

Legal Issues in 'Patents and Technology'

Issue: Can Complex Life Forms be Patented?

Introduction

- ❖ Human made micro-organism under the Patents Act, 1970
 - Section 2(1)(j) of the Patents Act defines “invention” means **a new product or process** involving an inventive step and capable of industrial application.

- ❖ Micro-organisms: “**Product of nature**”?

- ❖ Can a living, genetically-altered microorganism constitutes patentable subject matter?

- 2 ❖ The importance of “**Human Intervention**”.

Relevant Provisions of The Patents Act, 1970

- ❖ **Section 3 (b):** Inventions contrary to morality or which cause serious prejudice to human, animal or plant life or health or environment.

- ❖ **Section 3(c):** Scientific principles or abstract theory or discovery of living things or non-living substances.
 - **Example 1-** Bacillus sp. IN123 comprising rDNA (ribosomal DNA) sequence represented as SEQ ID NO: 1 (Deposition No. XXXXXXX).
 - **Example 2 -** A novel agent for promoting cardiac development activity, said agent having SEQ ID NO: 1, wherein the agent is obtained from the perivitelline fluid of horseshoe crab, Tachypleus gigas.
 - **Example 3 -** An isolated peptide that is structural equivalent of a cupredoxin or cytochrome that can inhibit parasitemia in malaria-infected red blood cells and intracellular replication of a malarial parasite in malaria-infected human red blood cells.

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Relevant Provisions of The Patents Act, 1970 (Contd.)

- ❖ **Section 3(d):** Discovery of new form of known substance which does not result in enhancement of Efficacy.
 - **Example 1-** Pre-protein A being one of the factors which primarily control glucose metabolism in mammals having C-peptide, wherein said C-peptide comprises two amino acids selected from XY, YZ and ZX.
 - **Example 2 -** A crystal of a peptide consisting of SEQ ID NO: A, wherein said crystal comprises an asymmetric unit, said asymmetric unit comprises four molecules of said peptide per Zn^{2+} and further wherein the crystal belongs to space group X, Y, Z.

- ❖ **Section 3(e):** Mere Admixture resulting only in aggregation of the properties or a method of making such mere admixture.

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Relevant Provisions of The Patents Act, 1970 (Contd.)

❖ **Section 3(h):** Method of Agriculture and Horticulture.

- **Example 1-** A method of growing leguminous plants as inter-cropping for improving fertility of soil by augmenting nitrogen content of the soil.

❖ **Section 3(i):** Method of Treatment.

- **Example 1-** A method of monitoring drug response in a patient suffering from cancer treated with a combination of Gemcitabine and P1446A, comprising detection of a gene signature with at least two drug response markers, wherein the said drug response markers are selected from the group consisting of P21, REV3L, FGF5, PTK7, POLH, P27 and SSTR2.

❖ **Section 3(j):** Plants and Animals in whole or any part, seeds, varieties, species other than microorganisms and essentially biological processes are not Patentable subject matter.

Relevant Provisions of The Patents Act, 1970 (Contd.)

- ❖ **Section 3(k):** Mathematical or business method or a computer programme per se or algorithms.
 - **Example 1** - A data processing method, wherein a first chemical substance is a compound; a second chemical substance is nucleic acid, protein or a complex thereof.
 - **Example 2** - A computer-assisted method of generating a compound that inhibits the glutamine formation active site activity of a glutamine synthetase polypeptide.

- ❖ **Section 3(p):** Traditional Knowledge Related Inventions.
 - **Example 1** - Serum of pigeon possessing the anti-paralysis activity.

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Relevant Decisions

❖ *Dimminaco AG v. Controller of Patents and Designs*, [(2002) I.P.L.R. 255 (Cal)].

- An invention relating to a process for preparation of infectious Bursitis Vaccine.
- Patent Specification- “ *From of Treatment with L. reuteri... In addition to use of a liquid suspension of L./ reuteri either freshly grown or as **lyophilized cells resuspended in a chosen liquid**, patients are given the same number of L. reuteri cells in a gelatin capsule, once a day*”. (Emphasis supplied)
- The meaning of the word “manufacture”.
- Does the process have to result either in an article or a substance?

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Relevant Decisions (Contd.)

❖ *Dimminaco AG v. Controller of Patents and Designs, (Contd.)*

- *“It is also admitted that there is no statutory bar to accept a manner of manufacture as a patentable even if the **end product contains a living organism**. It is of course, true whether a claim for grant of patent is an invention or not, has to be decided in the facts of each case. A new and use full art or process is an invention. In the instant case, the novel process claimed in the patent application in its original version and amended version is a new process for preparation of vaccine involving chemical steps under specific scientific conditions. **The said vaccine is useful for protecting poultry against contagious Bursitis infection. Therefore, it is a new process and such process is apparently patentable under section 5 read with section 2(I)(I) of P.A. Therefore, where the end product is a new article, the process leading to its manufacture is an invention.**” (Emphasis supplied)*

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Conclusion

- ❖ Patenting of **Higher life forms**.
 - Genetically engineered process
 - Genetically engineered higher form.

- ❖ Patentability of **Complex life forms**.
 - Against public order and morality?

- ❖ Patent on **Higher forms vs Lower forms**.

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THANK YOU!
Questions?

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