Meeting Enablement Requirement In Patent Applications Dealing With Biological Material – Indian Perspective

Introduction

A patent application has to meet various requirements of patentability for it to be granted. One such requirement of patentability is the enablement requirement. A patent application is said to be enabled if the application provides sufficient details that enables a person of ordinary skill in the related filed to practice the invention.

Patent applications dealing with biological inventions involving living organisms may face specific challenges in meeting the enablement requirement. In several instance, it may not feasible to fulfil the enablement requirement by simply disclosing the details about the invention in the specification of the patent application.

Such challenges may be caused because the description concerning living organisms especially microorganisms, how so ever elaborate it might be, would lack the reproducibility factor due to the typical characteristic features associated with such species. It is also difficult to analyze the properties of some species completely. As an example, the microorganism isolated from soil cannot be described in detail except some documentation about their properties which may be provided. In addition, it is not easy to ascertain if the isolated strain of the species belongs to the same ecological niche. Even in cases that involve changes in characteristics of species such as genetic mutation, it is difficult to replicate the experiments for obtaining exactly the same change in mutation features. Hence, the inventions involving the subject of biotechnology, biochemistry or microbiology are usually subjected to complete disclosure by depositing the relevant biological material at some authorized depositories.

Budapest Treaty and Indian Patent system

Indian Patent system offers a provision for submission of the biological deposit in order to complete the patent specification. The patent application related to bio-technology which does not fully disclose the invention due to reasons discussed earlier and hence need to fulfil the requirement of deposition, can be usually done within the scope of Budapest treaty. The Budapest Treaty is an international treaty administered by the World Intellectual Property Organization (WIPO) and was signed in Budapest, Hungary on April 28, 1977 with a total of 79 countries being a part of it by the year 2014. This treaty provided a platform for the deposition of biological material at a single international body rather than making the deposition in several countries where the patent applicant needs to file the application. India

became a member of the Budapest treaty in 1977. The provisions of the Budapest treaty could be found in the Patent Act 1970, Section 10(4)(d)(ii) as "*... if the applicant mentions a biological material in the specification which may not be described in such a way as to satisfy clauses (a) and (b), and if such material is not available to the public, the application shall be completed by depositing the material to an international depository authority under the Budapest Treaty...*"

The treaty does not define any limitation for the type of material to be included as the biological material and also does not restrict the biological material to 'micro-organism' but it does accept wide variety of materials including fungi, bacteria, plant spores, eukaryotic cell lines, genetically modified material or materials that can be used for expression of a gene, plant tissue cells, nucleic acids, etc. As per Section 3(j) of Patent Act 1970, "*Plants and animals in whole or any part thereof other than micro-organisms but including seeds, varieties and species and essentially biological processes for production or propagation of plants and animals are not inventions.*" The above mentioned section excludes the micro-organisms from being non-patentable subject matter. Hence, patentable inventions would undoubtedly encompass genetically modified micro-organisms.

Amendments in Indian Patent system with respect to Biological deposition

In 2002, a decision concerning *Dimminaco – A.G. Vs.Controller of Patents & Designs and Others*, the High Court held that the invention, related to a process of preparation of a vaccine for protecting poultry against Bursitis infection, is patentable wherein it emphasized that the way of manufacture of the said vaccine cannot be considered as unpatentable even though it involved living organism as end products. The argument set by the Controller was mainly concerning the fact that the claimed process involved a natural process and the end product involves a living organism. However, in this matter, the courts emphasized on the significance of 'vendibility test' rather than the criteria of 'manner of manufacture'. The vendibility test considers the factors that result in the invention giving rise to some 'vendible' product which can be commercialized or that can assist in enhancing the properties of the vendible product or would assist in the preservation or preventing deterioration of such products. The term 'vendible' was defined by the courts as something that can be passed on from one entity to another via purchase or sale.

Post-effects of the above mentioned case was observed in the year 2002 when amendments in the Patents Acts 1970 were introduced with regards to grant of patent such that biotechnological, biochemical and microbiological processes were included within the scope

of chemical processes. In addition, this newly introduced Patents Amendment Act 2002 modified the definition of the term 'invention' as any 'new product or process' that involves non-obviousness and industrial applicability, whereas the earlier definition mainly focussed on the 'manner of manufacture' as per the previous Act. Further, the enablement criteria were satisfied by means of deposition of biological samples at the International Depositories as per the Budapest Treaty.

Procedural regulations for biological deposition

For India as a member country, the Budapest treaty makes it obligatory for an applicant to deposit the biological material with an international depository authority (IDA) not later than the filing of the application in India. Owing to the fact that the deposit is the source of description for satisfying the enablement criteria, it is significant to make the deposit on or before filing in order to actually complete the specification. In any case, the depository authority will allow availability of the biological material to the public only after the publication of the patent application.

The International Depository Authority (IDA) in India is situated at Chandigarh, *viz*. Microbial Type Culture Collection and Gene Bank (MTCC) which was recognized as an IDA on October 04, 2002. Another IDA in India is the Microbial Culture Collection (MCC) located in Pune. These depositories keeps a database of its collections and transactions with maintenance of electronic record. The process of deposition requires submission of duly filled forms obtainable from the IDA depending on the type of species being submitted and the subsequent payment of the deposit fee for storage (as per rule 12.1 (a)(I) of the Regulations under Budapest Treaty). The form for deposition is termed as BP/1 whereas the one used for performing the amendment in the technical description is BP/7. In addition, there are some essential criteria regarding the purity of submitted samples and the submission mode or type of sampling involved. The IDA pursues the tasks of performing the viability tests, sub-culturing the material and also preservation of the original samples submitted by the inventor.

Once the deposit has been made, the applicant is provided with an accession number by IDA that relates to that particular deposit. The Indian patent office requires the applicant to provide reference to the deposit within three months of filing of the patent application. However there has been a discrepancy in following these regulations owing to which the Indian patent office, in a notification dated July 02, 2014, issued a forewarning to the

applicants with regards to the consequences of not depositing the sample related to their patent applications. The notification was released in view of many patent applicants who deposited their samples much after the filing date or who did not include a reference in the specification within three months of the filing date.

The other forms involved in the process include the acknowledgement of receipt of the submitted sample on BP/4 form and a viability statement issued on BP/9 form. There is also a provision for requesting IDA to send the copies of receipt and viability statement to the depositor and also the patent agent. In addition to the deposition task, the complete application also demands a mention of the source of origin of the biological sample. In case the application specifies the source of the biological material to be from India, then it is required that the applicant should submit a permission taken from National Biodiversity Authority at any time before the patent is issued. A complete specification also demands a clear mention of all the details related to the characteristics that would be required for the material to be correctly identified. These details include the name, address of the depository organization and the date and number associated with the material deposited at the institution.

In conclusion, the Indian Patent system offers the inventors with a convenient mode of depositing the biological samples for enabling completion of specification. In addition, the amendments in the Indian statutes widens the scope for better biological inventions.

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