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ABSTRACT

The thesis deals with issues of patentability and patent-eligibility of biotechnology innovations in the pharmaceutical industry, focussing particularly on the Indian context. Patentability and patent-eligibility of pharma-bio innovations is dilemmatic because they employ or contain living and modified organisms or their genetic material. Herein we considered, apart from novelty, inventive step and industrial applicability, the requirement of specification also as a patentability parameter. In this background, patentability and patent-eligibility of Expressed Sequence Tags (ESTs), Isolated and Purified genes, Genome, Gene Therapy, Single Nucleotide Polymorphisms, Cloning, Genetic Testing tools and techniques, Xenotransplantation, Embryonic Stem Cells (ESCs), GMOs (Genetically Modified Organisms, wherein organisms include microbes, plants and animals), vaccines etc. has been analysed. Norms in U.S. patent law and European Patent Convention were looked into to evolve better norms and practices in the Indian patent system. It was found that all patent systems had a tough time evolving any fixed long-term parameters and the contours of patent eligibility keep shifting from time to time.

Another related problem analysed is of biopiracy which occurs when bio-resources and associated Traditional Medicinal Knowledge (TMK) from developing countries are accessed and used, without permissions, to create patent protected 'nature derived drug product'. Also, biopiracy can occur when TMK of one country is wrongly patented in another sans any change. We assessed how such malpractices can be curbed using patent laws particularly by use of databases like TKDL and by requiring 'disclosure of source country of genetic material' used in a bio-invention as part of patent specification. Another problem is of 'anti-commons in biomedical research'. It arises when many basic technologies are patented thereupon making follow-on innovation more expensive since downstream innovators will have to negotiate

licenses from those who control patents over basics. This has necessitated the evolution of several remedies each of which were considered and found to be partially inadequate. It was finally found that our hypothesis that 'Provisions of Indian Patent law are insufficient to deal with patentability and eligibility conundrums arising due to biotechnology innovations in the pharmaceutical industry' was proven. Therefore, to remove the lacunae, we recommended the following:

1. Indian Morality Board: Since patent-examiners alone are not, considering their scientific backgrounds, most suitable arbiters of morality, therefore, a Morality Board must exist to reduce subjective assessments by them and to prepare reviewable list of controversial innovations to be excluded under "public order or morality" clause.

2. Rule foiling Xenotransplantation monopolies: IPO must adopt policy of rejecting 'any procedure for creating or making xenotransplants or for enabling specifically xenotransplantation, or for altering/manufacturing animals therefor'.

3. ESCs and IPO's Practice: IPO must adopt European practice regarding ESCs by excluding patenting of anything requiring destruction of human embryos at whatever preceding stage, wherein an embryo is "any human ovum" as soon as it is fertilized or "a non-fertilized human ovum" which is rendered "capable of commencing the process of development of a human being" by whatever artificial process.

4. Genes Patents and IPO's Faulty Practices: Contrary to Indian law, certain 'isolated gene' patents have been granted. IPO examiners must be better trained to avoid such errors.

5. Genetic Research: IPO must consider ineligible any "isolated and purified gene" and also any "synthetic DNA" which mimics or is functionally identical to a natural DNA. Also cDNA must remain patent ineligible.

6. **Clarity on Genetic Testing**: Even '*in vitro*' procedures of genetic testing/diagnosis should be kept patent ineligible under s. 3(i) of Indian Patents Act.

7. International Criterion for 'Disclosure of Source' within Specification: Such an additional patentability criterion will help to minimize the problem of biopiracy.

8. Patent-Free Basics: For resolution of the 'anti-commons' problem, certain basic or foundational pharma-bio innovations must be kept unencumbered or patent-free.