Patently Unfair Trade

India's state-protected pharmaceuticals industry is being patented, privatised and plundered by WTO trade rules, argues **HANS LOFGREN**

India's pharmaceutical industry, the world's fourth largest by volume, is a major exporter of relatively cheap generic medicines to both developed and developing countries. In 2001, the Mumbai-based firm Cipla commenced exports of a generic version of a triple-combination drug for the treatment of HIV/AIDS to Africa for around US$350 (for a one-year course). The price charged by the multinational drug companies was around US$12,000. The response of the 'big pharma' companies, supported by the US government, was to attack the Indian firms and their customers, notably the South African government, in the courts and the international institutions. This caused public outrage that ultimately forced a withdrawal of the legal action against South Africa, and the prices for HIV/AIDS drugs charged by the multinationals were also lowered. Still, the need for HIV/AIDS drugs in developing countries is far from being met, and US resistance to generics remains a key factor hampering supply.

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Large-scale Indian exports of generic medicines were made possible by the absence of product patents for drugs, which were abolished (along with patents for agro-chemical products) in the early 1970s. Process patents were recognised but firms were free to develop alternative processes to manufacture a wide range of bulk and finished drugs at low cost. There were also high tariffs and restrictions on the importation of ready-made formulations, and transnational drug companies were required to reduce their stake in their Indian subsidiaries. The Indira Gandhi Government of that period subscribed (in some respects at least) to Nehru's vision of autonomous industrialisation, and sought to encourage the development of an indigenous pharmaceutical industry and to provide access to low-cost medicines. All in all, until recently, India was an unattractive market for the multinationals and many abandoned the country altogether. In 1970, domestic companies supplied only around 20 per cent of the drug market; by the 1990s this figure had increased to around 80 per cent and India had achieved self-sufficiency in the production of most basic medicines. But the nationalist period of state-protected industry development has now come to an end. Since 1991, India has embarked on a shift towards liberalisation, privatisation, and integration into global markets, and the pharmaceutical sector has been progressively 'opened up' in respect of trade and foreign investment. The election in 2004 of the Congress-led United Progressive Alliance (UPA) government, supported in parliament by the Communist Party of India (Marxist) and other Left parties, is unlikely to change the general direction of economic policy.

Recently, the Indian government re-introduced product patents for pharmaceuticals, which will impede access to affordable drugs — including new HIV/AIDS medications — for the poor in India and other developing countries. The new patent regime has been forced on India by the World Trade Organisation (WTO) and the requirements of the TRIPS agreement (Trade Related aspects of Intellectual Property Rights). TRIPS is one of the three pillars of the WTO along with trade in goods and services. The now taken-for-granted linkage between international trade regulation and intellectual property rights (IPR) is the outcome of an initially covert lobbying campaign by the transnational pharmaceutical companies from the 1980s, which received early endorsement by the US government. This campaign was remarkably successful, and when the WTO was established in 1995 a global IPR system was adopted as a central aim. At the time, IPRs (patents, copyright, trademarks, for example) attracted little public debate and scrutiny, but since the eruption of the 'anti-globalisation' movement at the WTO Seattle meeting in

1999 their social and economic implications have been paid ever-increasing attention by social movements and critical analysts. In recent years, the debate has also been fuelled by the increasingly aggressive pursuit of strong IPRs by the pharmaceutical, software, publishing, entertainment and other industries. In India, a fierce political battle is now being waged over drug patents that has far-reaching implications for other developing countries that have come to rely on access to relatively affordable Indian generic drugs.

TRIPS requires twenty-year product patents in all fields, including medicines, and obliges signatory states to provide effective enforcement mechanisms. Developing countries were given a transition period until 2005 and the least developed countries until 2016. Before WTO, nations could design IPR legislation in accordance with their particular circumstances and in many countries pharmaceutical patents were not recognised. Indeed, most OECD countries introduced pharmaceutical patents only when they had reached a high stage of economic development. Thus Japan introduced drug patents in 1976, Switzerland in 1977, Holland, Italy and Sweden in 1978, and Spain and Norway in 1992. Yet developing countries, with huge public health needs and virtually no drug patents to protect, are now prevented by TRIPS and US intimidation from adopting IPR arrangements consistent with their economic and social circumstances.

TRIPS recognises some public health safeguards and these were re-affirmed, at the instigation of India and other developing countries, in the Doha Declaration of 2001, which states that 'the TRIPS agreement does not and should not prevent members from taking measures to protect public health' and, 'the agreement can and should be interpreted and implemented in a manner supportive of WTO members' right to protect public health and, in particular, to promote access to medicines for all'.

But the practical significance of such pronouncements is undermined by pressures from the multinational drug companies, the US government, and also the European Union, whose objective is the implementation — through regional and bilateral trade agreements (such as the one recently entered into with Australia) and general bullying — of 'TRIPS plus' provisions that go beyond the requirements of the WTO. Most developing countries lack both the technical resources to negotiate effectively in the very complex area of IPRs and the political and economic power to stand up to global companies and the governments in the US and Europe. A further threat to flexibilities notionally available under TRIPS is emerging from within the World Intellectual Property Organization (WIPO), where the US and its allies are pursuing the aim of a fully harmonised global IPR system that would do away with any leeway for national legislators.

The Indian Patents Act has been modified in the past decade to bring it closer to TRIPS, but the government procrastinated on the most crucial step — the introduction of product patents — due to strong opposition by sections of the domestic pharmaceutical industry and public health groups. By late 2003, the Bharatiya Janata Party (BJP) government had prepared a final amendment bill but its electoral defeat put a stop to its passage through parliament. The new UPA government was and remains in a quandary in respect of product patents and TRIPS, not least as a consequence of its parliamentary reliance on the Left parties. On 26 December 2004, as the WTO deadline of 1 January 2005 was about to expire, a revised version of the former government's patents bill was introduced as a Presidential ordinance. This decree is now the subject of intense debate.

Of particular concern to many domestic drug firms, social movements and the Left is the point also made by an editorial in the *New York Times* (18 January 2005):
The decree is so tilted toward the pharmaceutical industry that it does not even take advantage of rights countries enjoy under the WTO to protect public health.

The precise implications of the new IPR regulations are not yet clear, and amendments are likely when the bill is presented to parliament, but the critical change is that the 'reverse engineering' model, which underpinned the expansion of India's pharmaceutical industry in the past three decades, is now disallowed. New drugs will be granted patents for twenty years (previously process patents only applied for five to seven years). Prices for new medicines will be substantially higher than would have been the case under previous arrangements. Patents will also be granted for some drugs already on the market (thousands of applications are pending) which will result in generic versions having to be withdrawn, driving up the cost of these medicines in India and in countries to which India exports. For example, it will not be possible to produce and export generic versions of post-1995 or any future 'second line' HIV/AIDS medicines — prescribed when the effectiveness of 'first-line' cheaper medications has been exhausted — unless voluntarily licensed by the patent holder. The new legislation also includes 'data exclusivity' provisions that are likely to further impede the timely introduction of generics. The term 'data exclusivity' refers to the prevention of access for generic companies to clinical trial and other data lodged with national regulators by the originator (multinational) company. This can be a means (distinct from patents) of extending the marketing monopoly enjoyed by originator companies, and 'data exclusivity' is pursued aggressively through many of the recent so-called free trade agreements (including an agreement with a group of Central American countries).

For the multinational drug companies, India now beckons as a profitable market with a huge potential for expansion. An executive was recently quoted as saying:

There could easily be 70 to 80 million people [in India] who can afford expensive medicines, just as they go out and buy expensive cars, branded clothes and consumer goods. That is equal to the size of a UK or a Germany (Reuters, quoted on IP health 30 December 2004 <lists.essential.org/pipermail/ip-

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health/2004-December/007323.html>).

This is a vision that excludes the health and wellbeing of hundreds of millions of Indians living in poverty.

Proponents of the TRIPS regime argue that the impact on consumers will be marginal since most drugs are out of patent and will continue to be available as generics. Their view is also that IPRs provide incentives for research and development to discover new medicines, and the future of the Indian industry is said to be in discovery and innovation rather than 'reverse engineering'. Further, it is suggested that India now has a bright future as a location for investments in drug production and research.

But, as already noted, existing drugs eligible for patent protection and all drugs introduced in the future will be priced in India at a level beyond the reach of most of the population. There is also the distinct possibility that the 'big pharma' companies will reverse to the pre-1970s practice of supplying the Indian drug market largely through imports. The most advanced of the domestic firms will be further integrated into the global innovation and production networks of the multinationals, defusing the competitive threat posed by hitherto relatively independent, highly efficient Indian generics manufacturers. Nor will the introduction of product patents bring about, in the foreseeable future, research and development activities of significant magnitude. Although more research and development is undertaken than a decade ago and there are reports of interest in locating more clinical trials to India, these are marginal activities in the context of the Indian pharmaceutical sector as a whole or global research and development in the biosciences. The research and development undertaken by the multinationals is directed, first and foremost, at the chronic diseases of the rich, and Indian firms oriented towards the world market operate according to the same logic. The Indian government's Planning Commission posits that 'priority needs to be given for the initiation of new drug development for diseases of relevance to the Indian population', but needs-driven discovery research or, for that matter, the supply of essential drugs as public goods, is not easily reconciled with success in a globally integrated pharmaceutical market. It is striking that HIV/AIDS medications are not widely available to Indian patients despite the groundbreaking role of Indian companies in exporting relatively cheap generic HIV/AIDS drugs.

In response to these changes, public health activists in India are currently building a domestic and global campaign under the slogan 'Right to Health' for modifications to the proposed patent legislation, co-ordinated through the Global Campaign against Indian Patents Amendment (GCAIPA <www.gcaipa.org>).

This campaign faces an uphill battle. The forces that are now reshaping the Indian pharmaceutical industry will not bring about an improvement in the health conditions of the vast majority of the population. The significance of the new patent regime is that India is again an open market with drug regulation compliant with the needs the multinational companies. Soon it will be possible to look back at the period of state support for an autonomous domestic industry as an historical interlude.

Hans Lofgren teaches Politics and Public Policy at Deakin University. He recently visited India to study developments in the drug industry.