and contacts to whom he could have transmitted the infection, so as to fortify the immune responses of individuals deficient in this respect and thereby liable to develop leprosy. It is a doable proposition. This was the way small pox was eradicated. The undertaking though appearing large is far smaller than what was done for polio. The achievement will be historical.

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G. P. Talwar is in the Talwar Research Foundation, New Delhi 110 068, India.
e-mail: gptalwar@gmail.com

COMMENTARY

Indian pharmaceutical industry: policies, achievements and challenges

Rajesh Kochhar

The Indian pharmaceutical industry is a success story from a national as well as developing nations' perspective. India accounts for 10% of the world's production of pharmaceuticals and ranks third in the world in terms of volume. In value terms, however, its share is only 1.4% and the rank 14th (ref. 1). This statistics underlines the important fact that India produces world-class generic drugs at a low cost. Indian domestic pharma market, currently valued at US$ 12 billion, is largely self-sufficient with patented drugs playing a minimal role. India exports both bulk drugs and formulations (tablets, etc.). For the year 2012–13, India's pharmaceutical exports stood at some US$ 14.7 billion, registering a growth rate of 11% (ref. 2). About 55% of exports are to USA and to a lesser extent other regulated markets such as Europe, Japan and Australia. These countries primarily buy bulk drugs, but they are now increasingly buying formulations as well.

However, it is in the case of the poor and low-income countries that Indian generic drugs are playing an extraordinary humanitarian role. UNICEF's 2012 Supply Annual Report (p. 37) recognizes India as the largest supplier of generics[3]. About 50% of the essential medicines that UNICEF distributes in developing countries is sourced from India; Belgium which supplies vaccines comes a distant second. India can justly be proud of the signal role it has played in suppressing AIDS in Africa and other poor countries. Nearly 70% of the medicines for AIDS patients in 87 developing countries purchased by various agencies, including UNICEF and Clinton Foundation since July 2005 has come from India. The independent international medical humanitarian organization Médecins Sans Frontières (MSF) rightly calls India the 'pharmacy of the developing world'.

In 1996, the US Food and Drug Administration (FDA) approved the combination antiretroviral (ARV) drug therapy for AIDS, which turned out to be effective indeed. By 1997, the number of AIDS deaths in USA had declined significantly. Unfortunately, the benefit of the therapy was denied to the poorer parts of the world. The drugs are patented in USA and marketed by pharmaceutical companies, in some instances as exclusive licensees of the US Government. Patents relating to AIDS drugs were granted across the globe, including in South Africa. The AIDS drug cocktail cost about US$ 1000 a month, obviously beyond the reach of most patients and their governments. The patent-holding companies, refused to lower the prices. In 2001, the Indian pharma company Cipla, led by Yusuf Khwaja Hamied, offered to sell generic medicine at about US$ 30 a month. The powerful Big Pharma, using all legal and political weapons at its command, objected to the sale of generics in territories where it held the patents. Finally, thanks to a worldwide campaign led by a handful of dedicated people, Big Pharma was forced to retreat. By this time 10 million or more people had already unnecessarily died of AIDS. It is matter of record that AIDS-death rate in Africa showed a decline only in 2007, a full 10 years after the introduction of ARV (Table 1). How Africa coped with AIDS is the subject of a critically acclaimed award-winning 2013 documentary 'Fire in the blood'.

Indian Patent Act

From 1972 till 2005, Indian drug manufacture was governed by the Patent Act of 1970 which refused to grant a patent for a product, thus encouraging drug companies to produce generic drugs through reverse engineering, unmindful of their patenting elsewhere. In 2005, India was obligated to allow product patents in accordance with Trade-Related Agreement on Intellectual Property Rights (TRIPS); but making effective use of the permitted flexibilities, the new system protects the interests of generic manufacturers as well as patients. The Indian patent regime does not permit ever-greening, that is patenting of minor

Table 1. AIDS timeline

1982	AIDS defined
1983	HIV recognized as the cause of AIDS
1987	US Food and Drug Administration (FDA) approves the first antiretroviral (ARV) drug, AZT. At US$ 1000 for a year's supply, it became the most expensive drug in the world's history
1995	AIDS deaths reaches an all time high
1996	FDA approves combination drug therapy (drug cocktail) costing US$ 15,000 a year. AIDS converted from death sentence to chronic disease
1997	Introduction of drug cocktail drastically reduces AIDS deaths in USA, but the disease continues to flourish elsewhere
1999	More than 95% of all HIV-infected patients found in the developing world
2001	Yusuf Khwaja Hamied (Cipla) offers to sell generic AIDS drugs at a small annual cost of US$ 350; Big Pharma exerts national and international pressure to prevent sale of generics to protect its patents and profits, leading to avoidable death of a million African patients
2007	Finally, thanks to a successful high-profile campaign, African AIDS death figures decline, but only a decade after the introduction of ARV

changes in existing drugs. At the same time, patent laws continue to provide for compulsory licensing of vital new drugs on payment of royalty.

It is noteworthy that the Indian pharma patent policy came about because of successful lobbying by the Indian pharma companies (led by Hamied) and not due to a top-down decision[4].

Currently, patented drugs account for only 1% of the market in India, which with its vast and expanding wealthy class is a coveted destination for international drug companies[5]. They are buying well-established Indian companies; challenging India's patient-friendly laws in Indian courts, and exerting international political pressure to get the laws amended. So far, the Supreme Court of India has upheld the validity of the Indian laws.

In 2008, the multinational pharma major Bayer won an Indian patent for Nexavar, a kidney cancer drug. On 9 March 2012, the Controller of Patents, Mumbai, granted the first-ever compulsory license to Hyderabad-based company Natco to make 'a generic version' of Bayer's Nexavar. In March 2013, India's Intellectual Property Appellate Board (IPAB) upheld the grant of compulsory license to produce and market Nexavar by paying Bayer a 6% royalty. The decision noted that Bayer had not made Nexavar 'reasonably affordable'[6]. Bayer sold the drug in India at a whopping US$ 5500 for a month's dose. Natco's version would cost US$ 175. Cipla, which has been selling generic Nexavar in India for years prior to the Natco license, promptly cut the price of its product by 75%, making it available at US$ 130 for a monthly dose.

In 2006, the Swiss pharma giant Novartis filed a patent for Glivec, a highly effective treatment for leukaemia. Bringing the seven-year high-profile legal battle to an end, the Supreme Court of India in its ruling of 1 April 2013 declared the drug to be a case of evergreening, that is, it did not represent a major advance over previous versions. It is noteworthy that Glivec enjoys 'protection in 40 jurisdictions around the world'. The judgment attracted global attention, including an editorial in the *New York Times*[7].

US pressures

The 2014 report on International IP Index issued by the Global Intellectual Property Center (GIPC) of the US Chamber of Commerce, ranked India at the bottom in a list of 25 countries in terms of protection and enforcement of intellectual rights. India had enjoyed the same distinction in the 2013 report. Releasing this year's report on 29 January 2014, Senator Orrin Hatch placed India at the top of the list of countries which 'seek shortcuts that undermine and even steal American intellectual property'. Hatch said: 'Indeed, India is the biggest battlefront we face in the fight to protect US intellectual property rights abroad. In addition to localization policies that coerce American companies into transferring their technology, India also misuses its own intellectual property system in an effort to boost its domestic industries. Even the basic legal tenants of intellectual property are at risk in India. The Government of India has granted a compulsory license to its domestic industry so it can freely manufacture generic copies of a patented product merely because the product had not been "worked", or manufactured, in India. And India continues to arbitrarily invalidate legitimate patents held by US companies by creating an extraneous requirement for patentability that's out of step with the rest of the world'[8].

The 2014 report notes (p. 27) with apprehension that 'Given the prominence and size of India's generic pharmaceutical industry, other countries have taken notice and begun to introduce similar provisions into their own laws and regulations'[9]. Indeed, South Africa has on the anvil a healthcare intellectual property law that is similar to India's. It now turns out (January 2014) that international drug companies hatched a covert plan to sabotage the proposed law.

In India, Big Pharma is seeking remedies from within the legal system, trying to subtly influence it, and at the same time get it changed to its advantage. The multi-dimensional pressures on India have increased after the Novartis ruling and may even be working. In 2007, Pfizer/Sugen was granted patent on a specialist anti-cancer drug, Sutent. Cipla opposed the patent in 2008 and got it revoked in September 2012. Things moved fast after that to Pfizer's advantage. By June 2013, Pfizer had managed to obtain prompt and effective interim relief from the Delhi High Court, the Supreme Court and the IPAB 'in a shorter time than any patient or generic company has ever been able to in the Indian court system'[10].

As the *New York Times* noted in an editorial on 4 April 2013, India is the world's largest supplier of generic

medicines and its policies affect billions of people around the world. They also affect the bottom lines of Big Pharma. The Office of the United States Trade Representative (USTR) has been preparing since 1989, an annual report known as Special 301 Report. The report identifies trade barriers to US companies and products due to the intellectual property law in other countries. Each year the USTR must identify countries which do not provide 'adequate and effective' protection of intellectual property rights or 'fair and equitable market access to United States persons that rely upon intellectual property rights'. The USTR must also undertake annual surveys of foreign countries' intellectual property laws and policies.

By statute, the annual report must prepare a 'priority watch list' and a 'watch list', containing names of countries whose intellectual property regimes are deemed of concern. More seriously, it must compile a list of 'priority foreign Countries' which are judged to have inadequate intellectual property laws; these countries may be subject to sanctions. India is currently on the priority watch list. The US industry trade group, Pharmaceutical Research and Manufacturers of America (PhRMA) believes that Washington should take a tougher line by downgrading India to a priority foreign country so that punitive action can be initiated.

Throughout history, patent laws have been enacted to protect national interests. Their defence, however, is couched in universal language to deflect criticism. Even post-TRIPS, India has so far successfully managed to retain a patent regime that aims at producing high-quality generic drugs at low prices for use in the country and other middle- and low-income countries as well as in rich countries. India's patent laws are serving as a role model for many other countries. India is being subjected to ever-increasing pressure to reverse its direction and enact laws that protect and advance the interests of Big Pharma. Will India be able to withstand these pressures? Only time will tell.

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ACKNOWLEDGEMENTS. This work has been supported by a History of Science research grant from the Indian National Science Academy, New Delhi. I thank Charlotte Chunawala, Head, Corporate Communications, Cipla for sending me a copy of the autobiography of K. A. Hamied.

Rajesh Kochhar is in the Mathematics Department, Panjab University, Chandigarh 160 014, India and Indian Institute of Science Education and Research, Mohali 140 306, India.
e-mail: rkochhar2000@gmail.com