

## **THE PATENT SECOND AMENDMENT BILL**

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This session of Parliament is about to put in place one more WTO derived legislation. The Second Patent Amendment Bill has just cleared the Rajya Sabha and will almost certainly clear the Lok Sabha in the next few days. The other post –WTO legislation that India has already enacted are the Plant Variety Protection and Farmers' Rights Act, 2001 and the act on Geographical Indications, 1999. The latter is intended to provide protection for special products like Basmati rice and Darjeeling tea.

After the Uruguay GATT round, India had accepted certain conditions in the field of Intellectual Property Rights (IPR). These included a changed IPR system for drugs and agrochemicals, a *sui generis* form of protection for breeders of new varieties of seeds and patents on microorganisms. In the drugs and agrochemical sector, India has already enacted the Patent First Amendment Act, 2000 which was brought in to grant Exclusive Marketing Rights (EMR) to drugs which had received a patent in any WTO member country.

India, which so far affords process patents only, has committed itself to introducing product patents in the drug and agro-chemical sector but only by 2005. The current Patent Bill does not grant product patents. For the time being, the process patent regime will apply in India. Apart from the chemical sector, the current Patent Bill facing the Lok Sabha, has important provisions pertaining to genetic resources and Indigenous Knowledge.

The Patent Bill is by and large positive and succeeds in protecting many important aspects. For example discoveries will not be patentable under the Indian law. To qualify for a patent, invention will have to be demonstrated. The blurring of the distinction between discoveries and inventions in many legal systems, most notably the USA, has led to patents being granted on products of nature rather than inventions of the human mind. Plants and animals and species of plants and animals have been kept out of the purview of patents, so have plant varieties and seeds. New varieties of crops and their seeds are thus outside the patent system. Though the Indian law permits process patents, this will not apply to the crucial sector of food. Methods and processes of agriculture and horticulture cannot be patented nor can any other biological processes.

Special attention needs to be paid to the fact that the Patent Bill has come out against the patenting of cells, cell lines, cell organelles like mitochondria and genes. This is a very important and positive step and has to be seen in the context of the demand of the biotechnology industry to allow the patenting of cells and genes. The corporate sector has been putting a lot of pressure on countries to introduce cell and gene patents in their national legislation. The draft Indian law does not allow the patenting of plant or animal, and by inference, human genes.

The Life Science industry wants patents on genes that they use to make transgenic crop varieties and after the human genome project has identified the over 30,000 human genes, there has been a scramble to claim patents on them. The reason is the lucrative markets that open up

for the diagnosis and treatment of disease once the functions of genes have been identified. If gene patents were to be allowed, the great promise of gene therapy for inherited disorders would be transferred solely into the hands of large corporations. At the ethical level, patenting human genes would mean granting a monopoly to the patent holder, on a common human heritage. Several groups and governments have seriously opposed this move. The Indian Bill has taken a correct stand and done well to disallow gene patents.

In addition to cells and genes, the Patent Bill also blocks the patenting of parts of cells like mitochondria, which are emerging as important research tools in genetic engineering and the transfer of genes. Mitochondria are little bodies inside cells which also contain genetic material. The kind of patents that were granted on the cell lines derived from the tumours of patients who had been operated in hospitals in the US, will not be possible under the Indian law. The provisions of the draft Act aim to keep important biological materials in the public domain so that all scientists and researchers can access them. This will enable research to serve public goals, rather than merely create products that can be accessed only by the rich.

Another strong feature of the Patent Bill is the protection it grants to Indigenous (traditional) Knowledge and to products derived from it. The Indian Systems of Medicine use medicines and treatments developed over generations by local communities. Plant based products have become greatly sought after in this herbal era when the global sale of herbal products is slated to touch 5 trillion dollars by the year 2020. Rampant biopiracy resulting in the patenting of turmeric and Neem based products and countless other products based on the indigenous knowledge of communities across the world is cause for great concern to the developing countries whose knowledge is being pirated.

The present Indian Bill addresses this problem in the domestic context. Specifically, it says that any invention which is traditional knowledge or derives from traditional knowledge, or duplicates such knowledge, or joins up pieces of such knowledge, cannot be patented. This clause would prevent patents of the kind taken by Bloomberg in the US, on *Phyllanthus amara* commonly called *Bhoomi Amla*. According to indigenous knowledge, *Bhoomi Amla* cures liver disorders and it is used for treating everything from jaundice to sluggish livers. Bloomberg's US patent is for a product based on *Phyllanthus amara* that cures hepatitis B and C. This kind of clear derivation and duplication of traditional knowledge presented as an invention would not be accepted under the new Indian law.

The first step for protecting indigenous knowledge and the healing properties of medicinal plants was already taken in the first Patent Amendment Act which granted EMRs. According to that Act, exclusive rights cannot be claimed on drugs belonging to the Indian Systems of Medicine. This protection for the knowledge of communities is a positive step and is similar to the protection offered by the legislation of other Asian nations like Thailand and the Philippines.

The most negative feature of the pending patent law, from the point of view of biological/genetic resources is the provision that will allow micro organisms like bacteria, virus, and fungus etc. to be patented. This breaks down the moral barrier that has so far existed against the patenting of life forms. We will have to be careful that this precedence does not open the doors

to the patenting of other, higher life forms like plants and animals eventually. Civil society needs to be vigilant and the campaign against patents on life must continue with vigour. However to mitigate the damage, Gene Campaign has submitted a list of definitions to be used for the purpose of the Act of what can be called a micro organism and what cannot, as also what can and what cannot constitute an invention, plus special exemptions for sensitive sectors like the environment, defence and food. We hope to have these qualifications included at the rule making stage so that the scope and impact of microorganism patents is restricted to the maximum extent.

The patent Bill makes distinct concessions to the biotechnology sector . Process patents will be allowed on microbiological, biochemical and biotechnological processes. In this way, methods of genetic engineering, processes in the pharmaceutical industry using microorganisms and related processes will be patentable. There is a curious detail in this section on what constitutes a patentable process which reflects the special adjustments made for the biotechnology sector. Processes and methods for making plants resistant to disease and for increasing their value or the value of their products, will be patentable. This appears to be tailor made for the Bt cotton situation and other Bt and Bt like approaches to introduce resistance to disease.

One thing is becoming evident from the new post- WTO legislation that is coming in. There is a greater understanding among policy makers of the central importance of genetic resources and the crucial need to have control over them to ensure the food and livelihood security of the Indian people. Civil society campaigns for strong Farmers Rights over seeds have borne fruit and now we have a block on cell and gene patents and protection of Indigenous Knowledge. This kind of attitude will help to at least undo the worst of the damage inflicted by the unthinking or compromised positions that India took in the Uruguay GATT Round.