

# IPRS In The Pharmaceutical Sector

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## Abstract

## INTRODUCTION

The impact of intellectual property rules and practices on the health of poor people in developing countries has generated substantial controversy in recent years. Although this predated TRIPS, <sup>1</sup> and featured prominently in the TRIPS negotiations, impetus has been added by the coming into force of TRIPS, and the dramatic rise in the incidence of HIV/AIDS, particularly in developing countries. For the developed countries, the pharmaceutical industry was one of the main lobbyists for the global extension of IP rights. <sup>2</sup> For developing countries, a major concern was how the adoption of intellectual property regimes would affect their efforts to improve public health, and economic and technological development more generally, particularly if the effect of introducing patent protection was to increase the price and decrease the choice of sources of pharmaceuticals.

We are aware of the importance of effective patent protection for the industry most directly involved in discovering and developing new pharmaceuticals. Indeed, without the incentive of patents it is doubtful the private sector would have invested so much in the discovery or development of medicines, many of which are currently in use both in developed and developing countries. The pharmaceutical industry in developed countries is more strongly dependent on the patent system than most other industrial sectors to recoup its past R&D costs, to generate profits, and to fund R&D for future products. Successive surveys have shown that the pharmaceutical companies, more than any other sector, think patent protection to be very important in maintaining their R&D expenditures and technological innovation. <sup>3</sup> The industry understandably takes a close interest in the global application of IPRs, and generally resists the contention that they constitute a major barrier to access or a deterrent to development in developing countries.

## PHARMACEUTICAL INDUSTRY IN INDIA

India produces pharmaceutical formulations but over 400 Active Pharmaceutical ingredients are manufactured in India from basic stage. Ancillary industry is also fully developed and full range of Pharmaceutical manufacturing equipment is locally produced.

The organised sector of the Pharmaceutical Industry has played a key role in promoting and sustaining development in this vital field. International and Indian companies associated with this sector have stimulated, assisted and spearheaded this dynamic development in the past fifty seven years and helped to put India on the pharmaceutical map of the world.

The value of the pharmaceutical market in India was U.S.\$ 6.0 billion in 2004. It grew by 6.4% over 2003. Although India accounts for 16% of the world population, the sales of pharmaceuticals is just 1.8% of the global sales in terms of value and 8% in terms of volume. Globally, it ranks 4th in volume and 14th in value terms.

The Pharmaceutical Industry in India has quality producers and many units are approved by regulatory authorities in USA and UK. Today, India has highest number of U.S. FDA approved manufacturing facilities outside U.S.A. It has a pool of personnel with high managerial and technical competence as also skilled workforce. Its track record, particularly in the area of improved cost-beneficial chemical synthesis for various drug molecules is excellent. The export of Bulk drugs and formulations in 2004 were to the tune of US\$ 4.1 billion.

The Indian market has some unique advantages. India has a 57 year old thriving democracy. It has an educated work force and English is business language. It has a solid legal framework and strong financial markets. Over 9000

companies are publicly listed. Professional services are easily available. There is already an established international industry and business community. It has a good network of world-class educational institutions and established strengths in Information Technology. The country is now committed to a open economy and globalisation. Above all, it has about 200 million middle class market, which is continuously growing.

For the first time in many years the international pharmaceutical industry is finding great opportunities in India.

As India is a Founder Member of WTO (World Trade Organisation), it is obliged to introduce TRIPS (Trade Related Aspects of Intellectual Property Rights) compliant IPR regime on 1st Jan, 2005. India ushered in Product Patents Regime by introducing “The Patents (Amendment) Ordinance, 2004” on December 26, 2004. Later, the Parliament after debating the provisions of the Ordinance passed “The Patents (Amendment) Bill, 2005”. This signals the start of a new era for the Pharmaceutical Industry in India. The new Act will boost R&D and will help to bring in Foreign Direct Investment in the industry and contribute to improved healthcare.

The salient features of the Act are:

- After a gap of 35 years, product patent protection has been extended to pharmaceuticals, chemicals, biotechnology products and food for a period of 20 years.
- Provisions relating to Exclusive Marketing Rights (EMRs) are deleted and a transitional provision is introduced for safeguarding EMRs already granted.
- To meet emergent health situations (in accordance with the Doha Declaration on TRIPs and Public Health), a provision is made for enabling grant of Compulsory License for export of medicines to countries which have insufficient or no manufacturing capacity.
- Provisions relating to opposition procedures, with a view to streamlining the system by having both Pre-grant and Post-grant opposition in the Patent Office, have been modified.
- There is an addition of a new proviso to circumscribe rights in respect of mailbox

applications so that patent rights in respect of the mailbox shall be available only from the date of grant of patent and not retrospectively from the date of publication.

- The provisions relating to national security to guard against patenting abroad of dual use technologies have been strengthened,
- Several provisions are included with a view to rationalising time-lines, allowing flexibility and reducing the processing time for patent applications and simplifying procedures. 3

### **INDIA'S NOW-LIBERAL EXPORT-LED GROWTH STRATEGY**

The 1970 Indian Patent Law was the outgrowth of a report submitted by a 1959 committee that examined the reasons for the high cost of drugs in post-independence India. The Committee concluded the high prices resulted from the monopoly control foreign-based pharmaceutical companies exercised over the production of drugs thanks to the prevailing patents regime.

The dismantling of India's 35 year-old patent regime is in keeping with the Indian bourgeoisie's abandonment of its post-independence national economic strategy in favor of a drive to make India a cheap labour center of manufacturing, office-processing and pharmaceutical and computer software development for the world capitalist market.

To attract foreign capital and promote the development of “internationally competitive” Indian firms, public spending has been slashed, public sector enterprises privatized or closed down, free trade zones established where traditional worker rights and labour standards don't apply, and public investment diverted from agriculture to the mega-projects sought by big business. Now, to comply with the WTO, a patents regime is being put in place that will drive up the cost of drugs.

Relatively cheap drugs has arguably been the only benefit India's working population has derived from the country's health care sector, which is one of the most privatized in the whole world. The various levels of Indian government spend just 1 percent of annual GDP on health care.

As part of their strategy to pry open the markets of developing countries for the transnationals, the US and other advanced capitalist countries introduced the issue of

intellectual property rights and patent grants (previously considered as non-trade issues) into the 1986 Uruguay round of the General Agreement on Tariffs and Trade (GATT) negotiations.

Initially, the Indian ruling elite along with those of other developing countries such as Brazil and South Africa opposed the inclusion of TRIPS as part of the world trade negotiations. But in 1989 they capitulated and agreed to the advanced capitalist countries' demands that, under the pretext of creating worldwide uniformity in patent grants and intellectual property rights, a legal mechanism be created whereby the multinationals could profit from the product patents they had obtained from western governments.

In order to mollify critics, the developing countries obtained some “flexibility” in the wording of TRIPS, including the power to grant manufacturing licenses of generic versions of patented drugs (compulsory licensing) when required to “protect public health” and to facilitate challenges to patents application before they are granted (pre-grant opposition).

In practice, however, the right to grant licenses to manufacture patented drugs to meet health emergencies has proven hollow, because it opens the country to the threat of expensive litigation and even trade sanctions. For example, when the Thai government attempted to issue a compulsory license for the manufacture of AIDS drugs AZT and DDI, in 1999-2000, to tackle an estimated 1 million HIV infections, the US government stepped in and threatened the Thai government with trade sanctions if it went ahead and issued the license.

Compliance with WTO regulations is not simply a matter of aligning national laws through legislation. It involves substantial administrative expenditure by national governments, expenditure that ultimately is borne by the masses. According to the World Bank economist Michael Finger, such administrative cost for overseeing just 3 sections of the WTO treaty will be in excess of \$150 million per year, a considerable sum even for a large country like India.

### IMPORTANT TIPS

Several policy recommendations follow from the analysis for action, both at

the international and Indian level. At the international level, the main recommendations are as follows:

- To explore evidence of patents on restricted access

to technologies in developing countries and to advise countries to how to balance intellectual property rights-competition law interface in this regard.

- To advise the innovative developing countries on strengthening existing systems of health innovation and LDCs on how to build innovation systems while dealing with the effects of full-scale TRIPS compliance.
- To generate awareness that IPRs may not necessarily be an impetus to innovation.
- To advise countries on enacting procedures that expedite the use of compulsory licensing provisions under 30 August 2003 Decision. These should be directed towards rectifying distortions both on the demand side (LDCs) and the supply side (developing countries with manufacturing capabilities). On the supply side, countries need advice on kinds of incentive structures for private sector that promotes their continued engagement in such activities.

Policy recommendations for action at the Indian level that follow from the analysis are as listed below:

1. The Indian government needs to invest extensively in strengthening existing institutions such as local competition enforcement agencies, patent examiners, an informed judiciary which is more attuned to the public health and local industry needs in a country like India, and price control mechanisms in order to promote access to medicines in the local market and other LDCs.
2. The patent regime incorporates several major TRIPS flexibilities. But it also contains several provisions that are open to different sets of interpretations and therefore whether all the flexibilities that are permissible under the TRIPS Agreement will be used by India in day-to-day practice or not, is still much in the open.
3. Other rules affecting the industry, such as those on data exclusivity should be enacted only after taking into consideration the interests of the generics industry and the scope of its impact. If the generic industry in India is curbed further, a large amount

of cheap supply of medicines at very competitive prices will be seriously affected.

4. The government should apart from providing an expedient administrative procedure for the implementation of Section 92(A) of the Act, create a higher level of awareness amongst the local industry on the option of compulsory licensing to supply to other least developed countries. This could result in a more conducive attitude amongst the firms to deal with requests from other least developed countries in future.
5. The government should, in a concerted effort with the industry, plan ways in which to reduce bottlenecks to pharmaceutical R&D in the local Indian context. These will be very helpful to aid the industry to devise and implement strategies for survival.
6. The government should strengthen its activities in terms of identifying key areas where there is potential (for example, clinical research) and invest in development of these facilities systematically.

7. Promotion of R&D into diseases of the developing world, as the survey goes on to show, will remain a public good problem, irrespective of the capacities in the pharmaceutical sectors in developing countries. The government of India (either singularly or in collaboration with other governments in developing countries) should initiate more public R&D programmes that utilize the strengths of the Indian industry to find cures for neglected diseases.<sup>4</sup>

## References

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