

## **Legalising the pharmaceutical drug cartel**

When Indira Gandhi addressed the World Health Organisation in 1981, she stated her vision of a better world would be one in which medical discoveries would be free of patent and there would be no profiteering from life or death. Sadly, she could not have foreseen the creation of an international agreement like the Trade Related Aspects of Intellectual Property (TRIPS), and how a later Government would draft the current Patents Amendment Bill in a form which could not be further from her ideal.

As a signatory to the World Trade Organisation (WTO), India, like the other developing country Member States, is required under TRIPS to update its laws on intellectual property rights (IPRs). Having already updated its copyright and trade mark laws to broaden protection and enforcement of such rights, the Government now has until 1 January 2005 within which to amend its laws relating to patents or face action from other Member States of the WTO.

The history surrounding the negotiation of the TRIPS Agreement reads like a mafia story where the industrialised countries of the north, as a result of pressure from the pharmaceutical, software and phonogram industrial lobbies, forced the agenda to have the standard of protection for IPRs universalised and recognised as a trade issue. The real coup de grace came when the TRIPS Agreement was negotiated and created to fall under the authority of the WTO and thus bind its Member States. It is difficult to think of an international agreement other than TRIPS which has as its objectives the promotion of competition and social and economic welfare, yet on the other hand effectively allows a legal cartel to exist.

Substantial research has been carried out by national and international organisations on the potential effects of TRIPS on drug prices within India and other developing countries. Phrases ranging from “medical apartheid” to “national health disaster” have been used to describe the impact of the new patent regime being forced by the multinational pharmaceutical giants via the WTO and TRIPS. A study carried out by the International Monetary Fund (IMF) economist A. Subramanian, an organisation which has never been a true friend of the poor and developing countries, found that drug prices in Malaysia, where patent protection for pharmaceutical products already exist, were from 20% to 760% higher than India and reflected a profit-maximising behaviour by the pharmaceutical companies based on what the market can bear. Even the findings of the British Government’s Commission for Intellectual Property Rights, set up to review the effects and impact of TRIPS and IPRs on developing countries, has stressed that governments of developing countries should use what available checks and balances there are within TRIPS to ensure that any new legislation implemented around patents does not exacerbate a healthcare disaster which is likely to occur as a result of developing countries having to change their patent laws.

India’s existing Patents Act, passed in 1970, has been the beacon of welfare legislation in the developing world for having negated the ability of the large multinational pharmaceutical companies to create and control price monopolies for life saving drugs. By not allowing patent protection on pharmaceutical products per se

but only the process behind the creation of the drug, generic drug companies in India have been able to create their own versions for the same drugs produced by the multinational pharmaceuticals but at a fraction of the price to the purchaser. However, under the current Patent (Amendment Bill) 2003, this and other changes which impact the accessibility to affordable drugs are all about to change. The Bill if implemented as is, stands to have severe repercussions for the majority of the population and other developing and least developing countries which are reliant on India's generic drug industry for cheap affordable medicine. So why is the Indian Government rolling over to its masters at the WTO and not implementing the available checks and balances that exist within TRIPs, which it fought so hard to include during the negotiation stages? Why has there not been an open public debate on the current Patent Bill which potentially could starve millions, poor or middle income earners, of the drugs they need to survive? Is the Government putting trade before its citizen's health?

It is accepted that as a result of the agreement reached under TRIPs the new Patents Act in India cannot avoid granting patents on pharmaceutical products which will result in killing the generic drug industry and its ability to offer the same medicine at a fraction of the price. Whilst this particular issue is insurmountable, there are a number of the draft provisions in the current Bill which do not take into consideration the few balancing provisions available within TRIPs so as to prevent a total disregard for its public. So what are the key issues which the current draft Bill fails to include.

Firstly, it proposes to extend the scope of patentability by allowing patent protection for the new use of known drugs, otherwise known as "evergreening". Therefore, if a particular patented product used for treating disease X is also found to be useful for treating disease Y, then a patent can be granted for its new use. This will enable pharmaceutical companies to extend for a further 20 years the monopoly over the initial patent for the product relating to disease X once it is close to expiration. As a result, this type of provision blocks the commercialisation of such products and will never fall into the public domain where they can be copied and sold at more affordable prices. TRIPs does not require its Member States to extend the scope of protection for existing patents. However, by including such a provision in the draft Bill, the Government is increasing the powers of the pharmaceutical giants to control the drugs market.

Secondly, the Bill fails to provide a provision, as allowed under TRIPs, which enables any organisation or member of the public to oppose a patent application which should not be considered patentable for lack of invention or newness. Such a provision is key in order to put a check on the evergreening of existing patents, in particular where it relates to medicines, as well as other trivial applications. Moreover, considering the lack of resources of the Indian Patent Office to examine thoroughly applications under new patent laws, an opposition procedure to protect public interest is imperative. As a result this is likely to result in several invalid patents being granted without challenge and any attempt to invalidate such patents during an infringement action will prove costly and burdensome as the burden of proof would lie with the infringer as opposed to the owner of the patent as was the case previously. It is somewhat surprising to see the Government avoiding the inclusion of such a provision when countries like Australia, Brazil, Canada, China, France and the UK all offer an opposition process.

Last but not of least importance, the draft compulsory licence provision is loaded with cumbersome procedural formalities and is unlikely to serve as a way of curbing the patent monopolies. TRIPs sets out a none exhaustive list which allows for Member States to seek a compulsory licence from the patent holder where there is, for example, a national emergency or other circumstances of extreme urgency and the need to reproduce a patented product. This is often the case with life saving drugs such as antiretrovirals for HIV/Aids treatment. However, the proposed amendment fails to take advantage of the ability to offer compulsory licenses where the patent holder fails to respond or refuses to deal with the request in a stipulated time. Argentina, Brazil and China have all included such a provision in their patent laws. Furthermore, the Bill fails to incorporate entirely the decision of the TRIPs General Council passed on 30 August 2004 allowing the grant of compulsory licenses for export purposes to countries with no or insufficient manufacturing capacity in the pharmaceutical sector. This could have severe effect on countries which depend on India's ability to generic life saving drugs.

The social issues surrounding the Patent Amendment Bill are far reaching but the Government appears reluctant to debate or disclose its intentions and, as the clock ticks nearer 1 January 2005, it will be feeling the pressure from the pharmaceutical cartel and the WTO to push the Bill through as it is. The Government needs to realise that implementing TRIPs does not require a TRIPs plus regime and the saving provisions it contains can save lives. This Government is elected to serve and protect its citizens, but it seems it is bowing to the power of the pharmaceutical drug lords.

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