

Patents at the Cost of Patients

Patents at the Cost of Patients A random survey of what people traveling abroad from India carry with them will often reveal a strange assortment which include pressure cookers, masalas and medicines. In a strange way India is till one of the nicest places to fall sick in, at least the medicines are still relatively affordable. But that situation may change if the Patent (3rd Amendment) Bill is passed in its current form. In the wave of media splashes that has dominated India (from the Shankacharya to Tendulkar's form and the battle of the Ambanis), we have ignored a quieter storm that has been brewing and will take us by surprise unless we act decisively.

It is indeed a curious anomaly that issues which have the greatest impact on public interest are often the least debated, while issues which invoke passionate debate seldom have any significant public impact. One possible reason for the lack of any serious debate on the patent amendment bill may be the general feeling that patent law is an esoteric techno legal field which is best left to the experts, the committees and policy makers. The bill is however far too important to be left to the experts, and it is vital that there be a larger public debate on the flaws of the bill and its impacts.

The bill seeks to amend The Patent Act, 1970 as a part of India's obligations under the TRIPS agreement, but a closer reading of the bill reveals that it goes far beyond our required mandate under the TRIPS agreements and will have an adverse impact on our fundamental right to health and will endanger the ability to access essential medicines at an affordable price. A number of analysts have even characterized the proposed amendments as a TRIPS Plus legislation, which takes on itself the task of adding more draconian measures than even those required by the TRIPS agreement. This is indeed curious given India's history of opposing the TRIPS agreement at the initial stages, and India's role as a spokesperson for many developing countries right through the history of the TRIPS negotiation, and India's advocacy of public health concerns which resulted in the Doha declaration.

The warning signs are there for all to see. It is estimated that there will be an increase of anywhere between 200 to 700 % in the price

of certain antibiotics. The Affordable Medicines treatment Campaign (AMTC) notes that the impact of monopoly on access to medicines is already being felt in India. The Controller of Patents has granted an Exclusive Marketing Right (EMR) to Novartis AG, for the drug called Gleevec used for the treatment of patients suffering from Chronic Myeloid Leukaemia (CML), a life threatening form of cancer. EMR is granted as a transitional arrangement before providing product patent protection. Gleevec is sold by Novartis AG at Rs. 1,20,000 per month.. The generic version of the drug was otherwise available to CML patients at Rs 9,000–12,000 per month. The EMR, if enforced will result in the withdrawal of generic version of Gleevec from the market. Consequently, the overwhelming majority of patients that suffer from CML every year in India will be denied access to this life saving drug. India still remains one of the cheapest countries in the world for medicines, and this has been the result of a rather well thought out policy. Without needing to make it into an assertion of nationalist pride, it is still remarkable to see the foresight of some of the policy makers who were able to enable the transition of India (from being one of the most expensive country for drugs in the fifties) to the present scenario where India has emerged as an important exporter of medicines to countries which do not have any production capacities.

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The bill which seeks to formalize product patents in pharmaceutical and agricultural inventions effectively reverses 35 years of India's drug policy and it is therefore imperative for us to locate the bill within a larger history of health infrastructure in India. At the time

of independence, India only controlled ten percent of its pharmaceutical market and its drug prices were among the most expensive in the world as a result of the patent monopolies that allowed large corporations absolute control over the market. The Government of India then appointed the Ayyangar Committee in 1957 to recommend reforms to India's patent law to tackle this problem.

The Ayyangar Committee found that 80–90 percent of the patents in India were held by multi national companies, and that more than 90 percent of these patents were not even being exploited in India. The Committee stated that the existing patent regime system was being exploited to achieve monopolistic control over the market in vital industries such as food, chemicals, and pharmaceuticals, resulting in medicines being unaffordable. The suggestions made by the Ayyangar Committee went on to form the basis for the Patents Act, 1970. India passed the Indian Patents Act of 1970 which attempted to assist in the development of the pharmaceutical industry by making new medicines at affordable prices and by making those medicines readily available to the public ensuring its national development at the expense of foreign corporations. The 1970 Act only allowed for 'process patents' for pharmaceutical patents but not the end product itself. This essentially meant that an Indian pharmaceutical company could find an innovative or new way to make an existing drug through the process of reverse engineering.

During this period Indian pharmaceutical companies were able to reproduce existing drugs rapidly and at a low cost, thereby making them competitive in both foreign and domestic markets. There has been a dramatic improvement in health infrastructure in India from 1947 till date and India is currently one of the cheapest countries for drugs. By 1991, Indian firms accounted for 70% of the bulk drugs and 80% of formulations produced in the country and in 1996 of the top ten firms by pharmaceutical sales, six are now Indian firms rather than the subsidiaries of foreign multinationals. Domestic firms now produce about 350 of the 500 bulk drugs consumed in the country. There are over 250 large pharmaceutical firms and about 9,000 registered small-scale units, and the Indian Drug Manufacturers' Association (IDMA) estimates that there another 7,000 unregistered small-scale units producing drugs. The generic drug industry has been vital in ensuring that drugs are

available at readily at an affordable price. For instance there are at least 50 firms offering the important drug Ciprofloxacin.

In recent times, the most striking success of Indian pharmaceutical companies has been their ability to provide access to HIV/AIDS drugs at an affordable price. Till 2000, antiretroviral (ARV) drugs were not accessible to the vast majority of people living with HIV/AIDS (PLHA) all over the world because of the high price. Multinational drug companies priced ARV drugs between US\$12–13,000 annually per person. From 2000 the prices started falling after manufacturers from India introduced generic versions of ARV drugs. These generic drugs are currently provided to patients for as low as US\$ 140 annually per person. This was possible because of the absence of a product patent regime in India.

Further, the absence of product patent protection has also facilitated the introduction of fixed dose combination (FDC) of ARV drugs. A three-in-one cocktail pill introduced by the generic manufacturers substituted two pills for six pills per day. Thus the FDCs increased the accessibility as well as availability of ARV drugs. The introduction of FDCs became possible only because of the absence of product patent protection in India. The introduction of a product patent regime will prevent generic companies in India from manufacturing these FDC's.

While it is true that as a signatory to the TRIPS agreement, there is little that can be done at this stage in terms of preventing the introduction of product patent in pharmaceuticals in India, it is however vital that we ensure that we do not amend the Patent Act in a manner that will compromise on the fundamental right to health or endanger the right to access medicines at an affordable price. The national Working Group on Patents has stated that there may be a full review of the TRIPS process that is required given the seriousness of the crisis.

In its current form, the proposed amendment will result in a sharp increase in the price of life saving drugs, especially those required by people suffering from HIV/ AIDS, and it also threatens the ability of a large number of generic drug manufacturers to produce and export low cost drugs. Even the savings provisions of the Patent Act such as 'compulsory licensing' (which allows the over riding of patents in public interest) are rendered cumbersome, and finally the

amendments to the Act makes it impossible for people to challenge the validity of certain patent claims at the stage of the grant of the patent. So what exactly do the amendment seek to do and why do we have to be concerned about them? Firstly, the Bill proposes to extend the scope of patentability beyond the TRIPS requirements by amending Section 3 (d) to allow patent protection for the new use of known drugs. Thus for instance if a drug X is used currently for asthma, and at a later stage it is found that it can also be used for fighting cancer, then a patent can be granted for its new use. This will enable pharmaceutical companies to extend the monopoly over the drug even after the expiry of original patent. There is no obligation under TRIPS to provide patent protection to new use of known drugs. • In 1994, researchers at Children's Hospital in Boston discovered that thalidomide had anti-angiogenic properties that made it a candidate in oncology, and also began to explain its dramatic effects in limb development in the human foetus. • Celgene acquired the rights to Children's Hospital's thalidomide MOU patent in 1998. Celgene recorded 2002 sales of US \$119 million for Thalomid, 92% of which came from off-label use of the drug in treating cancer, primarily multiple myeloma.

While a large number of pharmaceutical companies justify the grant of patent monopolies on the basis of the large investments required to sustain research for the production of new drugs, the fact remains that a large part of the research that takes place is at the level of finding new uses for old drugs, and we need to take with more than a pinch of salt, the tall claims made by the pharma industry about R & D costs.

Secondly, the Bill proposes to do away with the pre-grant opposition procedure. Under the current patent regime, there is a provision that allows for people to make an opposition against a patent application. This is a critical provision that can be used to oppose patents on the grounds that they are not new inventions or patents that do not meet the requirements of patentability or are against public interest. Currently, there are approximately 6,000 applications pending in the mailbox, which were filed after 1995. In the absence of pre-grant opposition, these 6,000 applications will escape much needed public scrutiny. Public scrutiny is crucial to ensure that patents are not granted to drugs that do not meet the requirements of the eligibility of patentability.

Thirdly, the Indian pharmaceutical companies rely on the ability to export generic drugs to countries without a manufacturing capacity. This is directly linked to the ability to grant a compulsory license after which manufacturing can take place, The track record of the US is abysmal on the question of compulsory licensing revealing a hypocritical double standard. The US industry has been opposed to the idea of compulsory licenses for countries like India and Brazil which have the manufacturing capacity to meet the demands at a low cost, while they have themselves not hesitated to declare compulsory licenses for 'national emergencies' such as the Anthrax scare after 9/11. If the anthrax fear was a national emergency then most developing countries are in a perpetual state of emergency with HIV and other life threatening diseases. The Amendment Bill proposes to permit compulsory licensing for export purpose if there is a compulsory license in the importing country having no or insufficient manufacturing capacity in the pharmaceutical sector. This ignores the fact that Least Developing Countries (LDCs) need not provide product patent till 2016. In the absence of patent protection, issuance of compulsory license is impossible. In that event, the Indian drug companies would not be able to export to Least developed countries.

Lastly, the Bill fails to revamp the compulsory licensing mechanism. Even though the Chapter on compulsory licenses in the Patents Act 1970 states the need for protecting the public interest, the same spirit is not reflected in the substantial provisions. Cumbersome procedures without any time line for the final disposal of application makes the compulsory license mechanism an impractical option to curb abuse of patent monopoly.

India is obliged to meet the deadline of making its Patent laws completely compliant with the TRIPS agreement by 1st January 2005. However the deadline cannot be used as a blackmail against the raising of critical public interest questions, and the worst case scenario for India if we default on the deadline is that we will be brought up before the WTO for non compliance. For a country which is used to cantankerous litigation, this is certainly not as scary as it initially looks, and we could do a lot better to ensure that we do not take any action that will be detrimental to the interest of a large section of people vis a vis health, even if it means angering the United States and the pharmaceutical monopolies.

It is also perhaps time for us to ask ourselves why the amendment has not been taken as seriously by the general public as it ought to have been. The simple answer of course would be the fact that there is not enough information or knowledge on the technical questions of the proposed amendment. There is of course an element of truth in this assertion (even the text of the proposed amendment is not available online), but beyond the question of information may lie a deeper problem.

The issue of product patents and its impact on drug prices has been seen as an issue which only affects those who suffer from HIV AIDS, and for most middle class Indians, this is seen to be a problem that does affect them and is a problem that only 'others' face. The externalizing of the issue in this manner, apart from revealing the vulnerability that many HIV AIDS patients find themselves in, also skews the debate. The fact is that while people who suffer from HIV AIDS are those who will be most directly affected by the amendment, the larger issue is the coming into place of a regime of product patents which signals a radical shift in the ability of pharmaceutical companies to reverse engineer drugs and make them available at lower prices. This is a much larger issue that cuts across all diseases and will become as much of a problem for other ailments as it is for HIV AIDS.

Finally , there is a larger question that needs to be addressed, namely the relationship between intellectual property, the proprietary knowledge system that it advances and the public interest. It is important to reiterate that intellectual property is an issue of extreme public interest in which we all have a stake, much beyond the narrow question of the profits of a few monopolistic companies, be it in software or in the pharmaceutical sector.

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