Balance of Competition and Intellectual Property Laws in the Indian Pharmaceutical Sector

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The intellectual property regime in India grants a certain degree of monopoly rights, while the competition law tries to control such monopolies, requiring a balance between these two, while judging the parameters of developmental needs and economic situation, and needs and demands of the domestic scenario. The paper addresses the questions: (a) whether this balance is necessary? (b) whether the two regimes are balanced well? (c) whether other external measures are required?, and a comparison of all these with the international standard.

Keywords: Intellectual property regime, competition law, pharmaceutical industry

Competition law is accepted as originating with the Sherman Act of 1890 in the United States of America, and is essentially a legal framework to ensure curbing of monopolistic measures in commerce and industry. The idea is to encourage the competitive activity in the markets, and facilitate a moderated form of rivalry between entities involved in research, development, production, and marketing much as a referee oversees a match, ensuring fair play and bringing out the best of both sides.

The question of the balance to be struck between the intellectual property protection and the competition law angle is one that is most pertinent in any field where research and development play a vital role in creating innovative products, which need protection, such that an incentive may be provided for further development, and protection is given to the exploitation of this technology or product, such that costs of development may be recovered by the entity in question. Yet this has to be balanced against the fact that this situation may lead to a monopoly, especially in view of the new patent regime that has been implemented in India in 2005. The other aspects to be considered are markets, consumers, who must be given access to the fruits of such development, and also the state which may necessarily have to step in, under certain circumstances, with measures like subsidies or plans by which both interests may be balanced at the cost of the government.

This problem is magnified in the pharmaceutical industry. The cost of production is huge, and the changing intellectual property regime carries with it certain consequences in India. First of all, broadening of the patent system, by the Patents (Amendment) Act, 2005, seeking to make India compliant with international standards, ensures that the system prevailing by which Indian firms could cheaply reverse-engineer and reproduce certain drugs for which the main research was done at the cost of entities functioning outside the country, was such that there was no need for competition protection, and consumers could procure generic drugs at low prices.

The change occurred when India had to comply with the Agreement for Trade-Related Aspects of Intellectual Property Rights (TRIPS). In the process, costs of research and development are likely to be transferred to India, and for all drugs developed, produced, or marketed in India, the social and economic costs are going to grow enormously, necessitating recovery by these entities, which may lead to a situation of monopoly for over 20 year periods, as the patent protection now extends thereto. Competition law therefore, is now going to play a vital role, in the pharmaceutical industry, with heightening of intellectual property protection in India.

The main reason for restructuring or a new look at the competition policies, is because health care is an extremely important sector of any economy, and important insights into the workings of the health care field are required to develop a contemporary

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framework in which to analyse competitive conduct. The very dynamism of this sector requires competition and antitrust enforcers to keep fully abreast of all changes in those markets.\(^7\) The normal type of industries do not provide an analogous model for analysing the pharmaceutical industry, which faces financial, regulatory and community pressures that distinguish it, which affect significantly such analysis.\(^8\)

**Application in Indian Pharmaceutical Industry**

India has huge potential for biotechnology, with regard to its pharmaceutical industries. In a country where there is immense engineering talent, and huge demands in healthcare, the extreme emphasis is placed on biotechnology. The intellectual property regime is relevant to provide rewards, incentives and protection for such innovation and marketing, but the question dealt with in the scope of this paper, would be ensuring fair competition, with the welfare of the consumer and the market as the ultimate goal.\(^9\)

India’s Patents (Amendment) Act, 2005, introduced patent protection for pharmaceutical products, in accordance with the TRIPS, but possible effects on industrial development and public health still remain unclear, since the new regime hurts domestic firms, but promotes development of drugs suited to foreign necessity.\(^5\)

Intellectual property rights (IPR) are economically and politically significant, in a variety of ways. Patents, copyrights, trademarks, industrial designs, plant variety rights and geographical indications are frequently dealt with in the course of any discussion on the subject of the pharmaceutical industry, in the course of research and development, or in the course of marketing, business and the economic side of things.\(^10\)

**Evolution of the Pharmaceutical Industry in India**

The development of the pharmaceutical industry in India is a relatively recent phenomenon. It was during the 1950s and 1960s that the pharmaceutical sector started developing, and was a result of western pharmaceutical giants working with the Indian public sector. However, even this arrangement could not cater to India’s domestic needs. The Indian pharmaceutical sector has come a long way, from being a small player in the 1970s, to becoming a prominent provider of healthcare products; meeting almost 95% of the country’s pharmaceutical needs today.\(^11\)

Moreover, in order to ensure access to drugs, the government set prices at affordable levels, thereby not providing sufficient incentive, causing a situation in terms of a crisis in healthcare.\(^12\) The introduction of pharmaceutical product patents in India is expected to have a significant effect on public health and local pharmaceutical industries.\(^5\) It is in this regard that IPR is seen as the answer to protection of the process of production, and the equivalent, postproduction protection of the markets and the consumers, comes from competition or antitrust law.

The structure of TRIPS constitutes broadening of the existing patent system of many developing countries, including India. However, in the situation of excess demand in a knowledge intensive sector, it is primarily narrowing of the IPR which may bring about industrial competence and increase welfare, provided of course that the national system developed enough to permit local firms to emerge. This might be welfare enhancing, if it leads to a greater quantity being produced or lowering of price in the final market, or even at a global level, if other developing countries can thereafter obtain generic versions easily. India is making consistent efforts to emerge as a key player in the vibrant pharmaceutical industry.\(^13\)

The Indian biopharmaceuticals alone have the potential to reach US$ 2 billion market size by 2010.\(^14\) In fact, in 2003-04, biopharmaceuticals occupied the largest market share of 76% of the total biotechnology business in the country, amounting to Rs 2480 crores.\(^15\) Biopharmaceutical products fall under four broad categories, namely, vaccines, therapeutics, diagnostics and others, like statins. The vaccine business is the largest contributor, accounting for 47% of the market share, therapeutics 17%, diagnostics 10%; the rest 26% is accounted by others, primarily statins business. Biopharmaceuticals account for 75% of the total exports dominated by vaccines and statins.\(^16\) These statistics clearly show the way in which India is progressing.\(^13\)

On the other hand, it is also necessary to consider the entry of foreign players into the Indian scenario. Looking at the emergent situation there are important concerns, which arise with regard to India, especially as a developing country. Firstly, the obvious position is with regard to the advantage of multinational and transnational corporations over Indian entities, at every stage of the industry, and therefore, a possible abuse of dominant position. Another aspect is the effect that India will feel due to the monopoly power...
exercised by international entities, which may be functioning in India through mergers, direct investment, or directly having a presence in India. Since Indian firms are at the fledgling stage of building up capacities and capabilities, reduced contestability will have a harmful and deterrent effect. It is for this reason that there is necessity for a competition policy in India, to deal with such issues.

**India’s Approach to Competition Law**

**History of Competition Law in India**

The Monopolies and Restrictive Trade Practices Act, 1969 (the MRTP Act) was the first legislation with regard to competition law in India. This legislation was primarily designed to meet requirements of the then prevailing economic, social, and policy situation. Then came liberalization in 1991, and thus, the MRTP Act was outdated, and required immediate and intensive study, to assess the nature of amendments necessary to address the new situations that were arising, with the entry of foreign entities into the Indian scenario. Mergers, acquisitions, takeovers, and active investments were leading to a situation of necessity to protect domestic industries and markets.

For this purpose, the Government of India constituted a High Level Committee under the chairmanship of SVS Raghavan, with the aim of examining the MRTP Act, and gauging its relevance, and to bring about a new regime, which would be consonant to and able to protect the domestic entities from international competition. It was due to the recommendations of this Committee that the MRTP Act was ultimately phased out, with the introduction of the new Indian Competition Act, 2002. However, it is necessary to note, that even now, certain major provisions of the Competition Act are yet to be notified, and the MRTP Act continues to be in force in those regards, especially since the MRTP Act is to be repealed by the Competition Act, and the MRTP Commission is to be dissolved by a notification of the Central Government, which is yet to come.

**Current Situation Necessitating Attention in Competition Policies**

The research and development industry in India is fast developing and made strides in 1990s, thus, the Government of India responded with policy support and frameworks to allow safe, sustainable and secure development. India recognized importance of biotechnology as a tool to advance growth of agricultural and health sectors as early as in the 1980s, was borne out by India’s Sixth Five Year Plan (1980-85) which was the first policy document to cover biotechnology development, which proposed to strengthen and develop capabilities in areas such as immunology, genetics, communicable diseases, etc.

Special emphasis was placed on developing biotechnology in the Ninth Five Year Plan and accordingly, agricultural and allied biotechnology was given 26% of the total allocation, while medical biotechnology was given 13%. Once that sector stabilized, the focus in the Tenth Five Year Plan shifted to medical biotechnology, as agricultural biotechnology has 27% of total allocation, while medical biotechnology has almost 36%.

This development however, cannot occur in isolation and needs to be protected by measures under competition law, for example, restraining of anti-competitive behaviour, limitation of abuse of monopoly position in the markets and industries, and to promote development, access and consumer/market welfare. These are some of the aspects which need to be examined in the Indian pharmaceutical industry.

**Analysis of the Indian Regulatory Framework with regard to Drugs**

The drug industry in India did not have any price controls till 1962, when the government fearing a price increase, imposed a statutory price control on the prices of drugs and pharmaceutical products under the Defence of India Act, 1915.

In 1970, the Indian Patents Act, and the Drug Prices Control Order were passed and under the Indian Patents Act, it was declared that substances used in food and pharmaceuticals could not be granted product patents. Only process patents were allowed for a period of five years, from the date of patent grant, or seven years from the date of filing for the patent, whichever was earlier. This therefore provided a major thrust to the Indian pharmaceutical industry, as Indian companies through the process of reverse engineering and synthesis could produce drugs at significantly lower costs.

The next important legislation in the Indian perspective is the Drugs and Cosmetics Act, 1940 which governs the import, manufacture, distribution and sale of drugs in India. The Drug Controller General of India, an authority established under the Drugs and Cosmetics Act, oversees the conduct of
Potential for Anti-Competitive Practices in the Indian Pharmaceutical Sector

With regard to competition law, the basic question that needs to be considered is whether the growth of the Indian pharmaceutical industry, with a new patent regime and deregulated environment will benefit consumers. It has been concluded that there are three types of competition issues that may potentially arise in the pharmaceutical industry in India, in the form of collusions, horizontal or vertical mergers and acquisitions, and abuse of dominant position.\(^{11}\)

The first issue is with regard to activities amounting to collusions, though among Indian manufacturers, this situation has not yet emerged, though existence of such tendencies in certain segments with few competing manufacturers cannot be denied. Even international cartels inflict material damage on Indian consumers and business, and are therefore a source of concern. By offering extra profits to pharmacists and incentives to prescribing doctors, manufacturers are keeping medicine prices higher than necessary for Indian patients, which would adversely affect both the market and the consumers. The activities of pharmacists to extract higher profits would be collusive behaviour, prohibited by law and therefore illegal.

Secondly, with regard to anti-competitive practices as a result of mergers and acquisitions, such a situation is not envisaged at present since the Indian pharmaceutical industry is highly fragmented, which ensures free, fair and productive competition. However, with foreign entities entering the market, consolidation is occurring, as pressure on drug prices has made pharmaceuticals multi national companies to resort to mergers and alliances in an effort to reduce costs of development, combine product portfolios, and increase reach so as to spread expenditure over a larger base. Such mergers therefore raise concerns in India. The Competition Act, 2002 provides for merger review beyond a threshold level. The deals require complex analysis to examine the impact on different segments of the market. Conditions can be imposed that product categories are to be licensed as and when the need arises.

Thirdly, there is abuse of dominant position, which is tied in with the entire discussion on the new patent regime. Since the pharmaceutical industry is knowledge-intensive, intellectual property gives monopoly status to companies, often abused to the detriment of consumers. All this time, India did not allow product patents, making it difficult for companies to sustain a monopoly. However now, due to WTO and TRIPS, and in the light of new patent regime, abuse of dominance is likely to be quite frequent in India.

Point of Discussion

Pharmaceutical manufacturers are demanding more liberalization, as according to them, the competition and not the price control will improve availability and affordability of essential drugs. However, where the manufacturers decide to retard development in order to recover costs, or to make use of their dominant position as ensured by the patent regime, then the consumers might have to suffer, and this is something that is unacceptable in a developing country like India, where the healthcare industry plays a vital role, in provision of drugs, and other pharmaceutical products as a primary function, where other institutions such as medical insurance, good hospital facilities may not be available to all consumers.

Advancement in Indian Pharmaceuticals and Competition Policy Response

It is expected that the changes made recently to the IPR and specifically the patent regime in India, will have consequences in the health sector with regard to development and utilization in the pharmaceutical industries. So far, Indian companies could legally produce generic versions of drugs protected by patents, without breaching the law, which will now be illegal in the light of the product patent regime.\(^{5}\) This situation gave a certain edge to Indian firms, which were in competition with the international markets, which were restrained by legal systems. Thus, production could be by cheaper and more efficient processes, and the products could be marketed at cheaper rates, thereby ensuring that needs were also met indirectly.\(^{12}\)

The situation therefore, is not just the competition in India but at an international level also. In India, the
position is now changing with increased IPR protection, there is a gradual shift by which other entities in the international markets are getting interested in India. This has a significant impact for companies, which are engaged in manufacturing generic drugs, as well as for the consumers who will not be able to afford drugs now, due to unavailability of cheap generic drugs and higher prices of drugs in general.\textsuperscript{21}

The Indian pharmaceutical industry is undergoing fast development since the Indian market is opening up immense opportunities for firms.\textsuperscript{22} The Indian pharmaceutical companies have been doing extremely well in developed markets such as the United States and Europe, notable among these being, Ranbaxy, Dr Reddy's Labs, Wockhardt, Cipla, Nicholas Piramal and Lupin. The industry globally ranks fourth in terms of volume and thirteenth in terms of value. However, it is pertinent to note that the industry has thrived so far on reverse engineering skills exploiting lack of product patents in the country, which no longer exist, which may be an unfair degree of competition, in the production and marketing of drugs.\textsuperscript{23}

Indian pharmaceutical firms have flourished under the Patents Act, 1970, as it was not an infringement to produce copies of new drugs using new processes, and selling them in India and other markets where product patents did not exist. Thus, the commercial experience gained allowed Indian firms to become competitive entrants in generic markets of developed countries, through early capacity buildup and learning effects.\textsuperscript{24}

However, with the advent of TRIPS, which introduced product patents in India for drugs patented in 1995 and beyond, will gradually weaken the advantage of Indian firms in the generics markets of developed countries.\textsuperscript{25} The costs of drug development can be attributed to the discovery, development, and approval process. That process includes five distinct phases, which involve a huge amount of investment, research and development, which takes a significant amount of resources, in which regard the Indian firms cannot compete with the bigger multinational and transnational corporations.\textsuperscript{26}

Unfortunately, while it is shown that, ‘We view the Indian life sciences sector not only as a market but also as a potential supplier and partner’,\textsuperscript{27} the actual position reveals exploitation of Indian research, and engineering potential.\textsuperscript{28} The need for an integrated policy with concurrent attention to education, social mobilization and regulation is an essential prerequisite for the progress of the Indian pharmaceutical industry.\textsuperscript{29} This is a tradeoff implicit in using a patent system to encourage innovation, where on one hand are static costs associated with monopoly pricing and, on the other, the dynamic gains associated with innovation.\textsuperscript{29}

This would place Indian firms at a distinctly disadvantageous position with regard to the big multinational and transnational corporations which are much better placed to afford a certain degree of research and development, testing, trials, certification, and then once patented, can recover the costs of all these, while taking the benefit of our own systems and protection, to make huge profits internationally, after making us pay for the research and development they carry out here.\textsuperscript{30} This is making us pay for the process of development. The Indian reverse engineering situation thus far was able to provide an alternative, but now that is taken away by our own IP regime, and so it is up to competition law, in India at least to deal with the situation as above-described.\textsuperscript{31}

At the same time it must be accepted that product patents have benefited other segments of the Indian pharmaceutical industry. It is important not to overlook the international competitiveness of Indian firms in innovative research, which will benefit Indian public health in the long run. Indian firms developing new chemical entities and receiving stronger protection are an indication of the drug candidates emerging from Indian pharmaceutical manufacturers. Multinational firms have become more comfortable in giving assignments to India due to the security afforded by product patents.\textsuperscript{5} This is the aspect of mergers, takeovers and acquisitions, which would also need to be addressed, by the competition law aspect.\textsuperscript{32}

However, it is important to note that these benefits are miniscule compared to the difficulties, which are impending with regard to affordability and accessibility, as the system now provides a period of protection during which manufacturers of innovator drugs can charge relatively high prices, earning profits to compensate for costs of discovery and development.\textsuperscript{33}

The aim of biotechnology in India, through continuously evolving biotechnology policy should be settled with a framework structured around use of biotechnology in a pragmatic and sensible way for the betterment of the masses.\textsuperscript{33} Unfortunately, whether
that happens in practice is the question that the
authors seek to answer in this regard, as it appears that
benefits to entities coming into India are more than
corresponding benefits to Indian entities.

**International Standards: A Case Study of a
Developed Country - The US Perspective**

A viewpoint of the United States of America (USA) would be the best standard by which one can examine the balances exercised between intellectual property, competition law and the responses to the markets. In USA, benefits to consumers from generic drug competition are dramatic. A Congressional Budget Office (CBO) report estimates that consumers saved $8-10 billion on prescription drugs at retail pharmacies in 1994 by purchasing generic drugs instead of brand name products.\(^{34}\)

The surging cost of prescription drugs in USA is an issue of utmost importance. Studies suggest dramatic increase in expenditures and have helped focus attention on the need to ensure competition in pharmaceutical markets.\(^{35}\) The steady updates are taken by the Federal Trade Commission (FTC) and other entities regulating trade, competition and development of drugs, because of continuously evolving methods, technologies and advances in medical and healthcare sectors.

One of the most beneficial statutes in the United States, was the Hatch-Waxman Act, 1984.\(^{36}\) This Act was passed as the Drug Price Competition and Patent Term Restoration Act, to accomplish balancing of policy goals\(^{37}\) to facilitate and encourage generic drugs, and to protect incentives of brand-name drug companies to invest in new drug development.\(^{38}\)

**Exploitation of the Market and Industry in US**

The FTC is the main organ for promotion of competition in the pharmaceutical industry and has been significantly involved in competition or antitrust cases arising in the context of the Hatch-Waxman framework. From the conduct observed by the FTC, it is suggestive that some firms may be exploiting the statutory and regulatory scheme by reaching agreements to delay the introduction of generic drugs.

In the light of the serious questions raised by its various generic drug investigations, in October 2000, the Commission proposed a focused industry-wide study of generic drug competition, through the FTC pharmaceutical industry study, designed to examine business relationships between brand-name and generic drug manufacturers to understand the extent to which the process of bringing new low-cost generic alternatives to the market and consumers, is being impeded in ways that are anticompetitive.\(^{39}\)

Pioneer firms have strong incentives to delay generic entry, as this could preserve millions in profits for pioneer drug companies. The typical steep price decline upon generic entry results in an enormous drop in market share and profits for the pioneer firm, and so this result is one that the companies would devoutly wish to prevent. Certain case studies\(^{39}\) are interesting in this regard in which the Commission challenged agreements with this object in mind.

**Abbott v Geneva**

In May 2000, FTC issued a complaint against Abbott Laboratories and Geneva Pharmaceuticals Inc,\(^{40}\) alleging that Abbott paid Geneva approximately $4.5 million per month to keep Geneva's generic version of Abbott's proprietary drug, Hytrin, off the US market, potentially costing consumers hundreds of millions of dollars a year, with a projection that Geneva's entry with a generic version of Hytrin would eliminate over $185 million in Hytrin sales in just six months.\(^{40}\) Geneva agreed not to enter the market with any generic version of Hytrin.\(^{40}\)

**Hoechst Marion Roussel v Andrx**

In this case, the Commission charged that Hoechst Marion Roussel, the maker of Cardizem CD, paid Andrx over $80 million to not bring to market any competing generic drug.\(^{41}\) Hoechst's Cardizem sales in 1998 exceeded $700 million. Hoechst had apprehended that a generic version of Cardizem CD, sold at 70% of the brand price, would capture approximately 40% of Cardizem CD sales in the first year. The complaint alleged that the agreement not to market was intended to delay the entry of other generic drugs, thereby denying consumers access to lower priced drugs.\(^{41}\)

**Schering-Plough v Upsher-Smith v ESI Lederle**

In this case, FTC issued a complaint against Schering-Plough Corporation and two generic pharmaceutical manufacturers, Upsher-Smith Laboratories and ESI Lederle, Inc, alleging agreements aimed at delaying the entry of generic versions of Schering's product K-Dur 20.\(^{42}\) Schering's K-Dur products had 1998 sales of over $220 million. In 1997, it was projected that the first year of low priced generic competition would reduce K-Dur 20's
sales by over $30 million. It was alleged that there was an agreement that Schering would pay Upsher-Smith for not to enter the market, thereby preventing other competitors from entering the market.

**FTC v Mylan**

FTC was also concerned about maintaining competition among generic firms. In this case, FTC sued Mylan Laboratories, alleging monopolization and conspiracy in connection with agreements to eliminate Mylan's competition by tying up supplies of the basic ingredients for two widely-prescribed drugs, lorazepam and clorazepate. The FTC's complaint alleged that these agreements allowed enormous price increases—over 25 times the initial price level for one drug, and more than 30 times for the other. In settlement of the Commission's case, Mylan agreed to pay $100 million for disbursement to qualified purchasers of lorazepam and clorazepate.

**Result of the Litigations in the International Context**

In all these cases, the common trend taken by the FTC was to rigidly safeguard the right of the consumers, by ensuring that fair competition was maintained, and these agreements were declared as anti-competitive, with some sort of restitution being made by the companies concerned. It is an action much like this, which might be necessary in India once the bigger multinational players enter the Indian domestic industry, which may have detrimental effects on consumers. This is why these cases in the context of a developed nation are so important. Even though healthcare schemes are firmly in place, and the nature of the country is such that increased drug prices and competition are worries not passed on to consumers, still emphasis continues to be given to maintaining competition in industry.

In the opinion of the authors, there are two valuable lessons to be learnt in the Indian context, the first being that we are nowhere near these standards and second, we must have thorough safeguards, for this reason precisely.

**International Perspective: Developing Countries**

**The Ugandan Perspective**

Uganda is considered a success story in combating HIV/AIDS, due to its method of balancing patent protection with public necessity, and careful handling of the competition situation. Access to treatment is a key part of national strategies to combat HIV/AIDS. Anti Retro Virals (ARVs) can increase the length and quality of life, and the productivity of patients. Research shows that the price of brand-name drugs fell significantly only when generics entered the market.Generic competition, use of the public health exceptions in TRIPS, and funding for health service are essential parts of the fight against HIV/AIDS in developing countries such as Uganda.

The introduction of generics led to decrease in prices of branded medicines between 22% and 70% in December 2000 as compared to prices in May 2000. By March 2001, the price of these drugs decreased between 44% and 48% of the September 2000 price. The largest decrease was of US$ 173 for a monthly dose of 40 mg to US$ 118 in December 2000, to US$ 23 in February 2001, and then eventually to US$ 6 in April 2002. Price reductions therefore helped patients get the treatment necessary for their conditions, and in controlling the disease.

Seven ARVs are patented in Uganda, five of which have generic equivalents imported from India. It has been accepted that access to treatment is a crucial element of national strategies to combat AIDS, and should co-exist with protection of production and competition between international drugs being imported and those produced. Thankfully, since international entities realize the gravity of the situation, prices are lowered, and still further so by the entry of competitors in the market. But the high price of medicines is still an impossible barrier for the very poor, and it was only when generic equivalents entered the market that the prices came down.

**The South African and Brazilian Experience**

Some countries had negative reactions to TRIPS, and South Africa and Brazil stand out with regard to the health issue. In South Africa, debates have concentrated on the Medicines and Related Substances Control Amendment Act, 1997, which was a reaction to the severe HIV/AIDS crisis that the country was facing and the lack of access to drugs due to unaffordability. The possibility to determine the patent rights application was a direct challenge to the pharmaceutical industry that reacted by moving the high court for the disputed sections to be declared unconstitutional, as they gave too much latitude to the government to curtail rights and to decide which rights should apply. Eventually, the petition was abandoned in April 2001 in the face of strong public opposition.
In Brazil, the government decided to take measures to facilitate access to drugs in the context of the HIV/AIDS crisis also. The US government objected to the requirement that unless it is economically unfeasible, inventors have the duty to manufacture the product in Brazil, and ultimately, a WTO dispute was initiated by the US but was withdrawn. Brazil then adopted a decree establishing rules concerning granting of compulsory licenses in cases of national emergency and public interest, and the definition of these concepts is so wide, that it includes public health, nutrition, protection of the environment, and elements of primordial importance for technological, social or economic development, such that fulfillment of most basic needs could be covered.48

The principle that health emergencies provide sufficient ground for rules derogating from TRIPS is now established, and the next step is looking at the fact that there is no reason why TRIPS cannot be further qualified to foster realization of basic needs.49 In practice, India also faces health emergencies like South Africa and Brazil, and in spite of this, patent amendments have been made attempting to put India in compliance with TRIPS obligations. In the process, certain elements have been set aside, which, together with other instruments such as the Drugs Price Control Order, have served well the interests of the country.46

This is likely to bring about a regime that is less favourable from the point of view of accessibility to drugs for Indian citizens of all levels. TRIPS cannot be implemented in isolation, as it must be remembered that India has number of other international obligations. As emphasized by UN human rights organs, the right to health requires that countries progressively take positive steps towards facilitating access. Dismantling the 1970 regime may constitute a violation of India’s obligations under the covenant on economic, social and cultural rights.50

Conclusion

A balance between IPR and competition is most important in developing countries such as India, which cannot afford to advocate the cause of development at the cost of citizens’ rights, or to be left behind, and therefore lose stakes in the international scenario. The balance in India has not yet been tested as no situations as envisaged as probable competition issues have emerged. However, in the light of possible consequences as obvious from other international examples in domestic contexts, it will soon be tried, and if proper implementation of both regimes is done side by side, no problems should arise. External measures necessitated, are merely in the form of government controls, subsidies, and if necessary, intervention of the state as an ultimate action on behalf of consumers, to protect domestic interests, just as the situation had warranted once before in India, in 1961. After looking at the standards set by practical examples from both developed and developing countries, it appears that India cannot aspire to see things from the perspective of the developed countries for various reasons. But there are important lessons to be learnt in application of the principles by which balances are struck, between necessity and development, and the most valuable are examples such as those from Uganda, South Africa and Brazil.

Certain general conclusions reached by authors are as follows:

(i) The Pharmaceutical industry is distinct from any other. In a normal market, firms can try to boost sales, and therefore profits, by reducing prices. But the drug market has certain special characteristics, with regard to generics, insurance, consumption patterns, etc.

(ii) In developed countries, insurance companies usually cover the drug consumers and so they do not pay directly for medicines. Consumption patterns are therefore not affected by drug prices, so firms have no incentive to keep prices low.

(iii) The situation is quite different in developing countries, where insurance is unheard of for many. Consumers are very often not the decision makers. It is the doctors and the pharmacists who have a significant role to play, and the companies often try to influence them, sometimes via huge incentives.

(iv) The Indian Competition Act, 2002 has all the required provisions of law, and merely needs to be accurately implemented in order to ensure that there is no situation arising which has been described by the authors.

The authors submit that a solution to this problem could in practice be very simple. The Competition Act, 2002 and the Patents Act, 2005 have to be read together. The idea should be that the manufacturers
are given freedom subject to certain conditional controls, which may be placed with a government authority such as the Drug Controller General of India. The basic premise would be that there is a need to amalgamate the authorities dealing with anti-competitive activities with an authority that understands the drug market, and is sensitive to needs of the consumers and the market.

Thus, the manufacturers have the freedom to develop and do their research and development, well protected by patents, and with the incentives and rewards that come with patent protection. On the other hand, conditions can be imposed such as those imposed by the FDA in the United States, allowing release of certain products, on the condition that if there is any violation of standards, and complaint of the same, the licenses will be revoked immediately and strict action will be taken against the company or firm concerned. Examples of this in action can be seen from the merger of Glaxo-Wellcome and Smithkline Beecham, allowed by EU on precisely these conditions, and reflected in the response of South Africa with approval to these conditions.

The situation warrants a different set of consequences for violation, which could be immediate voiding of patents, compulsory licensing, or drug prices control, as and when required. This may be the way forward for India.

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