



Challenges to the patenting of “essentially biological processes” in India

A recent decision from the IPAB on the patent eligibility of biological processes could change the biotech playing field in India, say Swarup Kumar and Shivaarti Bajaj.

Commenting on the US Supreme Court’s historic decision *Diamond v Chakrabarty*, 447 US 303 (1980), which permitted the patenting of life forms, Justice Warren Burger said: “No one will be able to deter the scientific mind from probing into the unknown any more than Canute could command the tides”. Probing into the unknown and the possibility of patenting one’s invention is what has catalysed scientific advancement in all fields of technology.

Nonetheless, the grant of patents in one of the most demanding fields—for life forms, biological materials and biological processes—continues to cause apprehension in view of the associated ethical, moral and political sensitivities.

Oncomouse case

The primary ground for opposing the patenting of life forms and essentially biological processes has been the position that ownership of or right over life forms and naturally occurring biological processes would be detrimental to society and may influence public morality and/or order. The *Oncomouse* case related to a transgenic mouse

made by researchers at Harvard University to develop cancer in order to aid the testing of drugs for cancer treatment. Patents were granted on different facets of the invention in Europe, Canada and the US among other jurisdictions, as each jurisdiction had its own law and practice.

For instance, the European Patent Office dealt with the issue of morality through a utilitarian balancing test that reviewed potential benefits of the invention—the treatment of cancer and medical research—against its negative aspects. On the other hand, in Canada, the patent office initially rejected the patent claims for *Oncomouse* as such but eventually allowed claims directed to the process for obtaining the *Oncomouse*: the “biological process”.

If one looks at international treaties to find uniform benchmarks in this area, there is much room for divergence. Illustratively, the Trade-Related Aspects of Intellectual Property Rights (TRIPS) Agreement allows member countries to exclude certain subject matter from patentability under Article 27.3. Such excluded subject matter covers “essentially biological processes”. However, in order to define the threshold of patentability, TRIPS

does provide leverage for member countries to define expressions such as “essentially biological processes” or set specific criteria for their patentability.

The Indian scenario

In India, the Patents (Amendment) Act 2002 introduced Section 3(j) which prohibits patenting of “plants and animals in whole or any part thereof other than microorganisms but including seeds, varieties and species and essentially biological processes for production and propagation of plants and animals.” The expression “essentially biological process” has not been specifically defined either in the statute or through judicial decisions or the manual of the patent office. On the other hand, it would appear that the US and the EU have taken steps towards defining in the statute or through judicial pronouncements the broad criteria for what constitute “essentially biological processes”.

In 2002, the path-breaking *Dimminaco* case (*Dimminaco v Controller of Patents and Designs & Others*) came before the Calcutta High Court and opened the doors to the grant of patents to inventions where the final

product of the claimed process contained living microorganisms. The matter related to a process for the preparation of a live attenuated vaccine for protecting poultry against bursitis infection. According to the Controller of Patents, the claimed process was only a natural process devoid of any manufacturing activity and the end product contained live attenuated material. Thus, the claims were considered unpatentable.

Hearing the appeal, the Calcutta High Court broke new ground with its observation that “if the end product is a commercial and vendible entity, and for that, presence of living virus / microorganism in the end product is necessary, it cannot be a bar to its patentability.”

The Indian Patent Office issued biotechnology guidelines in March 2013, but with no reference as to what constitutes “essentially biological processes”. In fact, the guidelines list several illustrative examples in relation to Section 3 (j) of the Patents Act. One of them states that a claimed method involving the step of cross-breeding for producing pure hybrid seeds, plants and crops would be an essentially biological process and thus not allowable under Section 3(j). But what this example fails to clarify is that if there are intermittent steps in the claimed method, which involve substantial human intervention, whether or not they would render the claimed method patentable.

In contrast, if one looks to the European Patent Convention, essentially biological processes as provided by Article 53(b) have been defined by Rule 23(b) (5) which states that “a process for the production of plants and animals is essentially biological, if it consists entirely of natural phenomena such as crossing or selection.” The expression “entirely” would appear to leave scope for interpretation open.

Monsanto case

The case of *Monsanto Technology v Controller General of Patents* (2013) brought this particular aspect into focus before the Indian Intellectual Property Appellate Board (IPAB) last July. Although the appeal filed by Monsanto against the patent office’s decision was eventually rejected by the IPAB, the patent office’s decision is extremely significant in that it interprets the expression “essentially biological processes”.

The Indian Patent Office had refused the grant of a patent to Monsanto for an invention described as “a method of producing a transgenic plant with increased heat tolerance,

salt tolerance, or drought tolerance” based on the following key grounds:

1. That the subject matter of claims was considered to lack inventive step in view of prior art documents cited in the office action;
2. That the claims in the application were not considered to qualify as an invention. The reason offered for rejection was that the structure and function of a cold shock protein was disclosed in the cited prior art, and was, therefore, obvious to a person skilled in the art to make a transgenic plant;
3. The claimed invention was considered unpatentable as it was regarded as a mere application of an already known cold shock protein in producing cold stress tolerant plants as well as plants tolerant to heat, salt and drought conditions; and
4. Last but not least, it was held that the claims in the Monsanto patent application fell under the proscription of Section 3(j) of the Patent Act. The primary reason offered for rejection under this ground was that the claims related to “essentially biological processes” of regeneration and selection, which in turn included growing of plants in specific stress conditions.

Dissatisfied by the controller’s decision, Monsanto filed an appeal before the IPAB. Considering the matter after hearing both parties, the board upheld the decision of the Indian Patent Office on the first three grounds listed above but, significantly, overruled the patent office’s findings on Section 3(j). The IPAB affirmed that the claimed method of the case being considered included an act of human intervention on a plant cell and produced in that plant cell some changes, which took it outside the proscription of Section 3(j).

Conclusion

Although Monsanto’s patent was rejected on almost all key grounds, the IPAB’s decision is a landmark one. The interpretation of Section 3(j) outlines a significantly forward-looking approach towards defining the elusive expression “essentially biological processes”. In this decision, a series of individual steps involving human intervention was considered sufficient to overrule the patent office’s finding that Monsanto’s claimed process was proscribed by Section 3(j) of the Patents Act. In the IPAB’s view, the method claimed did not involve a simple leap from prior art to the invention but entailed a journey with many generic method steps that were essentially biological which, taken in sequence, were not inventive. Therefore, the mere act of human

intervention was held not to change the position on patentability as the invention was otherwise found by the IPAB to be unpatentable in view of obviousness and new use of known substance.

Nevertheless, the fact that the human intervention factor—in the manner disclosed in the specification—was not only considered but also formed the basis of the IPAB’s decision marks a new chapter in the field of biotech process patents in India. The significance of this decision becomes more apparent when it is contrasted with the “broccoli and tomato” (G 2/07 and G 1/08) cases in which the European Board of Appeal held that a process for production of plants comprising the steps of crossing and selection is excluded from patentability even if it contains an additional step of a technical nature. Interestingly, the inclusion of an act of human intervention on a plant cell and production in that plant cell of some changes (technical) was considered enough to render process claims patentable in the *Monsanto* case.

In view of such a positive interpretation of Section 3(j) by the IPAB, jurists, biotechnologists and practitioners will have a crucial role to play in developing criteria as to what constitutes “essentially biological processes” and what does not. The good news is that subject matter that was once considered to fall beyond the realm of patentability is now beginning to be seen with a more nuanced eye and the stage looks set for interesting times ahead in biotech jurisprudence. ■

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