

HOW THE NEW PATENT LAW COULD DAMAGE YOUR HEALTH?

A critical view of the new Indian Patent (Amendment) Act 2005

The new Patent (Amendment) Bill 2005 passed on 23 March 2005 will inevitably change the face of how you are able to obtain life saving medicines and the price you pay for them.

Before this new Act, pharmaceutical drug manufacturers in India were allowed to produce their own versions of any medicine, without being able to claim ownership or a monopoly through a patent on the medicine. This has meant that prices of medicines in India have been some of the lowest in the world.

The new law will now allow any pharmaceutical drug company to patent life saving medicines in India. However, many of the life saving medicines, including new medicines being researched and approved, are owned in other countries by pharmaceutical MNC's such as Glaxo Smith Kline, Pfizer, Bayer, Eli Lilly and Novartis. Under the new Law these companies will now apply for patents in India on these medicines and new ones and have total ownership and monopoly rights in them. Already the indications are that of the 8,926 new patent applications which are waiting in a box to be processed and examined by the Patent Offices in India, many are in these companies names. As a result, it will be these companies, once they are granted patents for medicines, which will dominate and be able to control the price and availability of the medicines you need.

Statements from the Government and those in other political parties that the new Law will prevent further monopolies on existing patented medicines which are found to have new purposes for other illnesses, are inaccurate. Also inaccurate are claims that the new law includes procedures and measures which will allow the public to get quick, easy and cheap access to medicines which will be under patent. So how has the new Law failed to protect your right to medicine in a way you can afford and obtain easily? The following are the important points in the new Law which the Government could have changed, but instead chose to ignore:

Quick easy and cheap access to medicines when needed

To prevent the owners of medicines under patent from abusing their monopoly position, patent law allows other drug manufacturer/persons to ask the owner of a patent on a medicine to grant him/her permission to produce that particular medicine. In return, the person requesting permission to make the medicine must pay the owner of the medicine under patent what is known as a 'royalty', which usually is not more than say 4-5% of total sales that will be made from the person requesting to make the medicine. This system is known as 'compulsory licensing' and is supposed to be used in times when production of the medicine by the owner does not meet demand or is too highly priced.

Under the Law passed by the Government, other drug manufacturers/persons can only request the permission of the owner of the medicine **after 3 years** from the date that the owner is granted a patent. In addition, the person making the request has to go through many processes and wait a **further 6 months** after the three years before the request will be dealt with by the Patent Office, which handles these matters. Added to that, owners of patents on medicines request very high royalties before giving permission to make their medicines which causes further delay and often fight in courts. For example, in South Africa, Glaxo Smith Kline demanded that the company asking permission to make a much needed HIV/Aids drug, pay a royalty of 25%.

The Government did not have to include the 3 year rule, therefore, allowing for requests to be made immediately. In addition, the new Law could have made the process to request permission much simpler and quicker. What this means is if there is a need for life saving medicines which the owner of a medicine will not provide or provide at too high a price, you

will have to wait at least 3.5 years before anyone other manufacturer can request permission to make that medicine.

Ability to continue producing cheap versions of medicines under patent

The good news is that the new Law will allow manufacturers who have been making their own cheaper versions of medicines to continue to do so, but this is only for those medicines which have been waiting in a box at the Patent Office since 1995 ready to be patented, **but not** any new drugs which may be applied for after 1 January 2005. However, the manufacturers will have to show that they were producing and marketing their versions of the medicines which are in the box before 1 January 2005.

The problem with the new law is that it requires the manufacturers to pay a **'reasonable royalty'** to the owner of the patent of a medicine when it is granted, provided they have made a **'significant investment'** in making their versions of the medicines. These two requirements will cause problems for the manufacturers for two reasons:

1. The Government failed to include in the new law that a reasonable royalty will be between 4-5%. Instead, what will happen is that the owner of the medicine once it receives a patent will demand a high royalty figure such as 25% and, unless the manufacturer fights in court for a lower royalty, it will probably stop making the cheaper version of the medicine because any royalty more than 4-5% will increase the price of the cheaper medicine and not make it worthwhile to produce.
2. Deciding whether a manufacturer of cheap medicines has made a 'significant investment' will mean a lot of uncertainty and there is a possibility that only until the meaning of this is decided in court will it be clear. This means that current manufacturers of cheaper medicines may prefer to stop making the cheaper medicines rather than risk a law suit or pay excessive royalties.

New monopolies for existing medicines with new purposes

The new Law fails to prevent new monopolies being granted on existing patented medicines which are found to have new purposes for other illnesses.

The words which have been used in the new Law to describe those medicines that can be protected by patent and those which cannot are open to argument in the courts. For example, a minor enhancement to an existing medicine for heart disease could still mean a new patent being granted. Also under the new Law, where a new purpose is found for an existing medicine, ownership could be claimed under patent for such new use. What this means is that pharmaceutical companies could maintain ownership and control of medicines and, therefore, their prices, which otherwise should be allowed to be made by other manufacturers at a cheaper price.

The Government could have used wording which would not allow for existing ownership and continued monopolies on existing medicines to be extended. The failure to do so means that many existing medicines which may have a use for other illnesses may not be accessible at cheap prices for another 20 years at least.

The new Law will impact how you will access and pay for your medicines not only in the future, but starting now. Many of the manufacturers who are making cheaper versions of some key medicines such as for asthma, diabetes, heart diseases, HIV/AIDS, cholesterol, hypertension, bacterial or viral infections which you buy now are likely to stop because of the new Laws. Even if the manufacturers are able to continue to produce such medicines, the prices are likely to increase because they will have to pay the owners of such medicines to do so.