Schweizerisches Jahrbuch für Entwicklungspolitik

Schweizerisches Jahrbuch für Entwicklungspolitik

17 | 1998
Geistige Eigentumsrechte, was steht für die Entwicklungsländer auf dem spiel?

TRIPS and Pharmaceuticals: Implications for India

Pradeep S. Mehta

OpenEdition Journals

Electronic version
URL: http://journals.openedition.org/sjep/718
ISSN: 1663-9677

Publisher
Institut de hautes études internationales et du développement

Printed version
Date of publication: 1 April 1998
Number of pages: 97-106
ISSN: 1660-5926

Electronic reference
Pradeep S. Mehta, « TRIPS and Pharmaceuticals: Implications for India », *Schweizerisches Jahrbuch für Entwicklungspolitik* [Online], 17 | 1998, Online since 18 September 2012, connection on 19 April 2019.
URL : http://journals.openedition.org/sjep/718

TRIPS AND PHARMACEUTICALS: IMPLICATIONS FOR INDIA

PRADEEP S. MEHTA*

ON THE post-Uruguay Round world trade scenario, after the accords in agriculture and textiles and clothing, the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPs) is the issue affecting developing countries like India.

One of the seven intellectual properties covered under TRIPs is that of patents. It has been the contentious issue for several reasons. India is committed to amend its patent laws by the year 2005 (for technologies previously unprotected in its market). The objective is to change the patent system which, in turn, is supposed to facilitate research and development activities within the country.

This Briefing Paper examines the issue of patents and its impact on the pharmaceutical industry in India, both foreign and Indian firms.

1. TRIPS, PHARMACEUTICALS AND INDIA: AN OVERVIEW

According to the United Nations definition, a patent is a legally enforceable right, granted by a country's government to an inventor. A patent excludes other persons from manufacturing, using or selling a patented product or from utilising a patented method or process.

TRIPs covers seven types of intellectual property rights:

- trademarks
- trade secrets
- geographical indications
- industrial designs
- copyright
- integrated circuits, and
- patents

Except in the sectors of food processing, pharmaceutical and agrochemicals the Indian patent law is in conformity with the GATT provisions. In the aforementioned, only process patents are allowed.

As of today, India has a process patent regime regarding phamaceutical products. Therefore, the 1970 Indian Patents Act has to be changed inorder to bring it in line with the international laws on the patenting of pharmaceutical (and agrochemical) products.

Being a developing nation, India has a grace period of five years to change its patent laws under the agreement on TRIPs. In other words, the 1970 Indian Patents Act will have to be suitably amended by 31st December 1999.

* Secretary General, CUTS, Jaipur, India.

At the same time, developing countries like India are given a grace period of ten years for technologies previously unprotected in its market. During this interim period of ten years, all patent applications will be put in a «black box». However, pharmaceutical corporations can apply for an Exclusive Marketing Right (EMR) for their products for only five years, even before the country in question has fully phased in the new patent protection system.

The proviso is that the product must have been registered for a patent and has received marketing rights in any of the WTO member countries. Thus, it is a backdoor method for granting monopoly rights. Furthermore, there is also a grey area here. If marketing rights are granted for only five years, what will be its position over the five-year period, until the country in question actually has amended its patent laws?

Transnational corporations (TNCs) control 90% of all registered patents in the world. In fact, given such monopoly power over patents and the EMR clause, India, or for that matter any developing country, does not have any transition period. This is true in the case of protected technology, and if one interprets that from the patent/product-originating country angle. This is the haziest part of the TRIPs Agreement, with respect to the pharmaceutical and also the agrochemicals sectors.

2. TRIPS AND PHARMACEUTICAL INDUSTRY IN INDIA

The existence of process patents under the 1970 Indian Patents Act resulted in a robust growth of domestic pharmaceutical industry in India. At the same time, history also shows a decline in the business of foreign pharmaceutical companies in India (see Table 1 for Cross-Sectional Data and Table 2 for Trends).

Table 1 – Sales and Share of Big Companies in Indian Market, 1992

Company	Sales (Rs. mn)	Share (%)
Indian companies		
Ranbaxy	1689	4.4
Cadila	1467	3.8
Cipla	1175	3.0
Lupin	1031	2.7
Alembic	1008	2.6
TNCs		
Glaxo	2137	5.6
Pfizer	963	2.5
Hoechst	951	2.5
Boots	930	2.4
Burroughs Wellcome	826	2.0

Source: *New Horizons in India, The Consequences of Pharmaceutical Patent Protection*, Redwood H, Oldwicks Press 1994.

Table 2 – Indian Pharmaceutical Market, 1970 – 1993
Unit: In Percent

Sector/Year	1970	1982	1993
Transnational corporations	80	50	39
Indian private sector	10	48	60
Indian public sector	10	2	1

Source: *New Horizons in India, The Consequences of Pharmaceutical Patent Protection*, Redwood H, Oldwicks Press 1994.

Why is there such a paradox when the global business is expanding at a rapid pace? To answer such a seemingly incongruous *fact*, one has to take the following into account:

- the 1970 Indian Patents Act was the instrument that made it possible for the domestic pharmaceutical industry to expand rapidl:. because the Act *legalised* «reverse engineering» of drugs that are patentable as products, through-out the industrialised world, but unprotectable in India;
- well equipped with technological expertise, Indian scientists and businesses seized the opportunity to do «reverse engineering» on therapeutically innovative drugs discovered elsewere, and launched them on the domestic market as well as exporting them to other countries, with similar gaps in *their* patent cover; and
- strategic abdication of many transnational corporations who refused to compete without the patent cover. For example, the Sterling-Winthrop company wound up their business in the 1970s and sold their shares to the Indian partner Dey's Medical.

Furthermore, under the 1970 Indian Patents Act, the following points are relevant:

- no product patents are allowed in pharmaceutical, agrochemicals and food-processing sectors, only process patents are admissible;
- the Indian patent term of fourteen years from the date of filing for pharmaceutical processes is curtailed to seven years from the date of filing, or five years from the date of sealing a patent, whichever is shorter; and
- pharmaceutical process patents are automatically deemed to be endorsed a License of Right for three years from the date of sealing a pharmaceutical patent.

With the coming of the TRIPs Agreement, disputes have arisen with regard to the protection of pharmaceutical patents. The main provisions of the TRIPs Agreement with respect to pharmaceutical products are as follows:

- the minimum patent term will be twenty years from filing;
- patent protection is to be extended to pharmaceutical products;
- importation must be accepted as a *working* patent;
- compulsory licensing is relegated to special circumstances;

- in infringement suits, over process patents, the «burden of proof» is reversed;
- provide transitional arrangements – deferment of the acceptance of pharmaceutical product patents by developing countries for ten years; and
- limited exclusivity is granted to developing countries for pharmaceutical products whose patent applications are filed after the enforcement of the TRIPs Agreement.

3. CONSEQUENCES OF TRIPS: MYTHS AND REALITY

TRIPs does not provide for the retrospective patenting in India of drugs that are already on the market or covered by existing patent applications elsewhere. Taking into account the transitional period, there will be less impact on prices of new patented drugs on the Indian market during the 1990s and only a minimal effect until 2005. Thereafter, it will build up gradually from a pool of new drugs. Global progress, in research and development, is replenishing this pool at a steady but moderate pace, as older drug patents expire (see Box 1).

BOX 1 – PHARMA-QUAKE AS PATENTS EXPIRE

ABOUT 40 US drugs with $16bn sales in 1996 are set to loose patent protection by the year 2002. This will throw the gate open for competition from generic drugs.

Cheaper drug price and bonanza for generic drugs will alter the research and business of pharmaceutical majors.

To fill the patent gap, drug majors are turning more to biotechnology development and other partners. The pressing needs for new drugs have led to the earlier adoption of new technologies.

To avoid «Tagamat Crisis» (loss of patents), the companies are increasingly investing in riskier, cutting-edge technologies. Smithkline-Beecham is one of the first such companies to leap into new technologies for gene-hunting.

Again, Glaxo, after realising the futility of blockbluster dependency, is contemplating to develop a broader «portfolio» of drugs. The rationale is to minimise risks associated with the development of new drugs.

Source: *Wall Street Journal*, 13 August 1997.

Here, one has to consider the moderate pace of pharmaceutical innovation and of obstacles to market penetration of new drugs in India. Such consideration leads to the conclusion that, in value term, not more than 15% of the Indian market will be covered by patents some time after 2005. The remaining 85% of the market will continue to be exposed to the impact of generic competition. Patented products will themselves ultimately contribute to that generic pool when their patents expire.

The time scale of the introduction of pharmaceutical patents in India under TRIPs makes it certain that, if Indian drug prices rise during the remainder of the 1990s, it will not be for patenting reasons. The earliest start of premium pricing for patented drugs will be in the early years of the next decade. No significant effect can be anticipated until after 2005, because the weight of patented drugs on the Indian market will be too small for economic impact.

More important than the time scale of patent protection will be fundamental «checks and balances» which will slow down on the impact of premium pricing on Indian drug expenditure (see Box 2). Such balances are as follows:

- the low purchasing power of Indian patents;
- Government price controls under permanent or reserve powers;
- therapeutic competition from cheaper unpatented drugs.

Of these the second is the most immediate, whereas the first and the third are the most «durable» safeguards against a price explosion.

BOX 2 – COMPULSORY LICENSING OF COMMERCIAL MEDICINES POSSIBLE

ACCORDING to the Coordinator of the Forum of Parliamentarians on Intellectual Property, India, Mr. B.K. Keyala, compulsory licensing of pharmaceutical products «for commercial purposes» is possible, within the ambit of the TRIPs Agreement.

Argued Keyala: «India should draw strength from Arts. 7 and 8 of TRIPs and insist on compulsory licensing of pharmaceutical products for commercial purposes.»

The current understanding, under Art. 31 of the agreement, is that TRIPs provisions only allow compulsory licensing for non-commercial use. However, Art. 7, which outlines the objectives of the intellectual property agreement, states that implementation of the agreement should *inter alia* «contribute to the transfer and dissemination of technology».

Furthermore, Art. 8 gives member countries the right to adopt measures to «protect public health and nutrition» and «promote public interest».

India should interpret these articles in the national interest since the constitutional guarantee of the right to life encompasses the right to health, which requires «availability of medicines at affordable prices», said Keyala.

Source: *Press Trust of India*, 26 December 1996.

Here it will be interesting to note that Canada established the Patented Medicine Prices Review Board in 1987, under reforms to extend patent protection to brand-name pharmaceuticals. Until recently, the Board reached over 100 settlements with the pharma industry, which it claims has saved consumers about C$110mn. In a recent case, it ordered a US company, ICN Pharmaceutical's local subsidiary, to cut the price of its Virazole by almost 90% and pay a penalty of C$1.2 mn. Thus, there are precedents for such price regulations.

There is, nevertheless, a widespread belief among Indian companies that even if the remaining preconditions for R & D in India were met, they could not afford the cost of minimum scale operations, and that only TNCs would be in a position to benefit.

Evidently, TNCs have far greater financial resources, but they also have more diverse calls on those resources and are themselves obliged to make difficult choices when it comes to new R & D projects and facilities (see Table 3).

For TNCs, their challenge in India is whether the Indian authorities will pursue their declared objective of attracting global investment and R & D to India by meeting the essential pre-conditions.

Table 3 – Available Revenue for R & D Activities
Unit: As percentage of sales

9	global pharma companies in India (1992 – 93)	6.5
7	Indian pharma companies (1992 – 93)	7.4
10	Japanese pharma companies (1991 – 92)	20.6
8	global parent group[1] (1991 – 92)	32.0

1. 8 out of 9 companies of the first row.

Source: *New Horizons in India, The Consequences of Pharmaceutical Patent Protection*, Redwood H, Oldwicks Press 1994.

4. IMPACT OF TRIPS ON GLOBAL BUSINESS

As expected, the proposed changes in the intellectual property regime are welcomed by the global business and their subsidiaries operating in India. Big TNCs like Hoechst, Novartis, etc., have already set up 100% Indian subsidiaries. However, most of them are interested in playing a waiting game regarding their involvement in the Indian pharmaceuticals market.

They are likely to introduce their new patented drugs once the system of product patent becomes fully operational. Even in that case, most of the new drugs will either be imported as formulations or be formulated in India, by using imported bulk drugs. In short, India is unlikely to be a site for R & D and production of bulk drugs.

For example, according to Glaxo-Wellcome, it is holding back on investments in India because of concerns on Intellectual Property Rights (IPR). However, it plans to build up volumes in certain therapeutic segments, by allowing their Indian subsidiary to negotiate a cheaper price for imports from the parent company.

Under the TRIPs Agreement, India has to accept applications for the grant of product patents from 1st January 1995. According to one estimate, up to July 1996, 264 applications were received by the patent office.

Another area of concern is the pricing of drugs under the new patent regime. Though it is a fact that the prices of Indian drugs are lower than those prevailing in developed countries, the future price differential is unlikely to be large. The reason is to avoid any action against the dumping of bulk drugs.

5. IMPACT OF TRIPS ON INDIAN FIRMS

Axiomatically, the introduction of product patenting will affect the Indian pharmaceutical firms to a large extent. Certainly, they will be prevented from taking a circuitous route to growth through the adoption of process patents. At the same time, some of them are seriously concerned with the expansion of their business.
To achieve their aim, they are increasingly exploring the following options.

6. DEVELOPMENT OF NEW DRUGS

A necessary condition is to increase the expenditure on R & D activities. Drug discovery and development have to be included in the R & D strategy. In other words, the focus of R & D will have to be changed from the innovation of new processes to the invention of new products.

For example, Dr. Reddy's Laboratory (a leading Indian manufacturer) has focused its R & D expenditure on the development of new drugs for cancer, bacterial infections and diabetes. They have set up a research facility at the cost of Rs. 8 crore (approximately $2.3 mn).

However, a couple of structural weaknesses have to be taken into account. First, given the small size of Indian firms, even a sharp increase in R & D activities will not generate sufficient funds for the development of new drugs. Secondly, Indian firms lack manpower and other institutional mechanisms to launch new drugs successfully in the foreign market.

Given such limitations, the focus on R & D should be on:

- the development of in-house drugs that have the same therapeutic value of those existing in the market;
- the production of indigenous drugs, catering to the needs of India and other tropical countries, where TNCs have little or no interest in introducing drugs according to their needs.

7. PRODUCTION OF OFF-PATENT DRUGS

A realistic assumption is that, in near future, off-patent drugs will emerge as one of the important activity of Indian pharmaceutical firms.

Furthermore, off-patent (generic) drugs, made by the Indian firms, are going to meet most of the domestic demand. At the same time, it is incorrect to say that their therapeutic value will be less than the new, *on-patent* drugs.

With the increasing concentration of Indian firms on generic drugs, its export prospects are very high. Currently, the world market for generic drugs is $20 bn, and expected to grow to $40 bn by 2005. In order to take this opportunity, leading Indian firms (like Ranbaxy, SOL, East India Pharmaceuticals) are building their capacities to produce generic drugs.

For example, SOL (Hyderabad) has set up a separate division for the production of generics. Furthermore, it is expecting to generate more than 33% of its annual turnover from generics. Exports of generics will get on further boost from foreign investment in this area. US pharma giant Merck has set up a 100% subsidiary to produce and export generics.

However, Indian firms are going to face strong competition from other developing countries, and even some developed countries. Therefore, the long run success of Indian firms depends on improved efficiency and exploration of new markets through South-North and South-South cooperation, both at the producers'and consumers'levels.

8. PRODUCTION OF PATENTED DRUGS UNDER LICENSE

Global drug development and production have recently been undergoing structural changes. The reasons for such changes are:

- exponential increase in the cost of drug development;
- shortening of product life;
- stiff competition from generic drugs.

In order to gain maximum revenue within a short period, Indian firms are trying to get licenses from global pharma business to produce and market on-patent drugs.

However, two discernible facts are worth mentioning:

- global pharma companies that do not have much stake in Indian market will not hesitate to give licenses to Indian firms;
- companies with large subsidiaries in India (like Glaxo, Pfizer) are likely to introduce licensed drugs through their subsidiaries only.

9. MARKETING OF IMPORTED DRUGS

The fourth option for Indian pharma firms is the marketing of imported drugs. Many Indian firms are interested in entering into long-term arrangements with global businesses. For example, Ranbaxy has entered into an alliance with Eli Lilly.

The new and liberalised drug policy has removed import restrictions from all but eight category of drugs. Removal of import restrictions and proposed changes in IPR will lead to an increase in drugs import.

10. TRIPS: AVAILABILITY AND PRICES OF DRUGS

The aforementioned discussions on off-patent drugs reveal the fact that they will meet most of the demands. Therefore, even under the new patent regime (compatible with the TRIPs Agreement), the availability and prices of generic drugs will largely be unaffected.

However, the situation is different with respect to new (on-patent) drugs. There is no doubt that these drugs will be available in the Indian market (either through production or under license). But the effect on prices is ambiguous.

Under the customary theory of demand-supply, the price level should come down in future. The reason is increased supply rather than increase in demand. Albeit, this ideal situation may not be true in practice because of the following factors:

- the oligopolistic nature of global pharma business;
- the practice of transfer pricing by the global business, monitoring and regulation of prices by the Government will be difficult;
- the price situation also depends on the proportion of patented drugs being sold in the Indian market. At the same time, the global pharma business has

a large number of patented drugs that comes from their own R & D (see Table 4).

Furthermore, in the long run, medical biotechnology is going to be the area of research and development. Biotechnology base research of Indian firms (except the Government-owned Central Drug Research Institute) is poor, and they are unlikely able to produce many of these drugs.

Table 4 – R & D Position of World Pharmaceutical Majors, 1995

	Number of Drugs		
Company	**Own R & D (% of the total)**	**Under License**	**Total**
Hoechst	125 (66.1)	64	**189**
Glaxo-Wellcome	117 (76.0)	37	**154**
Merck & Co.	108 (85.7)	18	**126**
Smithkline-Beecham	77 (64.7)	42	**119**
El Lilly	61 (67.8)	29	**90**
Rhone-Poulenc	53 (68.8)	24	**77**
Yamanouchi	42 (68.8)	19	**61**
Pfizer	44 (73.3)	16	**60**

Source: Scrip, January 1996.

On the other hand, TNCs have a large base for research in medical biotechnology (see Box 3). Given such a dominant position, prices of on-patent drugs are likely to go beyond the reach of the consumers at large in the long run. Therefore, the real issue is not availability of new drugs in the Indian market, but people's access to them.

BOX 3 – HOECHST PATENTS AYURVEDIC HERB

HOECHST, Germany, patented the Indian medicinal plant *Coleus Forskohlii*, which is being used for ayurvedic medicine.

Traditional uses of this herb include treatment for cardiovascular disease, abdominal colic, respiratory disorders, painful urination, insomnia and convulsions.

In 1974, a large-scale screening of medicinal plants by the Central Drug Research Institute of India revealed the blood pressure lowering and anti-spasmodic effects of extracts from *C. Forskohlii.*

One of Hoechst's patents covers a specific formula of the plant extract and its use in treating cardiovascular disease and intraocular pressure.

According to a report by the Rural Advancement Foundation International, Canada, in 1997, Hoechst will begin worlwide marketing of its *C. Forskohlii* derived drug.

Source: *Press Trust of India*; 20 February 1997

Given such a hazy scenario, it is difficult to predict the future of the Indian pharmaceutical industry under the «new» regime of intellectual property rights and its relationship with international trade. However, certain broad trends can be pictured.

First of all Indian pharma companies are going to face stiff competition from the global business, despite the fact that, at least in India, the pharma market is *not* oligopolistic. At the same time, trends in research and development can make it so in the long run.

Therefore, Indian companies can either go for collaboration or concentrate on producing and marketing generic drugs. This futuristic conclusion is based on a realistic assumption which takes into consideration the poor research and market penetration strategies of Indian companies.

On the other hand, global pharma majors are unlikely to consider India as one of their bases for exploring «new» drugs through research. At the most, India can be an «assembly» point for some drugs.

The trickiest part is what position should the Indian government take regarding TRIPs and its impact on pharmaceutical market. The issue is a political economic one, and has to be approached from both angles – economics and politics.

Overall, the Government of India has two options:

- introduce an effective regulatory mechanism for «checks and balances» on the availability, access and price of essential drugs;
- develop research facilities for the introduction of «new» drugs, catering to the needs of the country.

Global businesses do not have any interest in developing tropical drugs. Given its traditional medicinal plant base, India can take a leading position in developing, producing and exporting those drugs.

The drug policy of the government has to be a pro-active one – to take advantage of the TRIPs regime. Compatibility between the above-mentioned two options serves as a base for rational and need-based drug policy.