayer brand compared to that offered by Natco Pharma. The order also stipulated that Natco will sell the drug at the price of Rs 8880 for a month’s supply and that the company will pay a royalty at 6 per cent of net sales. It has been reported that Bayer has challenged the Patent Office action of granting compulsory licence for Nexavar. The matter is further complicated by the fact that Cipla has offered the same drug at a price of Rs 6840 for a month’s treatment which is considerably lower than that of Natco. In addition, Bayer has sued Cipla of patent infringement in the production of Nexavar and a decision on that appeal is pending. The major R&D based MNCs fear that this case could be a precedent that could affect several other drugs not only in India, but in many other countries.

Flexibilities Available to Members in the TRIPS Agreement

Considering the complex requirements for the grant of compulsory licences, it is prudent to see whether through a more liberal interpretation of the existing provisions under TRIPS, it is possible to implement a more equitable and yet TRIPS compliant IPR system which will benefit the developing countries. For example, through fresh interpretations under Articles 1, 6, 7, 8, 27, 30, 31 and paras 4 to 6 of the Doha Declaration of 2001 (TRIPS and Public Health), can countries resort unilaterally to bring about appropriate legislations in their national laws to safeguard and protect domestic interests? If such an approach can be followed, countries which are threatened by the onslaught of multilateral trade rules as currently interpreted can benefit from the system, without violating the TRIPS Agreement.
Better Access to Drugs

To ensure better access to drugs by the needy, it is not sufficient to enable grant of compulsory licences under the provisions in TRIPS or under the Doha Declaration, countries should have the capability to utilise such licences and should have the capacity to manufacture them and market them effectively. Problems of maintaining quality standards, providing medical information including primary data on safety and efficacy, appropriate distribution channels and storage and transportation facilities are also important. According to the current terms under the TRIPS Agreement, import is equivalent to working of the patent and therefore local manufacture is not mandatory. Even though monopolistic prices made possible due to the exclusivity provided by the patent system often make the drugs unaffordable, in most developing countries, even lower prices are often times unaffordable to the majority of patients who need them. Drug price control systems which are operative in many countries still have to take into account realistic production costs which by themselves could be too high and hence unaffordable. Even though differential pricing in developed and developing countries of patented drugs have been advocated, innovator companies are wary of practising that route to assist developing countries, since that may create distortions in international trade. In spite of this, many companies are considering differential pricing structures for developing countries to ensure market access and reduce the burden on poor patients. Better resources mobilization and allocation at the national level to subsidise deserving patients’ drug costs or effective insurance schemes are the only answers. It is essential that R&D for new drug discovery and development should be made more cost effective with improved productivity in pre-clinical and clinical evaluations and faster drug approvals to bring down the overall costs and make the new drugs more affordable. R&D on neglected diseases is yet another area where developing countries need to concentrate since existing large R&D based pharmaceutical companies are unlikely to invest funds in that area considering the high costs of drug discovery and development and relatively small markets (in value terms).

Overall, access to drugs at affordable prices is a very complex matter and issues related to TRIPS Agreement and their impact on prices of drugs constitute only marginal contributing factors.

Way Forward

A number of suggestions have been mooted in this article in the hope that their implementation would improve access to affordable drugs. These include the issue of compulsory licences, parallel imports, statutory drug prices control and enforcing stricter standards for grant of patents. All these measures can contribute towards reduction in drug prices and consequently better affordability for patients. While patents and other instruments of exclusivity are responsible for high prices of drugs charged by the innovator companies till they go off-patent and become generic drugs, affording even the reduced prices would not be within the capability of poor patients or even the healthcare programmes of most developing countries. That some degree of relief from high drug prices can be achieved through one or more of the approaches suggested here is obvious from the fact that when patent protected drugs move to generic status, their prices drop dramatically. However, notwithstanding such possibilities, the question of affordability of drugs will remain an unsolved issue. For example, even if prices of anti cancer drugs such as Gleevec and Nexavar are lowered to one tenth the innovators prices, they would be still be outside the reach of even middle income groups of patients, not to speak of those below the poverty line. In fact, almost all the modern lifesaving or life supporting biotechnology drugs needed for intractable chronic diseases, even if they are made available at the generic price levels will cost over Rs 10,000 a month. In countries of the world where half the population have per capita income of less than US$ 1 a day, modern drugs even at generic price levels will be outside the limits of affordability.

Affordable Healthcare Guaranteed through Government Programmes

Even in one of most affluent countries, the US, healthcare costs have become a major issue of concern. While the insurance system is very much established and is the backbone of healthcare, expending 14-15 per cent of gross income on health has been making a severe dent on US economy. In addition around 30 per cent of the population is not covered through voluntary health insurance schemes. Realising the social, economic and political fallouts of such a scenario, President Obama signed the Patient Protection and Affordable Care Act35 in March 2010, which guarantees healthcare to the citizens through
universal health insurance at enormous costs to the Government. In India, health insurance is at its infancy and its modus operandi leaves much to be desired. Over three quarters of the people manage their own healthcare costs out of their pockets with no insurance or third party support. Unless some scheme to cover not only hospital expenses but also other costs including professional charges and drug costs is in place, the proposals and implementation of strategies to reduce drug costs alone will have only a marginal impact on the overall health costs for the country’s population. What is required is that while every effort should be made to reduce the impact of patents on drug prices, those efforts should be supplemented by national programmes to help poor patients handle their healthcare problems through governmental and non-governmental insurance schemes covering all components of healthcare. Drugs constitute just one component of healthcare costs and access to more affordable drugs will alleviate the overall problem only to a limited extent. Policies need to address not only the high prices of drugs, but also of all the other components of healthcare as well.

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