People before Patents.

The Success Story of the Indian Pharmaceutical Industry

by Richard Gerster

The colonial patent law of 1911 secured the Indian market to British industry. A large majority of drugs were imported from abroad until the Patents Act 1970 brought a turnaround. Early in the 21st century India has a highly efficient pharmaceutical industry, blossoming thanks to the weak patent protection of medicines. It provides essential drugs at affordable prices and creates considerable employment. Today over 90 percent of modern medicine consumed in India are produced locally. By 1 January 2005 India will have to comply with the Trade Related Intellectual Property Rights (TRIPs) of the World Trade Organisation (WTO). The new rules of the game may threaten India's achievements. During the last 20 years India enjoyed an annual rate of economic growth of six percent on an average. The pharmaceutical industry is part of India's success story.

"These days, when Indian migrants return from their home leave to the United States, you can be sure they carry lots of generic ciprofloxacin tablets with them", told me Ashish Shirsat, marketing manager of Blue Cross Laboratories Ltd. In Mumbai (formerly Bombay), India. The antibiotic Ciprofloxacin is in the US under patent up to 2003 from the German manufacturer Bayer and arrived in the media limelight following the growing anthrax scare and fear about bioterrorism. The returnees know why they do not buy Bayer's brand "Cipro" but one of 78 Indian brands. Blue Cross Laboratories indicate production costs for a 500mg tablet of 4 cents, a wholesale price of 7 cents, and a consumer price in the Indian drugstores of about 10 cents, depending on the manufacturer. Under political pressure Bayer offered the Cipro tablet at the "discount" price of 95 cents to the US Government. The regular Bayer wholesale price in the US is US$ 3.60, and the US consumer price US$ 6 – 60 times the price in India. Dr. Y.K. Hamied, Chairman of Cipla Ltd., a

leading Indian drug manufacturer, called the anthrax/cipro-case “an eye-opener that developing countries cannot afford patent monopolies”.

The case of HIV/AIDS

Cipla gained global reputation in the fight against HIV/AIDS. It was only in 1987 that the first HIV-positive case was registered in India, yet India already shows with officially 3.86 million the highest number of HIV-positive people in the world beside South Africa. Cipla Chairman Y.K. Hamied: “We should face the reality that India adds 3’500 HIV-positive cases every day, and a recent World Bank report says there will be 35 million cases by 2005 in India. This makes something like the recent earthquake in Gujarat look like a tea party.” In the red-light districts of the mega city Mumbai and along the truck routes the epidemic is spreading particularly fast. Ignorance and poverty are the most important causes of this. Often, AIDS patients die of tuberculosis, an illness still prevalent in India, because they lack the necessary resistance.

While the term HIV is used to describe the virus, AIDS is the name for the most severe phase of the illness triggered by the virus. There is no cure (yet) for HIV/AIDS. The number of HIV/AIDS deaths has, however, dramatically decreased in the USA and in Europe. Take Switzerland as an example: the number of AIDS deaths annually has dropped from a peak of 686 (1994) to 42 (2000). This must be attributed in the first place to the revolutionary drug combination therapy, which disturbs the life cycle of the HI-Virus. A disciplined taking of a combination of medical drugs can prevent the outbreak of AIDS or at least delay it for years. In particular, the transmission of the virus from a mother to her unborn child can be prevented with suitable medication.

In India, only 500 of 100 000 HIV/AIDS patients at most are getting medical treatment. Sexuality and along with it AIDS are taboo subjects. There is a widespread lack of hospitals and clinics, of personnel, of medical equipment, of medical drugs. There are no compulsory medical insurance schemes in India. AIDS is particularly common in the lower income groups. These people often do casual

work only. A monthly income of less than US$ 100 has to cover the basic necessities of life. There are often two infected persons per family but the savings are hardly sufficient for the treatment of one. “Although women and men are equally affected by HIV/AIDS, 85 percent of our patients are men. According to the Indian patriarchal culture they get preference. Second in line are children. Women sacrifice themselves for the others". This is how Dr Subhash K. Hira, director of the AIDS Research and Control Centre (ARCON) in Mumbai, describes the everyday situation.

A few years ago, the costs of an individual AIDS-combination therapy in India were, at US$ 8 500 per year, prohibitively high. But then, in 1993, Cipla Ltd. introduced the AIDS drug Zidovudine. Stavudine, Lamivudine and Nevirapine followed. They are all elements of the successful virus-inhibiting combination therapy. Cipla offered the AIDS drugs significantly cheaper than other companies. This in turn provoked the lowering of prices by the international competitors on the Indian market. In 2001, Cipla offered the anti-retroviral package at US$ 600 per year and patient to all African governments, and at US$ 350 or US$ 1 a day to the non-governmental charity “Doctors without Borders”. This compares with annual costs of more than US$ 10 000 in Europe and the US. Even at the low price level, purchasing of anti-retrovirals is beyond the budget of most of the developing countries. In an interview published in the South Bulletin in June 2001, Dr. C. P. Thakur, Minister for Health and Family Welfare in India, said: “If you were going to give anti-retrovirals to 10 per cent of our population affected with HIV/AIDS, you will be spending more than total the health budget of the country”.

The Indian pharmaceutical industry

The Indian pharmaceutical industry is a success story. 500 000 people are employed in this sector, in some 12 000 firms. 2 900 of them are large scale units, following a recent article by Pradeep Agrawal and P. Saibaba in the renowned Economic and Political Weekly of Mumbai (29 September 2001). In the pre- and post-production sector, a further 2.5 million jobs are thought to be involved. Compared to the general price index, drug prices have risen much less in the last 15 years and remain far below average. “Worldwide, India is a country of very low drug prices while

producing high quality medicines", Nihchal H. Israni, president of the Indian Drug Manufacturers' Association (IDMA), states proudly. Self-sufficiency with regard to pharmaceutics exceeds 90 percent – in spite of the policy of a more open economy pursued by India since 1991.

The secret of this success is the Indian Patents Act 1970. India had entered independence with the patent system of the British colonial masters, enacted in 1911. This secured the Indian market for the British industry. Prior to 1970, multinational companies dominated the Indian market with a share of 85 percent, pharmaceutics were largely imported whereas local production remained minimal. Section 83 of the Patents Act 1970 states "that patents are granted to encourage inventions and to secure that the inventions are worked in India on a commercial scale and to the fullest extent and not to enable patentees to enjoy a monopoly for the importation". At the turn of the century, the share of multinationals had declined to a share of 40 percent of India's market, including a substantial share of local processing by multinationals. 45 of the larger scale production units belong to multinational companies.

The "architect" of the patent law of 1970, S. Vedaraman, then director of the Indian Patent Office, summarises the spirit of the law as follows: "We are not against patents. And we are prepared to pay decent licence fees. But we in India cannot afford monopolies." Since then, India has done without product patents for pharmaceutics, with the exception of production processes that may be patented for seven years. In addition, the law allowed for compulsory licences granted by the state, in the case of a patent holder not granting voluntary licences on fair conditions. India profited from a large section of well-qualified experts who made good use of the new opportunities.

These moves did not find much favour with the multinational pharma-industry. It should not be forgotten, though, that in many industrial countries, the protection of inventions through patents was only developed in the last 30 years. The Swiss pharmaceutical industry in particular fought the enactment of a patent law at the end of the 19th century, in order to be able to imitate foreign drugs, such as Aspirin. In the German *Reichstag* (Parliament) Switzerland was considered a "state of robber

barons", in France a “country of counterfeiters”. Product patents for medical drugs have only been known in Switzerland since 1978. It is very clear whose interest they serve. Technology exporters profit from patent protection, which shields them from low-cost competition. Technology importers – in other words, most of the developing countries – want access to technical innovations as freely and cheaply as possible, i.e. no patent protection which creates monopolistic barriers. Indeed it was in this way that the economic development of Japan, Korea and Taiwan was able to thrive, due to the beneficial absence of patents.

The Cipla philosophy has for decades been to promote the principle of relying on one’s own strength. “For India, this means striving for a high degree of self-sufficiency in vital areas of health and nutrition, and for our business practice, it means aiming for the fulfilment of the needs of the Indian population, the use of indigenous raw materials and of local personnel", says Cipla managing director Y.K. Hamied. This philosophy, combined with technical expertise, must have been the reason that the Indian Council for Medical Research suggested to Cipla in 1990 that the AIDS drug Zidovudine be produced locally. Due to the state investing its limited means in prevention, the market remained small. In India, approximately US$ 2 million is turned over yearly for AIDS drugs. Of this, Cipla has a share of about 80 percent. This is only a small percentage of Cipla’s total turnover of more than US$ 210 million.

Indian pharma industry is very interested in the export of its pharmaceutics. Developing countries are an important market for Indian manufacturers because they produce high quality products at very competitive prices. But free trade is hampered by national and international patent rules. For a patent does not only constitute the sole right to produce a product but also to import it. Despite these barriers, India’s drug exports exceeded in the year 2000 for the first time US$ 1,5 billion. The success story of the pharmaceutical sector is part of a wider but less known “economic miracle”: India achieved average rates of economic growth for the last 20 years of six percent annually.

The case of South Africa

More than two thirds of all HIV/AIDS patients, i.e. 28 million out of 40 million, live in Africa south of the Sahara. On this continent, AIDS has already replaced wars and malaria as the most frequent cause of premature death. The World Health Organisation (WHO) expects that average life expectancy in Southern Africa will, in the next decade, *decrease* by 17 years to the age of 43 years, instead of increasing to 64 years. This is why AIDS in Africa is more than a health problem. AIDS signals a real social and developmental crisis.

In addition to preventative measures, South Africa wanted to facilitate the import of reasonably priced, good quality AIDS drugs and to stimulate production of AIDS drugs inside the country. The draft 1997 Medicines Act was intended to enable the government to grant compulsory licences for the production of vital medication. A joint company called Cipla-Medpro, consisting of Cipla and a local firm, submitted an application in South Africa. Jerome Smith, chairman of Cipla-Medpro, wrote to the government: ”We are able to bring the newest drugs into South Africa but patents are preventing us from doing it.” In effect, Cipla-Medpro already produced Zidovudine, Stavudine and Lamivudine for the export to countries whose laws allow for the import of imitation products.

The US pharma-industry did not like this project. That is why in 1999 the US Government intervened several times against the new patent law in South Africa and threatened massive trade sanctions. In the past, there had been similar moves against Indonesia and Thailand. It was US vice-president and presidential candidate Al Gore who was in the forefront of this campaign. American AIDS interest groups therefore attacked him directly during election campaign events. Some of the banners carried the slogan “Gore’s greed kills". When the media eventually reported less about Al Gore’s election campaign than about the AIDS conflict with South Africa and Gore’s role in it, the USA stopped their interventions and threats against South Africa after a few weeks.

In a parallel move, 39 pharmaceutical multinational companies accused the Government of South Africa to override its patents by the pending clause 15c of the

1997 Medicines Act which permits parallel imports and compulsory licensing. The dispute developed to a global debate on fundamental priorities of patents and public health. On 18 April 2001 the pharmaceutical companies dropped their lawsuit against these provisions. The South African Government acknowledged the TRIPs regime but maintained its legislative proposal and promised to seek the dialogue with industry before issuing compulsory licenses or proceeding to parallel imports. Cipla is about to get the first products registered in South Africa.

The TRIPS dispute

In spite the rich evidence of economic history, patent protection was winning the upper hand against the interests of developing countries. The vehicle in this crusade of the industrial countries for a global patent protection is the World Trade Organisation (WTO). A particular part of the WTO agreements (Trade Related Intellectual Property Rights – “TRIPs") prescribes worldwide minimal standards for patent protection. No country adopting a market economy and keen to be integrated in the world economy can do without WTO membership and so has to swallow the TRIPS pill as well. “WTO/TRIPS stand for a re-colonisation of the economically weak countries. The patent right is an obstacle in the fight against the AIDS epidemic. These economic rules of the game are partly to blame for the fact that people are dying", says Dr Subhash K. Hira, ARCON director.

The dispute in South Africa led to a world wide debate on the balancing of private profits and public health. Currently, most essential drugs are no longer patented. TRIPs is thus less an issue for the vast majority of existing essential drugs than it is for new and future essential drugs, patented after the final date of compliance with TRIPs, namely 1 January 2005. The TRIPs agreement contains a safeguard clause allowing developing countries faced with national emergencies to put in place compulsory licensing and permitting parallel imports. The WTO Ministerial Conference in Doha (Qatar) of November 2001 adopted a declaration on TRIPs confirming on the one hand the recognition of intellectual property rights by the contracting parties and stating on the other hand that in case of conflict public health may override commercial interests. It confirmed the right of governments to grant

compulsory licenses and the freedom to determine the grounds upon which such licenses are granted. It confirmed also the freedom of countries to decide on their own rules for implementing parallel imports. The least developed countries (LDC) were granted a 10-year extension up to 2016 to comply with TRIPs. Non-LDC developing countries like South Africa, Brazil or India will, however, have to comply with TRIPs from 1 January 2005 onwards.

"One shoe size cannot fit everybody. We therefore need TRIPs-North and TRIPs-South", says Cipla's Y.K. Hamied. Pradeep Agrawal and P. Saibaba conclude their thoughtful analysis "the TRIPS agreement is not in the national interest and should be renegotiated". The declaration of Doha, however, does not identify a need to change the TRIPs agreement. In practice the application of the flexibilities built into TRIPs in favour of public health concerns usually were challenged by multinational companies. In the words of the Health ministers of Belgium – being at the time president of the European Union Health Council – and South Africa according to their joint statement of 26 October 2001: "The pharmaceutical industry continues to intimidate and penalize those countries that explore the use of these legitimate clauses that are permitted within the TRIPs agreement." Only time will tell whether the Doha Declaration on patents and public health will make a difference for developing countries.

The patent bill

India has become a WTO member in 1995 and will have to apply the new TRIPS rules for medical drugs in its national patent legislation by 1 January 2005 at the latest. Product patents of at least 20 years duration will have to be provided for medical inventions after that date. The Indian pharmaceutical industry has been campaigning for the legal provision of anti-monopolistic safeguards like compulsory licensing, parallel imports, restricting the life of patents on essential drugs to 10 years, not allowing imports to be considered as working of a patent. The product patents per se, however, are no longer a matter of controversy.

A first attempt of 1995 by the Government of India to amend the patent law lapsed in parliament. After a dispute settlement procedure at the WTO – requested by the United States against the Government of India – another Indian attempt to get parliamentary approval failed. In order to comply with WTO/TRIPS, the Government of India finally issued in 1999 the Patents (Amendment) Ordinance, establishing a mailbox facility to accept product patent applications from 1 January 1995 onwards, and to provide exclusive marketing rights (EMR) to such applicants. A second part of the Patents (second amendment) Bill 1999 to adjust the Indian legislation to TRIPs has now been pending for more than two years before the joint committee of both the upper and the lower house.

The US pharma-producers still call India a “centre of commercial piracy". B. K. Keayla, Convenor of the National Working Group on Patent Laws, considers the perspectives very bleak unless the Indian government takes up the core proposals of Indian industry: “The existence of the majority of today’s 12 000 Indian producers is threatened and multinational suppliers are going to dominate the market with far higher prices. The 5 – 10 percent wealthy consumers will favour fancy imported drugs. Jobs will be lost and India’s balance of trade in the area of pharmaceutics will be in deficit again. We will be back in the situation before the Patent Act 1970." Keayla is appealing to the Indian parliament and government to fully exhaust those positive possibilities that are contained in the international TRIPS rules and to take up a revision of TRIPs in the WTO.

Marginal markets

Within the worldwide pharmaceutical market, with its annual turnover of US$ 400 billion, Africa South of the Sahara has a share of one per cent. Also India’s US$ 3,5 billion constitute barely one percent. One billion Indians, male and female, spend the same amount on medical drugs per year as seven million Swiss men and women. “The amount spent on drugs here in India roughly corresponds to the profit made by Novartis in the past year", says IDMA President Nihchal H. Israni. “Why can’t the North concede the same autonomy for the protection of inventions to the South which Switzerland in particular has for decades claimed for itself and used for its own benefit?”

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