There is a need for spreading awareness among the community and neighborhood regarding the child labour.

Law Colleges and other educational institutes should play a major role in creation of awareness and consequent eradication of many social evils like child labour. The Students of Law Colleges should actively be involved by forming groups to spread awareness among employer and employee and parents about the enactments passed by the Central and State Government and judgments passed by the Judiciary with regarding to protection of child labour and also explain the plan for reduction and rehabilitation of child labour in India.

PATENTABILITY OF MICRO-ORGANISMS – ISSUES, CHALLENGES AND LEGAL IMPLICATIONS

By

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In the contemporaneous world, it is deemed to be a matter of expediency, rather than calibrated choice, that human ingenuity, innovation and enterprise is rewarded. The premise of intellectual property law is that, recognizing and rewarding the innovator, fosters industrial and technical progress, paving way for a vibrant socio-economic structure.

Introduction:

A patent is an exclusive privilege in the form of a monopoly right, granted by State to the inventor or an assignee for a certain period of time in lieu of full disclosure of the invention. A patent is in the form of a negative right to exclude others from making, using, selling, offering for sale, or importing the patented invention for the term of the patent, which is usually 20 years from the filing date. Since it is a monopoly right, the grant of a patent must fulfil the three essential criteria of novelty, non-obviousness and usefulness. Every country in the world has same sort of conditions for granting patents.

In initial days of development of patent mechanisms there was an overburden of Ethical and Moral firewalls surrounding the idea of resting the right of commercial exploitation of certain substances and resources in the hands of a selected few. Patenting by many was opined as a capitalist centric idea[1].

With advancements in Pharmaceutical Industry and increasing stress on biotechnological research, pressure started mounting on policy makers to allow such patenting of basic life forms so as to encourage research and development [R&D] initiatives in the field which can contribute in exploring the unrecognized commercial utility of such life forms.

Definition and Meaning of Micro-Organisms:

A micro-organism or microbeis an organism that is unicellular or lives in a colony

1. Grubb W. Philips, 'Patents for Chemical Pharmaceuticals and Biotechnology Fundamentals of Global Law, Practice and Strategy' Oxford University Press, London, 2004. P.58.

of cellular organisms. First time the Micro-organisms was discovered by Anton Van Leeuwenhoek's in 1675, using a microscope of his own design[2].

Micro-organisms are very diverse, they include bacteria, fungi, archaea, and protists, microscopic plants (green algae); and animals such as plankton and the planarian. Some microbiologists also include viruses, but others consider these as non-living. Micro-organism freely available in the nature and they are not created by any individual action.

A general definition of a micro-organism is an organism that is microscopic (too small to be seen by the naked human eye) and which can be seen only under a microscope, usually, an ordinary light microscope. Micro-organisms are incredibly diverse and include bacteria, fungi, archaea and protists as well as some microscopic plants such as plankton and animals such as amoeba. Thus, it may consist of a single-cell or a cell-cluster.

In countries across the world the so called products of nature doctrine excluded living matter from patentability. The products of nature doctrine precluded patentability of materials existing in nature, including living matter. Under this doctrine, one could secure patents for fermentation processes and purified, naturally occurring chemical or biological compounds, as well as patents for micro-organisms as a culture or in combination with a carrier. The product claims for the micro-organisms, however, were not patentable because they comprised living material – micro-organisms.

Patenting of Micro-organisms in the United States :

In the United States of America, however the case of *Diamond v. Chakrabarty*, only that opened new vistas of bringing forms of life, specifically micro-organisms under the preview of patenting, in the case Supreme Court of the United States considered the question of whether a micro-organism is patentable subject-matter under the United States patent laws. *Chakrabarty*, a microbiologist, sought to patent a genetically engineered bacterium which degrades crude oil, a characteristic which makes it extremely valuable for controlling oil spills. The patent examiner denied *Chakrabarty's* patent claim for the bacteria itself, but allowed his claims for products and processes involving the bacteria. The examiner denied the bacteria patent, finding that a micro-organism is a product of nature which, as a living thing, and thus cannot be patented. However when the case reached the Supreme Court, in a 5-4 ruling, the Court held that a live, human-made micro-organism is patentable subject-matter under section as a manufacture or composition of matter.

The American patent law bases upon the principle that 'anything under the sun made by man is patentable'. This has lead to granting of patent to everything which is invented and this principle leads to granting of patent even to micro-organisms. In the case of *Diamond v. Chakrabarty*,[3] only that opened new vistas of bringing forms of life, specifically micro-organisms under the preview of patenting, in the case Supreme Court of the United States considered the question of whether a micro-organism is patentable subject-matter under the United States patent laws. *Chakrabarty*, a microbiologist, sought to patent a genetically engineered bacterium which degrades crude oil; a characteristic which makes it extremely valuable for controlling oil spills. The patent examiner denied *Chakrabarty's* patent claim for the bacteria itself, but allowed his claims for products and processes involving the bacteria. The examiner denied the bacteria patent, finding that a micro-organism is a product of nature which, as a living thing, and thus cannot be patented. However when the case reached the Supreme Court, in a 5-4 ruling, the Court held that a live, human-made micro-organism is patentable subject-matter under section as a manufacture or composition of matter.

2. www.en.wikipedia.org

3. 447. US 306 (1980)

In addition to the *Chakrabarty's* decision, revisions in Federal patent policy encouraged increased patenting of living organisms and related processes. Prior to 1980, no single patent policy existed for Government-supported research, despite the Federal Governments pre-eminence in biotechnology related research funding. Instead, each Federal agency developed its own rules, resulting in 26 different patent policies. Under this system, only about 4 per cent of some 30,000 Government-owned patents were licensed. Furthermore, the Government policy of granting nonexclusive licences discouraged private investment, since a company lacking an exclusive licence was unlikely to pay the cost of developing, producing, and marketing a product. Thus, potentially valuable research remained unexploited. To resolve this problem, Congress passed the Patent and Trademark Amendments of 1980 (Public Law 96-517) as amended in 1984 (Public Law 98-260) to promote efforts to develop a uniform patent policy that would encourage co-operative relationships and to commercialize Government funded inventions. From 1980 through 1984 patent applications by Universities and hospitals for inventions containing human biological increased more than 300 per cent as compared to the previous 5-year period. The policies adopted by Congress in 1980 and 1984, which gave statutory preference to small businesses and non-profit organizations, were extended to larger businesses (with some exceptions) in 1983. The Technology Transfer Act of 1986 (Public Law 99-502) granted Federal authority to form consortia with private concerns. Executive Order 12591, issued in 1987, further encouraged technology transfer programmes, including the transfer of patent rights to Government grantees. In combination with the *Chakrabarty's* decision, these actions helped spur patent activity.

International endeavours for Patentability of Micro-organisms:

For the smooth patenting of micro-organisms the world countries have enacted the Budapest Treaty on International Recognition of the Deposit of Microorganisms for the purpose of patent procedure on 28th April, 1977, the treaty primarily enacted for the purpose of deposits of micro-organisms at an international depositary authority to be recognized for the purposes of patent procedure". The treaty does not mention what is meant by 'micro-organisms'. As on today there are 37 international depository authorities (IDAs) are available for deposit of micro-organism in 20 countries in the world wide[4].

The coming into force of the General Agreement on Trade and Tariff Principles Trade Related Aspects of Intellectual Property regime covenants has completely paradoxised the patenting of micro-organisms. The Article 27 of the TRIPS mandates that patentability of micro-organisms if they have been effectuated further but there is no-clear cut definition is provided in the covenants what constitutes micro-organisms. The same Article also stipulates that the patentability for protecting the can be excluded public order or morality, including to protect human, animal or plant life or health or to avoid serious prejudice to the environment, thus there is no yardstick definition for member nations to follow in this regard. There is no clarity whether, the term would include only genetically modified organisms or naturally occurring substances.

The coming into force of TRIPS in 1995 has lead to universalisation of process of patenting of micro-organisms, on par with the international binding obligations our country also amended the Patent Law of 1970 three times in quick succession, in 1999, 2002 and 2005 and by 2002 amendment India recognized the granting of patents to micro-organisms and later by 2005 amendment deleted Section 5 of the Act, which provided for only process patents. The provision included inventions where only

4. www.wipo.int

methods or processes of manufacture were patentable. Therefore, the deletion of this section, paves way for product patents.

Position in India:

In India, the position was made clear after the 2002 amendment to the Indian Patents Act. Before the amendment, the unamended Section 3(j) of the Act stated that plants and animals in whole or in part thereof including seeds, varieties and essentially biological process for the production of plants and animals are excluded from patenting. As per international obligations India amended the Patent Act where on account of the micro-organisms can be patented provided they satisfy the other requirements.

In our country there is dearth of judicial dicta with respect to patenting of micro-organisms. However Kolkata High Court decision throws some light on this aspect. In *Dimminaco AG v. Controller of Patents & Design*[5], The applicant, *Dimminaco AG*, had applied for a process patent involving the manufacture of a live vaccine for protecting poultry against infectious bursitis. However, the application was rejected by the Indian Patent Office stating that the definition of invention in the Patents Act did not include a living organism thus any process that resulted in a live vaccine would not qualify as a manner of manufacture. The Kolkata High Court, rejected the findings of the Indian Patent Office and held that the dictionary meaning of the word manufacture does not exclude the process of preparing a commodity which contains a living substance. Following this decision process patent was issued to the applicant from the patent office.

Apart from the above case, another former case is *Vandana Shiva and others v. Union of India*[6], which briefly touches upon the issue of patenting of micro-organisms in the general light of patenting of all living forms. In the above case, four petitioners had sought a writ of *mandamus* restraining the Union of India from signing/ratifying the existing version of General Agreement on Trade Tariff Treaty, or to restrain the Union of India from, agreeing to sign and signing Article 27.5.3(b) of the Trade Related Aspects of Intellectual Property Rights (TRIPs) Agreement. They also seek a direction for exclusion of patents on life-forms including plants, animals, human beings produced through biological or microbiological processes, whether natural or modified on grounds of public morality and public order. They seek a further direction against Union of India from violating the fundamental rights and ensuring their protection while signing the Treaty, the right to health and nutrition ensured by the existing Indian intellectual property regime and patent system which had ensured the exclusion of patents on life forms and patents on products in the area of health and. agriculture on grounds of morality and public order and also in respect of rights of farmers including the right to seed as owners, producers, breeders and innovators *etc.*

The High Court of Delhi however took the view that the signing of any treaty, in this case the General Agreement on Trade and Tariff Treaty cannot be challenged if there is no infringement of fundamental rights of the citizens. The Court was of the view that it was a matter of policy which was best left to the executive. While citing British and American sources it concluded it was best to a non-interfering policy in this regard. The point to note here is the reluctance of the Courts to interfere with a matter of policy of the Executive even if the challenge is based on the grounds of public morality and public order. Since now the matter is somewhat settled after the decision of the Calcutta High Court, still a binding decision of the Supreme Court is

5. I.P.L.R. July, 2002 issue. (derived from Annual Survey of Indian Law, 2002, Vol. XXXVIII Pp.450-492)

6. AIR SC

still awaited to give a final verdict on the issue.

Conclusions and Suggestions:

Patenting of life forms may have at least two dimensions. Firstly, there is the ethical question of the extent of private ownership that could be extended to life forms. The second dimension relates to the use of IPRs concept as understood in the industrialized world and its appropriateness in the face of the larger dimension of rights on knowledge, their ownership, use, transfer and dissemination.

The TRIPS Agreement makes it mandatory to provide patent protection to micro-organisms and non-biological and microbiological production of plants and animals. This makes it difficult for the developing countries to exclude inventions within this category altogether. Hence, the strategy should be how to limit the scope of these provisions. As far as the patent protection of micro-organism is concerned, TRIPS does not provide a definition of micro-organism. The national rule-makers must define micro-organism in such a way as to include the following: bacteria, virus, and fungus and algas space.

Another important way to limit the scope of patent protection to biological materials is to make a difference between the concept of invention and discovery of Micro-organisms as such occur in nature. If any micro-organism is discovered it cannot be called invention, it falls in the category of discovery. Micro-organism when genetically modified falls in the category of invention because of human input. Genetically modified micro-organism may perform any number of activities. If a researcher is able to research upon a particular activity, and he is allowed patenting of his genetically modified micro-organism this will result in blocking of further research on that micro-organism.. Also since only inventions are qualified for patenting, naturally found micro-organisms, DNA structure, genes, blood cells, *etc.*, can be excluded from patent protection. Nations can also exclude certain inventions in biotechnology by relying on the exclusion provision available under the TRIPS Agreement which permits the State parties to exclude certain inventions which are injurious to health and environment of human and animals. Using this exception a member State can exclude terminator type technologies from patent protection.

The most important difference between the patent law of the India and developed countries is that India do not allow patenting of micro-organisms that already exist in nature as the same is considered to be a discovery as per the provisions of the Section 3(d) and therefore not patentable. But genetically modified versions of the same micro-organisms that result in enhancement of its known efficacies are patentable. European and Australia/US or some other approach better suits the needs of its emerging economy rather Indian approaches in relation to patenting of biotechnological product and processes. Companies and investors venturing into the biotech sector need to fully realize the significant role intellectual property plays in the commercialization process for biotechnological innovations. In years to come we can see some more changes may come with matters concerning the patentability of micro-organisms.

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