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CORRESPONDENCE

Patenting biotechnologies

The National Institutes of Health (NIH), Bethesda, is seldom away from controversies where patents are involved. Perhaps, as a major sponsor of biological research, it stands to gain more than any other corporate body in the USA. Bernadine Healey, the former Director of NIH, first pushed for patenting of random human gene stretches. These were dropped in a hurry when the scientific community protested. Even Medical Research Council of UK after beginning like NIH soon backtracked. Last month, however, NIH volunteered back into the hotseat. And this time, it is for patenting the basic technique of *ex vivo* gene therapy! The application made in 1989 had initially sought protection for all techniques of gene therapy, both *in vivo* and *ex vivo*. The claims were watered down by the US patent office and now the patent covers only those *ex vivo* manipulations in which malfunctioning human cells are genetically altered to produce therapeutic levels of protein outside the body and then replaced. Fortunately, this patent does not cover 'alternative techniques' and is restricted to the United States. Even then, the cover is big enough to alarm researchers Normally, this would not hamper research. Yet anyone wanting to, commercialize any form of gene therapy may have to get a sublicence to do so. With many players in the game, it does not appear likely that the patent will go unchallenged There has been of late some interest in gene therapy in India, and the US experience is a pointer for Indian professionals engaged in biotechnology.

What we Indians should especially take note of is the receptivity of the US patent office to changing technological and commercial scenario. The move by the US PTO underlines its realization that gene therapy is likely to succeed as a viable therapeutic technology in the coming years. The departure from its previous stance of insisting on extensive proof of the utility of the invention before granting a patent only strengthens this observation.

The Indian patent system, in comparison, has twisted itself into knots making compromises. Notwithstanding the failure of the bill in the Rajya Sabha and its dubious fate, the Ordinance does not have any teeth for biotechnology inventions. The current stance of the Patent Office to turn down anything genetic or involving DNA ('Agracetus syndrome') will do more harm than good to Indian science. There are several patentable inventions in the country's many laboratories that are not being patented abroad because of financial constraints, nor can they be patented in India because of the stance of the Indian patent office.

What laws apply to biotechnology patents in India? The Indian Patents Act of 1970 states that novelty, utility and a manner of manufacturing are the prerequisites to patenting. When a tangible substance or product results, the process can be patented [see 2(1)(J)]. Unfortunately, the Patent Office does not recognize methods of diagnosis, recombinant organisms, etc., as a substance or a tangible end-product. Read together with section 3(i), which states that 'any process for medicinal, surgical, curative, prophylactic or other treatment of human beings or any process for a similar treatment of animals or plants to render them free of disease or to increase their economic value or that of their products', the scope of obtaining a patent on biotechnological inventions in India is highly restricted. A crucial issue we have not addressed so far is defining microbial organisms in the legal context. Patents on recombinant organisms, elsewhere, are adjudged by the amount of human ingenuity involved and this calls for a legally defined reference point. Unlike other advanced countries, we have not made any distinctions between microbes and higher forms of life. Consequently, microbes are treated at par with animals and plants, and any method of modifying them contravenes the directives implicit in section 3(i) and therefore is not patentable. DNA probes, cloned and genetically engineered organisms are thus not patentable in India Any biotechnological process done *in vivo* (even in a microorganism) does not lead to a new 'substance' while also enhancing its economic value, thereby rendering the invention nonpatentable under the 1970 Act! For food and drugs, effective protection will still be 5 years, a disincentive when one realizes that drug development may take at least as long, if not more.

There is no concordance amongst the various patent offices of the country in their interpretation of inventions pertaining to biotechnology. There are instances where applications disallowed by one office have been admitted in another. To compound to that, it is understood that an internal communique from the Controller General forbidding patent protection for certain biotechnological inventions, assigning no grounds for such a stand, has befuddled patent attorneys. This obviously has no legal sanction under the Act, yet it is another potential obstacle for the patent seeker, who then has to resort to legal recourse.

Filing applications under the World Trade Organization (WTO) has been seen as an alternative. Product patent can no doubt be sought under the WTO, yet biotechnological issues are, in effect, sidestepped. The ordinance does away with Section 39*, which made it mandatory for an Indian inventor to first seek an Indian patent before applying anywhere in the world! Under the new regime, an identical application must first be accepted in a convention country after 1 January 1995 against which the inventor can seek exclusive marketing rights in India. If the invention was made in India, and a process patent for producing that particular 'substance' had been granted, with the approval of the Controller, the inventor can enjoy exclusive marketing rights for five years or till a patent is granted or the application rejected. In all other cases, the Controller would not be calling for a patent examiner's report till 31 December 2004. Thus, even filing under the WTO in India means a long cold storage, a not too satisfactory proposition when one knows the short life-span of biotechnology products. Though product patents can be obtained for drugs, medicines and agrochemicals, the amendment does not affect the existing restrictions on the grant of patent protection in respect of *substances produced by chemical reaction*, alloys, optical glass, semiconductors and intermetallic compounds.

Indian inventors seeking patents abroad are very often stymied by the substantive examination of the US PTO. In determining prior art, the US PTO scans the available literature, which is apparently disjointed with no obvious interconnections, and then mosaics them, to state that from the emerging cited literature the idea is a logical extension and, therefore, obvious. The other stumbling block is the protection of patents and their 'alternatives'. Any substance substantively made by a similar process having substantively similar properties and giving substantively similar results is deemed as an 'alternative'. The cost of clarifying and/or modifying claims in response to the examiner's report is also too costly to discourage further action.

There are several Indian laboratories doing good work with genetic probes. Since patenting gene sequences is not allowed and any diagnostic process is deemed unpatentable, many Indian researchers are losing out in the international race.

The new use of a known drug has again become patentable in the US. With the expertise available in the West to isolate, characterize and synthesize plant alkaloids and other natural products with therapeutic properties faster, there is a potential threat that soon our wisdom of traditional medicine will be rendered impotent.

So what corrective measures do we take? Primarily, the ambiguity of the new Act must be resolved. Scientists and legislators should come together to propose distinctions between microbial entities and higher life forms on a legal perspective. The cost of patenting abroad is discouragingly exorbitant. Having gone for patent harmonization, would it not be logical to offer Indian scientists a levelled playing field to commercialize their inventions? Can we not make it possible for them to patent their inventions in India speedily so as to obtain a priority date to beat their competitors? It is not enough that we impel our scientists to patent. It remains with our planners to make the patenting environment conducive. We tend to make our laws not by anticipating trends but by following footsteps, even when they do not lead in our direction. It is time that our law makers took cognizance of Indian research capabilities in the biotechnology, pharmaceuticals and agrochemical sectors and legislate to favour them in the troubled years of international competition. We have been for far too long, as a nation, walking forward with our eyes over our shoulders!

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*Section 39 is back, with the lapse of the Presidential Ordinance

Why not platinum?

This note is intended to draw the attention of geoscientists to the need of looking at the platinum content of continental sulphide deposits.

The discovery of attractive quantities of gold and silver in oceanic sulphide deposits prompted a renewed interest in the continental sulphide deposits. Several important and interesting papers on this aspect were presented during the Annual General Meeting of the Geological Society of India in December 1994. Surprisingly, none dealt with the platinum content. In fact, one of the first publications on ocean floor massive sulphide deposits by Hekinian *et al.*[1] did report on the platinum content of the East Pacific Rise (21°N) deposits Electron microprobe analysis revealed that platinum is present as a dispersed constituent in most sulphide phases that contain gold and silver. Its concentration ranges between 0.1 and 1.4% by weight. Further details of platinum in different sulphide phases can be found in Hekinian *et al.*[1].

Studies of oceanic sulphide deposits have been important in providing insights into the genesis of continental sulphide deposits which themselves formed in an oceanic setting once upon a time. So, when oceanic sulphides contain attractive quantities of platinum, why not look at the platinum content of continental sulphides, in addition to gold and silver?

If good amounts of platinum are indeed present in land deposits, it can change the scenario tremendously. One may also wish to have a fresh look at the platinum content of tailings from different sulphide deposits in the country.

1. Hekinian, R., Fevrier, M., Bischoff, J L., Picot, P. and Shanks, W. C., *Science*, 1980, **207**, 1433–1444

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