



How WTO/TRIPS threatens the Indian pharmaceutical industry

The Indian pharmaceutical industry is a success story providing employment for millions and ensuring that essential drugs at affordable prices are available to the vast population of this sub-continent. However, the new 'trade' rules of the World Trade Organisation now pose a serious threat to the industry and to the millions who are dependent on it for their health and livelihood.

Richard Gerster

INDIA has a highly efficient pharmaceutical industry, which started blossoming thanks to the virtual absence of patent protection of medical drugs. It produces, for example, its own AIDS drugs, which are sold much more cheaply than the original products from abroad. The new rules of the game of the World Trade Organisation (WTO) benefit the pharmaceutical multinationals from countries such as the USA, Great Britain and Switzerland, and threaten India's achievements. The people paying for this are AIDS patients - in poor countries.

'In India, eight million people are estimated to be HIV-positive,' Dr Raman Shetty explained to me. The official estimate is still at 3.5 million. Eight hundred thousand of these people have already developed AIDS. It was only in 1987 that the first HIV-positive case was registered in India, yet India already shows the highest number of HIV-positive people in the world. In the red-light districts of the megacity Mumbai (formerly Bombay) 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.

Prohibitive costs

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 far below 100 (1999). 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. The cost of individual AIDS-combination therapy, at more than US\$300 per month, is prohibitively high. 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% 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.

Successes of the Indian pharmaceutical industry

A few years ago, the costs of treatment were, at far above US\$700 per month, more than twice as high as they are today. But then, in 1993, Cipla Ltd., an Indian pharma-firm rich in tradition, introduced the AIDS drug Zidovudine. Stavudine and Lamivudine followed (the latter in 1998). Nevirapine is going to be launched soon. They are all elements of the successful virus-inhibiting combination therapy. Cipla offered the AIDS drugs at significantly lower prices than other companies. This in turn provoked the lowering of prices by the international competitors on the Indian market. Today, a packet of ten 100-milligramme capsules of Zidovudine, produced by Cipla in India, costs less than US\$5 (150 rupees). The original product of the British firm Glaxo Wellcome is sold for more than double the price in India, Pakistan and Indonesia - and costs five to six times more in the USA and Great Britain.

The Indian pharma-industry is a success story. Five hundred thousand people are employed in this sector, in roughly 20,000 firms. 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 ... prices (for) high-quality medicines,' Nihchal H Israni, president of the Indian Drug Manufacturers' Association (IDMA), states proudly. Self-sufficiency with regard to pharmaceuticals is far above 70% - in spite of the policy of a more open economy pursued by India since 1991.

The secret of this success is the Indian patent law of 1970. India had entered independence with the patent system of the British colonial masters. This secured the Indian market for the British industry; pharmaceuticals were largely imported from abroad and local production was minimal. The 'architect' of the patent law of 1970, S Vedaraman, then director of the Indian Patent Office, summarises the principle 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 pharmaceuticals, 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's 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, it was labelled 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 economies of Japan, Korea and Taiwan were able to thrive, due to the beneficial absence of patents.

'recolonisation'

In spite of this, patent protection is gaining the upper hand against the interests of developing countries. The vehicle in this crusade of the industrial countries for a global patent protection system is the WTO. One of the WTO agreements (the Agreement on Trade-Related Aspects of 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 stands 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 Hira, of ARCON.

India, too, became 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. First steps have already been taken in the patent law of 1999. But the US pharma-producers still call India a 'centre of commercial piracy'. Israni of the IDMA considers the situation very bleak unless the Indian government makes a countermove: 'Indian producers are being pushed out of the market and multinational suppliers are going to dominate the market with far higher prices. Jobs will be lost and India's balance of trade in the area of pharmaceuticals will in future be in deficit - in brief, a situation similar to the one before the patent law of 1970.' Israni is appealing to the Indian

government to exhaust fully those positive options that are still contained in the international TRIPS rules and especially to provide for effective enforced licences.

Export hurdles

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, (and) 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 why 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\$1 million is turned over yearly for AIDS drugs. Of this, Cipla has a share of about 80%. This is only a small percentage of Cipla's total turnover of US\$150 million.

Cipla is very interested in the export of its pharmaceuticals. More than 95% of all HIV-infected people - 34 million worldwide - live in developing countries. Each day, 16,000 more people are infected, each year six million more. It could be attractive for other countries to buy high-quality imitation products from India at reasonable prices. But free trade is hampered by national and international patent rules. For a patent constitutes the sole right not only to produce a product but also to import it. That is why Glaxo Wellcome can prevent the import of cheaper Zidovudine produced by competitors.

Until recently, there was no patent system for pharmaceuticals in Brazil. The new patent law of 6 October 1999 provides the possibility of issuing compulsory licences. On this basis, Brazil plans to buy raw material for AIDS drugs from abroad to the amount of US\$300 million this year. Cipla has made an offer.

US interventions

Two-thirds of all HIV/AIDS patients, i.e. 23 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.

South Africa has recognised that countermeasures using all possible means are necessary and has therefore launched a 'Partnership against AIDS Programme'. In addition to preventative measures, South Africa wants to facilitate the import of reasonably priced, good-quality AIDS drugs and to stimulate production of AIDS drugs inside the country. A new health law was intended to enable the government to grant enforced licences for the production of vital medication. A joint company called Cipla-Medpro, consisting of Cipla and a local firm, has already 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 produces Zidovudine, Stavudine and Lamivudine for export to countries whose laws allow for the import of imitation products.

The American pharma-industry did not like this project. That is why in 1999 the USA 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 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 his role in it, the USA stopped their interventions and threats against South Africa after a few weeks. Will it be possible for the Indian-South African firm Cipla-Medpro to supply AIDS patients in South Africa with reasonably priced drugs in the near future?

World Bank subsidies

India's tight resources for AIDS have, up to now, mostly been spent on prevention. In this regard, it is of essential concern to strengthen the self-confidence of women. There is hardly any money left for treatment. In

October 1999, the World Bank granted India a loan of US\$198 million for financing AIDS prevention and treatment for the years 1999-2004. Fifteen percent of this is reserved for treatment measures. The World Bank budget has been calculated on the basis of prices for Cipla drugs. In spite of this, the first commission went to the international competition.

Within the worldwide pharmaceutical market, with its turnover of US\$350 billion, India's US\$3 billion constitutes barely 1%. 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 Israni. 'Why can't the North concede to the South the same autonomy with regard to the protection of inventions which Switzerland in particular has for decades claimed for itself and used for its own benefit?'

Richard Gerster, Dr. oec. (Richterswil/Switzerland, holds a PhD Econ from the University of St Gallen (Switzerland). After many years of commitment to Swiss non-governmental organisations, he is now an independent consultant for the Swiss Government, NGOs and the World Bank. He has concerned himself with the North-South dimension in patent issues for over 20 years. Comments welcome to rgerster@active.ch.

(Aug-Sept 2000)

[BACK TO MAIN](#) | [ONLINE BOOKSTORE](#) | [HOW TO ORDER](#)

TWN