

CHANGING THE PATENT ACT: CAUTION NEEDED

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The Indian Patent Act, 1970, was considered an empowering act which enabled domestic interests to flourish. Product patents could not be granted in the food and drug sector and agriculture was protected from monopolies during a critical phase of growth. After the concessions India granted in the Uruguay Round and the emergence of the WTO, IPR legislation in the country had to be changed. The Indian Patent Act of 1970 had to be amended and product patents introduced.

The Patent Act has been amended twice already. The pending third amendment is slated to introduce a product patent regime for all inventions in the fields of food, chemicals and pharmaceuticals. There is trepidation about what else the third amendment could bring. A recent USAID –DBT collaboration touched upon the existing patent law. There is talk that genes could be brought under the patent law; a controversial and disputed clause called ‘data exclusivity’ which is suddenly being discussed in every meeting; and the agreement that only ‘inventions’ would be patentable is being threatened by making discoveries also patentable. All these are undesirable developments.

Let us take the new discussion on ‘data exclusivity’. This has sneaked into the debate recently, after the product patent regime became imminent. Data exclusivity refers to steps taken by some governments, chiefly the US, (through bilateral and regional agreements) to block competition from generic drug producers. ‘Data Exclusivity’ refers to test data that a pharma company submits to the country’s regulatory authority to get market approval. The practice in almost all countries has been for authorities to use this data when judging later applications by generic producers. This saves costs and allows generic drugs to be priced low. Asking for data exclusivity is anti-competitive since it impacts producers of generic medicines and it will affect drug price and access to medicines.

The US and big pharma want data exclusivity clauses to deny this data to generic drug producers so that they cannot compete. The sufferers in countries like India will be poor consumers who will find it even more difficult to access expensive drugs controlled by pharma multinationals. In India, the big pharmaceutical and the agrochemical industry like Monsanto, Syngenta, Bayer Crop Science, are pushing the government to include data exclusivity whereas most Indian drug companies are opposing it.

Data exclusivity protects investment, not innovation, which the product patent does fully. The government of India is obliged to grant protection to invented products. It is not obliged to secure the investments made by pharma companies. Most importantly, data exclusivity is not a TRIPS obligation. That is why the US is pushing it through bilateral and regional agreements. WTO members do not have to grant data exclusivity under Article 39.3, the only article touching upon test data. TRIPS refers to a need for data protection but does not suggest any way of protecting it. It certainly does not suggest any ‘exclusive rights’. The government has no reason to enter into TRIPS plus commitments.

With respect to microorganisms, the other major area of contention, Indian policy so far has been that no patents would be granted on microorganisms found in nature, only on genetically engineered ones. Apparently there is talk of reversing this and making natural microorganisms (bacteria, virus etc.) patentable. This would be not just against our interests but also in violation of the very essence of patent law, which is to reward inventions, not discoveries. If all discoveries could be monopolised by patents, the public would be cheated

of beneficial inventions and patent holders could make a lot of money recycling existing products in new garb. Microorganisms have direct economic value in key sectors like agriculture (biofertilisers, biopesticides) and pharmaceuticals (bacteria and virus producing antibiotics, vaccines) and we should proceed with caution, honouring our international commitments but not succumbing to either pressure or blandishments.

The suggestions to include cells and plasmids, genes and DNA as patentable subject matter in the new law, should be put down decisively. Because of the stake in biotechnology and genetic engineering there is great pressure from the multinationals backed by US government agencies in this regard.

The third patent amendment should not permit the broad overarching patents with a very wide coverage, as corporations try to claim. Where patents are granted, they should be restricted to the specific function that constitutes the particular invention, so that the microorganism patented for one particular product remains free for research and for others to produce other inventions. In keeping with our efforts in the TRIPS Council, to link WTO with the Convention on Biological Diversity (CBD) at least with respect to patents on bioresources, the Indian law must insist that patent applications must follow the protocol of the CBD, executing prior informed consent and material transfer agreements, as well as sharing the profits made on commercialisation of Indian microorganisms.