

**LECTURES ON "IPR" FOR SCIENCE
STUDENTS**
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By

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Dr. B.B.Singh holds a Master's degree in Physics and is a recipient of the Gold Medal for being the best student of the year. He obtained his Ph. D. degree in Radiation Biology from the university of London and is an elected Fellow of the Indian Academy of Sciences and also of the National Academy of Sciences of India. He has been awarded the degree of Doctor of Sciences (h.c.) from the International Open University, Colombo, Sri Lanka. He had held several important positions in India at the Bhabha Atomic Research Centre Mumbai and at the United Nations' International Atomic Energy Agency in Vienna. He has served as an expert in various countries including at the Syrian Atomic Energy Commission, Damascus. He is a scientist of international repute specializing in the fields of free radical biology and combination therapy of cancer with radiation and hyperthermia. He is a widely traveled scientist and has participated in 44 international conferences in over 32 countries and has been a member of the Organizing Committee of numerous international conferences held in India and abroad. He has to his credit 2 books and 163 original scientific papers published in as reputed scientific journals as *Nature* (Lond.) and *Science* (Wash.). He has been the President of Indian Biophysical Society, Indian Society for Radiation Biology and Indian Association for Hyperthermic Oncology & Medicine and a Hon. Member of International Society for Clinical Hyperthermia. He retired in 1998 as the Head of the Biochemistry and Radiation Biology Divisions of Bhabha Atomic Research Centre, Mumbai, India. He has served on the Editorial Boards of several International Journals including Intl. J. Radiat. Biol. (UK); Intl. J. Hyperthermia (UK); Radiation Phys. & Chem. (UK).



Dr. Singh also holds LL.B. degree from the Mumbai University specializing in Environmental Law and Consumer Protection. His research work at the J.C. College of Law, Mumbai on "Laws Relating to IPR in Biomedical Technologies in India" has earned him the degree of LL.M. from the Mumbai University. He has been a Research Fellow at the Institute of Intellectual Properties, University of Tokyo, Japan and is currently a member of the Editorial Board of the Intl. Journal of Nuclear Law (Paris). He is presently practicing at the Bombay High Court on laws relating not only to IPR issues but also in other branches of law such as Constitutional remedies & Writs, Public Interest litigations, Consumer Protection, Recovery of debts, Company matters including mergers and winding-up, arbitrations and conciliations, transfer of properties and cases complicated by Indian personal laws for child adoption and matrimonial disputes.

He has extensively toured India for over 5 years delivering public lectures on fallacies of the Indian Patent Bill before it was passed into an Act by the Parliament. He is an active member of several NGOs and social welfare bodies including Rotary International, Masonic Fraternities and Swadeshi Jagran movement. He is a very popular public speaker and a teacher for students of academic pursuits and has guided several research scholars for their master and doctoral degrees in various Universities.

LECTURE - 5

INDIAN PATENT ACT 2005

PATENTEE

WHO CAN APPLY FOR PATENTS (u/s 6)

1. Any person claiming to be the true and first inventor of the invention;
2. Any person being the assignee of the person claiming to be the true and first inventor in respect of the right.
3. Any legal representative of any deceased person who immediately before his death was entitled to make an application.
4. Employer: In the absence of special contract or contractual relations, express or implied between the employee and employer, the invention made by the employee should belong to the EMPLOYER. In India if the employee refuses to sign the documents for Patents, the employer will have to go to the Court for orders to declare the employer as inventor's assignee. In U.K. the employer may designate any person to sign the documents.

Application can be made by any of the abovementioned persons either alone or jointly with any other person.

PATENT ELIGIBILITY

WHAT CAN NOT PATENTED (U/Ss 3-4)

WHAT ARE NOT INVENTIONS

1. An invention which is frivolous or which claims anything obviously contrary to well established natural laws.
2. An invention the primary or intended use commercial exploitation of which could be contrary to public order or morality or which causes serious prejudice to human, animal or plant life or health or to environment.
3. The mere discovery of a scientific principle or the formulation of an abstract theory or discovery of any living thing or non-living substance occurring in nature;
4. The mere discovery of any new property or mere new use for a known substance or of mere use of a known process, machine or apparatus unless

such known process results in a new product or employs at least one new reactant

5. A substance obtained by a mere admixture resulting only in the aggregation of the properties of the components thereof or a process for producing such substance
6. The mere arrangement or rearrangement or duplication of known devices such functioning independently of one another in a known way
7. A method or process of testing applicable during the process of manufacture for rendering the machine more efficient
8. A method of agriculture or horticulture
9. Any process for the medicinal, surgical, curative, prophylactic diagnostic, therapeutic or other treatment of human beings or any process for similar treatment of animals to render them free of disease or to increase their economic value of that of their products.
10. 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 propagations of plants and animals.
11. A computer programme per se other than its technical application to industry or a combination with hardware.
12. A mathematical method or a business and or algorithms.
13. A literary, dramatic, musical or artistic work or any other aesthetic creation whatsoever including cinematographic works and television productions.
14. A mere scheme or rule or method of performing mental act or method of playing games.
15. A presentation of information.
16. topography of integrated circuits.
17. an invention which, in effect, is traditional knowledge or which is an aggregation or duplication of known properties of traditionally known component or components
18. Any invention relating to atomic energy falling u/s20 (1) of AE Act 1962

PATENTABILITY

WHAT INVENTIONS CAN BE PATENTED

Indian Patent Act s.2(j) & (ja) :

“Invention” means a **new product** or process involving an inventive step and capable of industrial **APPLICATION**

“Inventive step means a feature that makes the invention **not obvious** to a person **skilled in the art**.

1. SUBJECT MATTER:-

“For Patentability” US Congress (1952) stated “any thing under the sun that is made by the hand of man can be patented”.

Thus the things that exist in substantially in the same form in nature and are not made by human hand i.e. “PRODUCT OF NATURE” cannot form the subject matter of patenting. BUT the following factors must be taken into consideration in formulating Patent laws;

- (i) the "**human factor**", in terms of utilization of enormous human resources of technically highly qualified nature which was involved in the invention;
- (ii) the "**economic factor**" wherein considerable financial resources might have been invested in the invention, and
- (iii) the "**political factor**" which determines the advantages the invention may offer to the public.

BUT In Cuno Engineering Corp. v/s Automatic Devices Corp. The Hon'ble Court has remarked:-

*"It has been recognized that if **an invention or improvement** is to obtain the privilege position of a patent, more ingenuity must be involved than the work of a mechanic skilled in art That is to say, the device, however useful it may be, must reveal the flash of creative genius, not merely the skill of the calling. If it fails, it has not established its right to a private grant in public domain."*

Discovery v/s Invention:

Discovery is uncovering something which is already existing in nature but which has not yet been discovered i.e. it was covered until someone uncovered it. Thus discovery is mere knowledge about something existing in nature whereas an invention implies the ability of a human being to use this knowledge in a technical way.

Example: Some one walks into the woods and finds a very appealing fungus and that some one with a terrible headache which makes him less prudent, eats the fungus and his headache disappears instantaneously. That is a discovery since that person discovered that the fungus is useful as a cure of headache, he has acquired knowledge about the fungus without using this knowledge in any technical way. The same hypothetical person discovers the appealing fungus, takes it to his laboratory, analyses it and is able to extract, isolate and purify by a technical process a substance that happens to be useful as a cure for headache, he has made an invention.

2. NOVELTY: - NON-OBVIOUSNESS

Novelty is an absolute criterion i.e. something is new if it does not form part of the state of art. The state of art consists of all knowledge available whether in written or oral form.

Sec.103 35 US; "A patent in The state of art consists of all may not be obtained if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which the subject matter pertains. Patentability shall not be negated by the manner in which the invention was made."

In *Graham v/s John Deere Co (383US 1, 1966)*, the US Supreme Court suggested the following four aspects which must be analyzed for "non-obviousness":-

- (a) the scope and content of the prior art are to be determined,
- (b) differences between the prior art and claims at issue are to be ascertained,
- (c) the level of ordinary skill in the pertinent art to be resolved.
- (d) the secondary indicia of non-obviousness such as commercial success and long-felt need should also be considered because if a product attains a high degree of commercial success, there is a basis for inferring that such attempts have been made and failed. Thus the rationale is similar to that of long-felt demand and is for the same reason a legitimate test of invention but commercial success alone cannot be taken as the test of non-obviousness.

In this connection, in *Hybritech v/s Monoclonal Antibodies Inc.* the Circuit Judge Rich while recognizing the phenomenal market success for their diagnostic kits, remarked:-

"With respect of the objective indicia of non-obviousness, while there is evidence that marketing and financing played a role in the success of the Hybritech's kits, as they do with any other product, it is clear to us on the entire record that the commercial success here was due to the merits of the claimed invention".

Another controversy is in respect of the novelty of chemical substances occurring in nature. The EPO case laws have established that a substance can be considered novel if the already naturally occurring identical substance was not available to the public. EPO Guidelines also state that a substance freely occurring in nature is a discovery and is not patentable. But when a substance occurring in nature has to be isolated from its natural surroundings by a process and that process is patentable,

then the substance per se may be patentable. US Patent case laws support similar views.

3. SKILLED IN ART

The determination of the appropriate level of skill in the art has often proved a difficult task in the US Courts and this task of defining the ordinary skill was performed by the US Court in the *Environmental Designs Ltd. v/s Union Oil Corp.* wherein the US Court provided the following guidelines in determining the level of ordinary skill in art:

- (a) the educational level of the inventor,
- (b) type of problems encountered in the art,
- (c) prior art solutions to those problems,
- (d) rapidity with which the inventions are made,
- (e) sophistication of the technology,
- (f) educational level of the active workers in the field.

A further guidance on the "skill in art" is provided by the European Patent Office Board of Appeals in *T 60/89 (OJ 1992, 268)* which rejected the argument that the person of skill in art should be considered a Nobel Laureate. The Board concluded:

"It is the opinion of the Board that the skilled person in the field of genetic engineering in 1978 is not to be defined as a Nobel Prize laureate even if a number of scientists working in this field at that time were actually awarded Nobel Prize. Rather it is understood that the skilled person was to be seen as a graduate scientist or a team of scientists of that skill, working in laboratories with developed facilities from molecular genetics to genetic engineering techniques at that time."

4. INDUSTRIAL APPLICATION - UTILITY

Industrial application, till recently was not a major issue in patent law. Industry should be understood in its broader prospective including any physical activity of technical nature i.e. an activity which belongs to the useful or practical arts as distinct from aesthetic art and it does not necessarily imply the use of machine or manufacture of an article and could cover e.g. a process for dispersing fog or a process converting energy from one form to another. However requirement of industrial application implies a "commercial exploitation" with purpose of achieving "financial gain".

Earlier view on the utility was expressed by Circuit Judge Story in *Lowel v/s Lewis (Circuit Court, D Massachusetts 1817, 15F.Cas 1018)* had remarked:

"all that the law requires is that the invention should not be frivolous or injurious to well being, good policy or sound morals of the society. The word "useful" therefore, is incorporated into the Act in contradiction to mischievous or immoral. For instance, a new invention to poison people or to promote debauchery or to facilitate private assassination, is not patentable invention. But if the invention steers wide of these objections, whether it be more or less useful is a circumstance very material to the patentee but of no importance to the public. If it be not extremely useful, it will silently sink into contempt and disregard..... By useful invention in the Patent Act, is meant an invention, which may be applied to a beneficial use in society, in contradiction to an invention injurious to the morals, health or good order of society or frivolous and insignificant".

4.1 Utility & Substantial Utility:

USPTO 2001 Utility Guidelines exclude "throw away", "insubstantial" or "non-specific" utility and call for well-established utility (i) if a person of ordinary skill in art would immediately appreciate why the invention is useful based on the characteristics of the invention, and (ii) the utility is specific, substantial and credible. EPO Guidelines are identical.

The US Supreme Court in *Brenner v/s Mason* remarked as follows:

"Whatever weight is attached to the value of encouraging disclosure and of inhibiting secrecy, we believe, a mere compelling consideration is that a process patent in the chemical field which has not been developed and pointed to the degree of specific utility, creates a monopoly of knowledge which should be granted only if clearly commanded by the statute. Until the process claim has been reduced to production of a product shown to be useful, the metes and bounds of that monopoly are not capable of precise delineation. It may engross a vast, unknown and perhaps unknowable area. Such a patent may confer power to block off whole area of scientific development without compensating benefit to the public. The basic quid pro quo contemplated by the Constitution and the Congress for granting a patent monopoly is the benefit derived by the public from an invention with SUBSTANTIAL utility. Unless and until a process is refined and developed to this point- where specific benefit exists in currently available form- there is insufficient justification for permitting an applicant to engross what may prove to be a broad field This is not to say that we mean to disparage the importance of contributions to the fund of scientific information short of invention of something "useful" or that we are blind to the prospect that what now seems without "use" may tomorrow command the grateful attention of the public. But a patent is not a hunting license. It is not a reward for the research, but compensation for its successful conclusion. A patent system must be related to the world of commerce rather than to realm of philosophy."

4.2 Utility & Safety :

In *In re Anthony*, the Examiner rejected the application on the basis of lack of utility because the compounds were not shown to be safe and effective, the appeal Court remarked:

"It is Examiner's position that where a drug, which has a recognized toxic reaction associated with its use coupled with the fact that the nation's safeguarding agent, the FDA has banned such drug from the market as being unsafe and to date has not lifted such ban, that such drug is not safe for use within the meaning of (utility) 35 USC Sec. 101."

The Court reversed the decision stating that *"absolute complete proof of safety is realistically impossible"* and *"that many valued therapeutic substances or materials with desirable physiological properties, when administered to lower animals or humans, entail certain risks or may have undesirable side effects"*. *that the Congress clearly gave the statutory authority and responsibility in this area to FDA and not to PTO and, that the criteria for patentability in the*

PTO and safety and efficacy in the FDA are fundamentally different“. In the end, the Court reversed the rejection by the Examiner.

4.3 Practical Utility & Human Therapeutic Efficacy

Lack of safety and efficacy has been always an issue while examining the utility criterion for biomedical inventions particularly the pharmaceutical inventions. *In re Brana*²⁸, the applicant filed patent application Serial No. 213,690 for 5-nitrobenzo(de) isoquinoline-1,3-dione compounds being for use as anti-tumour substances. The applicants had demonstrated in vitro efficacy of the chemicals in tumour lines P388 and L1210. The Examiner rejected the application based on a challenge to the utility criterion of the claimed compounds and the amount of experimentation necessary to use the compounds, and it was upheld by the Board of Appeals and Inferences wherein the Commissioner contended that the cell lines P388 and L1219 are not diseases but tumour models in animals and hence the specification does not provide a specific disease against which the claimed compounds can be used. The Commissioner further contended that the tests offered by the applicants to prove utility were inadequate to convince one of ordinary skill in the art that the claimed compounds are useful as anti-tumour agents.

The Judges at the Federal Circuit reversed the Board's decision. The Judges examined in detail the procedure for Phase-I to Phase-II clinical trials before release of any compounds for human use and finally remarked:

“FDA approval however, is not a prerequisite for finding a compound within the meaning of the patent law. Usefulness in patent law, and in particular in the context of pharmaceutical inventions, necessarily includes the expectation for further research and development. The stage at which the invention in this field becomes useful is well before it is ready to be administered to humans. Were we to require Phase-II testing in order to prove utility, the associated costs would prevent many companies from obtaining patent protection on promising new inventions, thereby eliminating an incentive to pursue, through R & D, potential cures in many crucial areas such as treatment of cancer. In view of all the foregoing, we conclude that applicants' disclosure complies with the (Utility) requirements of 35 USC Sec.101,”

PATENT PROSECUTION

Section 7(4)

Every such Application (not being a convention application or an application filed under PCT designating India) shall be accompanied by a provisional or a complete specification.

Section 10(4)

Every complete specification shall-

- (a) fully and particularly describe the invention and its operation or use and the method by which it is to be performed;*
- (b) Disclose the best method of performing the invention which is known to the applicant and for which he is entitled to claim protection; and*
- (c) End a claim or claims defining the scope of the invention for which the protection is claimed; -----*

Section 112: 35 U.S.C.

Specification shall contain:

1. *A WRITTEN DESCRIPTION OF THE INVENTION:- designed to ensure that the Applicant was in possession of the claimed invention at the time the application was filed and it serves to put the public in possession of what the claimant claims as the invention. The written description is also to prevent an inventor from overreaching by requiring that he disclose his invention as originally filed in such detail as to enable a future skilled person to determine whether later filed claims were encompassed in the original invention specification particularly in context of continuation application where the inventor seeks to be entitled to the filing date of an earlier application.*
2. *AN ENABLING DISCLOSURE:- to teach a person skilled in the art to which the invention pertains how to make and use the full scope of the invention without undue experimentation.*

UNDUE EXPERIMENTATION

THE CONCLUSION IS REACHED BY WEIGHING FOLLOWING FACTORS:

1. The quality of experimentation necessary
2. The guidance provided in specification
3. The availability of working examples
4. The nature of invention
5. The state of art
6. The relative skill of those in art
7. The breadth of the claims
8. The predictability and nonpredictability of art.

The biological arts unlike mechanical arts, are considered unpredictable because scientists are unable to precisely predict how simple changes in temperature, pressure, pH etc. will affect biological processes. **HENCE IN BIOTECHNOLOGICAL PATENTS ENABLEMENT MUST BE MORE DETAIL**

EXEMPTION

RESEARCH TOOLS

(EXPERIMENTAL USE)

Sec.47(3) Indian Patent Act 1970 states:

“The grant of a patent under this Act shall be subject to the condition that any machine, apparatus or other article in respect of which the patent is granted or any article made by the use of the process in respect of which the patent is granted, made or used, and any process in respect of which the patent is granted may be used, by any person, for the purpose merely of experiment or research including the imparting of instructions to pupils”;

The experimental-use doctrine was first expounded in the US in 1813 by Justice Story in *Whittemore v. Cutter* as follows:

"it could never have been the intention of the legislature to punish a man who constructed a patented machine merely for philosophical experiments or for the purpose of ascertaining the sufficiency of the machine (itself) to produce its described effects."

In Embrex Inc. vs. Service Engg. Corpn. (216E3d1343 (CAFC2000) the Judges have held that “there is no such thing”. Thus a patented analytical balance might be used to design and improve the balance itself but not to weigh things even in research.

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