KARPAGAM ACADEMY OF HIGHER EDUCATION

(Deemed to be University Established Under Section 3 of UGC Act 1956)

Coimbatore – 641 021.

LECTURE PLAN
DEPARTMENT OF BIOTECHNOLOGY

STAFF NAME: Mr Nishu Sekar
SUBJECT NAME: I.P.R., ENTREPRENEURSHIP, BIOETHICS & BIOSAFETY
PRACTICAL SUB.CODE: 17BTU314A
SEMESTER: III CLASS: II B.Sc (BT)

S.No	Lecture Duration Period	List of Practical's
1	3	Proxy filing of Indian Product patent
2	3	Proxy filing of Indian Process patent
3	3	Planning of establishing a hypothetical biotechnology industry in India
4	3	A case study on clinical trials of drugs in India with emphasis on ethical issues.
5	3	Case study on women health ethics.
6	3	Case study on medical errors and negligence.
7	3	Case study on handling and disposal of radioactive waste

17BTU314A I.P.R., ENTREPRENEURSHIP, BIOETHICS & BIOSAFETY PRACTICAL 3H - 1C
Total hours/week: L:0 T:0 P:3 Marks: Internal: 40 External: 60 Total: 100

Practical

1. Proxy filing of Indian Product patent
2. Proxy filing of Indian Process patent
3. Planning of establishing a hypothetical biotechnology industry in India
4. A case study on clinical trials of drugs in India with emphasis on ethical issues.
5. Case study on women health ethics.
6. Case study on medical errors and negligence.
7. Case study on handling and disposal of radioactive waste

References

1. Jack Kaplan, M., (2009). *Patterns of Entrepreneurship* (3rd ed.).
2. Gupta, C.B., & Khanka S.S. (2004). *Entrepreneurship and Small Business Management*. Sultan Chand & Sons.
3. David Holt, H., (1992). *Entrepreneurship. New Venture Creation*.
4. Sateesh, M.K. (2010). *Bioethics and Biosafety*. I. K. International Pvt Ltd.
5. Sree Krishna,V. (2007). *Bioethics and Biosafety in Biotechnology.* New age international publishers.

CLASS: II BSC BT COURSE NAME: I.P.R., ENTREPRENEURSHIP, BIOETHICS & BIOSAFETY PRACTICAL

COURSE CODE: 17BTU314A BATCH-2017-2020

EX. NO-1 PROXY FILING OF INDIAN PRODUCT PATENT

Patent can be registered in India as per the Indian Patent Law. A patent can be registered by filing a patent application with the Indian Patent office. The patent application can be ordinary application, National phase application under PCT or a conventional application. Generally an ordinary application is filed with the Indian Patent office to obtain a patent. An ordinary application does not claim a priority from any other application. Further, after filing of a patent application, the patent application is examined by an examiner of the patent office. After examination of the application, a FER or first examination report is issued by the examiner containing a list of objections, to which an applicant or his authorized agent has to file a response. If needed, the examiner can call an applicant or his agent for a hearing. Once the examiner is satisfied with the response filed by an applicant, he may put the application in order for grant.

BENEFITS OF PATENT REGISTRATION

- Patent grants exclusive right to commercially exploit the rights over an Invention
- Inventor can assign his rights in favour of another person against consideration
- having patent on invention make chances of getting designated as startup high
- Exclude all others for using, selling, offering for sale your invention in your country
- Having patents help you in raising finance as investor values it

PROCESS OF PATENT REGISTRATION

- Write down your invention (idea or concept) in maximum detail possible
- Use drawings, diagrams, sketches to explain how Invention works

- Check if the invention is patentable or not in terms of the Patent Act
- File the patent application with specification, drawings and Claims to government
- Patent office to examine the application and if found in order will advertise it for grant of patent

DOCUMENTATION FOR PATENT REGISTRATION

- Authorisation to patent attorney to file for patent in India
- Fill the patentquestionnair, where information is collected for making the application
- Drafting of specification in great detail so that any other person of same skill can perform it
- Declaration of Inventorship to be signed by the Inventor
- In case of International application, the prior art documents

PRICING

Filing	**Patent Drafting**	**Government Fee**
Includes patent filing with provisional as well complete specification	Depends on the level of engagement, request you to seek separate quote	Differs based on application type and nature of applicant
Rs. 15,000	Case to Case	On Actual

EXPEDITED PATENT PROCESS

Step 1: Prior art search

Prior art search is a process to find any evidence that there is a previous knowledge of the invention before date of filing of the patent application. To be patentable, the invention must be new and no prior art should exist.

Step 2: Provisional Application Filing

We strongly recommend to file a provisional application of Patent immediately after the invention is conceived. So, that even if it is leaked it should not create prior art against the invention being applied. The provisional application must contain the maximum possible disclosure of the invention.

Step 3: Complete Specification

Filing Within 12 months of filing the provisional application the complete specification must be filed with drawings and claims of the invention. The final specification must be search with which a person of same skill can perform the invention.

Step 4: Patent Examination

After filing the complete specification, a request for examination of Patent must be filed. There is an alternate method for express examination of Patent. After examination, the patent examiner comes up with report which may be favourable or with objection.

Step 5: Patent Publication

Once a favorable examination report is issued the application can be advertised, however for that a request has to be made after expiry of 18 months. However, an early publication request can be made to the patent office. So, that it is advertised within 4-5 months.

Step 6: Patent Granted

After three months of the publication of the trademark in the Trade Marks Journal, the application is processed provided there is no third party opposition to it. Trademarks Registry will accordingly issue a registration certificate. Term of Trademark Registration Trademark protection in India is perpetual subject to renewal of the registration after every 10 years.

WHY TO OBTAIN PATENT REGISTRATION

Legal Protection-

Only owners of registered patents are allowed to take action or sue for damages in case of patent infringement. Patent protection is not enforceable for inventions that are not registered.

Competitive Edge

Patent registration will provide a unique competitive edge for the business. Competitors will not be allowed to use the patented invention for similar goods or services.

Global Patent Protection

A patent registration in India can be used as the basis for patent registration in other countries, if required. Foreigners and Foreign entities can also register a patent in India, if required.

20 Year Validity

Patent registrations in India are valid for 20 years from the date of filing of patent application, irrespective of whether it is filed with provisional or complete specification.

Tax Break

Special patent regime has been announced in the 2016 budget. Income from foreign use of patent developed and registered in India will be taxed at the rate of 10% only.

EX. NO-2 PROXY FILING OF INDIAN PROCESS PATENT

Filing a patent application in the Indian Patent Office is the first step towards securing a patent to your invention in India. To file a patent application, a set of forms has to be submitted to the patent office. The forms can be submitted online

(http://ipindiaonline.gov.in/epatentfiling/goForLogin/doLogin) if you have a class 3 digital certificate. Alternatively, you can send true copies (hard copies) to the p patent office. The patent office charges 10% additional fee if applications are filed offline.

Please note that, the most important factor in filing a patent application is preparing a patent specification. Drafting a patent specification is a highly skilled job, which can be only preformed by persons who have both technical as well as patent law expertise. If a person or company is serious about protecting their intellectual property, it is highly recommended to use the services of professional patent practitioners.

It is recommended to avail services of professionals to file patent applications, as mistakes will prove costly. Thorough understanding of the Indian Patent Act is essential for filing patent applications. Patent agents have understanding of the Indian Patent Act and are the only persons (other than the applicant themselves) authorized by the Patent office to file patent applications on behalf of the applicant. Invn Tree employs patent agents.

Indian patent offices are located at Delhi, Kolkata, Mumbai and Chennai. The patent application has to be filed in the appropriate office based on your/your company's location.

The addresses of the patent offices in India and their respective territorial jurisdiction.

Office	Address	Territorial Jurisdiction
Mumbai	Intellectual Property Office, Boudhik Sampada Bhawan, Near Antop Hill Post Office, S.M. Road, Antop Hill, Mumbai – 400 037. Phone: 24137701, 24141026, 24150381, 24148165, 24171457 FAX : 24130387 Email: mumbaipatent@nic.in	The States of Maharashtra, Gujarat, Madhya Pradesh, Goa and Chhattisgarh and the Union Territories of Daman and Diu & Dadra and Nagar Haveli

Chennai	Intellectual Property Office, Intellectual Property Office Building, G.S.T. Road, Guindy, Chennai-600032, Phone: 044-22502081-84 FAX: 044-22502066, Email: chennai-patent@nic.in	The States of Andhra Pradesh, Karnataka, Kerala, Tamil Nadu and the Union Territories of Pondicherry and Lakshadweep
New Delhi	Intellectual Property Office, Intellectual Property Office Building, Plot No. 32, Sector 14, Dwarka, New Delhi-110075, Phone : 011-28034304, 28034305 28034306 FAX:011- 28034301,02 Email: delhi-patent@nic.in	The States of Haryana, Himachal Pradesh, Jammu and Kashmir, Punjab, Rajasthan, Uttar Pradesh, Uttaranchal, Delhi and the Union Territory of Chandigarh.
Kolkata	Intellectual Property Office, Intellectual Property Office Building, CP-2 Sector V, Salt Lake City, Kolkata-700091, Phone : 23671945, 1946, 1987, FAX-033-2367-1988, Email:- kolkata-patent@nic.in	The rest of India

Once you have identified the patent office in which you have to file your patent application, it is now time to get an overview of the forms that have to be submitted.

To file a patent application, you will have to submit form 1, form 2, form 3 and form 5. Subsequent to filing these forms with the appropriate fees, you will receive a patent application number from the patent office. You can choose to file form 9 (optional) and form 18 along with fiing a complete application or after filing a complete application. You can download the Indian patent application filing forms.

In the table below, the list of forms that have to be submitted and their respective fees is provided. Please note that, the fee mentioned is for E-filing only. The patent office charges an additional fee of 10% over the fee for applications filed offline.

Form	title	Patent office Fee (INR) 1$ = ~ 60 INR E-Filing only			Comment
		Applicant- Natural person/ Startup	Applicant – other than natural person		
			Small	Others except	

			Entity	small entity	
1	Application for Grant of Patent	1600	4000	8000	Mandatory
2	Provisional/Complete Specification	No fee*	No fee *	No fee *	Mandatory
3	Statement and Undertaking Under Section 8	No fee	No fee	No fee	Mandatory
5	Declaration as to Inventor ship	No fee	No fee	No fee	Mandatory
9	Request for Publication	2500	6250	12500	Optional
18	Request for Examination of Application for Patent	4000	10000	20000	Mandatory

* – A fee of 160/400/800/sheet, based on the type of applicant, is applicable for each sheet exceeding 30 sheets in a patent specification. Further, a fee of INR 320/800/1600/Claim, based on the type of applicant, is applicable for each claim exceeding 10 claims in the patent specification.

Indian Patent Filing Cost Calculator

It should be noted that Forms 1, 2, 3 and 5 can be submitted online. All forms of the patent office can be filed online.

An overview:

Form 1 – Application for Grant of Patent

As the name suggests, this form is an application for grant of patent in India. In this form, you will have to furnish information, such as, name and address of the inventor(s), name and address of the applicant(s), information corresponding to prior patent applications relating to the current invention, which you or any authorized entity has filed, and some declarations, among other information.

(Added after receiving comments from Mr. Naren). Please note that a local communication address (address in India) has to be provided. This point is of importance to foreign (Non-Indian) applicants.

Form 2 – Provisional/Complete Specification

Form 2 is used to furnish your patent specification. The patent specification can be provisional or a complete patent specification depending of the type of patent application (provisional or

complete) you are filing. You might find our article on "What are the different patent filing options?" useful.

If you are filing a provisional patent application, then use the following preamble in the first page of Form 2:

The following specification describes the invention

On the other hand, if you are filing a complete patent application, then use the following preamble in the first page of Form 2:

The following specification particularly describes the invention and the manner in which it is to be performed

Note that, if you are filing offline, 2 copies of the patent specification has to be sent to the patent office. Additionally, count the number of sheets and claims (extra fee for more than 30 sheets and more than 10 claims) and calculate the appropriate fee. While counting the sheets, even the drawing sheets will have to be taken into account.

Form 3 – Statement and Undertaking under Section 8

Form 3 is used to furnish information/actions relating to patent applications filed in other countries for the current invention. Additionally, any information relating to the rights corresponding to the present patent application has to be furnished. Further, you would be using form 3 to undertake that you will be keeping the patent office informed in writing the details regarding corresponding applications for patents filed outside India.

Form 5 – Declaration as to Inventor ship

This application is used to declare the inventors of the subject matter sought to be protected using the current patent application.

Form 9 – Request for Publication

If this form is not filed, then the patent specification will be published by the patent office after 18 months from the priority date (filing of the first patent application for the current subject matter). On the other hand, by filing this form, you can generally have your patent specification published within 1 month from filing this form. Note that the patent rights start from the date of publication of the patent application (enforceable after grant of patent).

Form 18 – Request for Examination of Application for Patent

This form can be filed within 48 months from the priority date. The patent office will not consider your patent application for examination unless this form is filed. Hence, if you wish to expedite the patenting process, filing of form 9 and 18 at an early stage is advised.

A startup can also request for expedited examination of their patent application. The fee for this is INR 8000. At present, the patent office has limited this request to about 1000 request in a year.

EX. NO-5 CASE STUDY ON WOMEN HEALTH ETHICS

Case study : Ethical issues associated with consent for intrapartum clinical trials

Postpartum hemorrhage (PPH) is defined as blood loss of 500ml or more within 24 hours of delivery. Blood loss of more than 1000ml is considered as severe PPH. Atonic PPH is the most common cause of maternal mortality and morbidity in low income countries, particularly in Africa and Asia where it contributes to 30% of maternal deaths. Maternal mortality and morbidity due to atonic PPH can be prevented by the use of prophylactic uterotonic agents during the active management of third stage of labour. Though oxytocin injection is the ideal uterotonic for this purpose, the requirement of strict cold storage for maintaining its efficacy prevents it from being used in many low and middle income tropical country settings. Carbetocin RTS (room temperature stable) has been considered as a promising intervention for reducing PPH in settings where cold storage is difficult to maintain.

This trial aims to evaluate the effectiveness of Carbetocin RTS 100 mcg, intramuscular (IM) compared to Oxytocin (10U), IM in preventing PPH in vaginal deliveries. This is a multicentre, non-inferiority, randomized controlled trial. Women with singleton pregnancy expecting to deliver vaginally will be approached early in labour (<=6 cms of cervical dilatation) for participation and written informed consent will be taken. There will be audio- visual (A-V) recording of the entire consenting process (only in India). All eligible consented women will be randomly assigned at second stage of labour when vaginal delivery is imminent, with allocation sequence to receive a single dose of Oxytocin (10U), IM or a single dose of Carbetocin RTS 100 mcg, IM. Placental delivery in all women will be conducted by controlled cord traction immediately after cord clamping. Blood loss will be measured using BRASSV drape for one hour following delivery. The main objective of this trial is to determine if Carbetocin RTS is similar in efficacy to Oxytocin in preventing PPH.

<u>Ethical issues concerned with consent for intrapartum trials</u>

Informed consent is the heart of ethical research. For any consent to be ethically valid, it should meet certain critical criteria – disclosure and understanding of relevant information, decision making competency of the participants, voluntariness of the decision and indication of agreement (e.g. written consent).

Meeting all these criteria and obtaining ethically valid consent from labouring women while conducting intrapartum trials is challenging because there is little time available during labour to provide trial specific information necessary for the participant to understand and decide to sign the consent form. Moreover women during labour may be anxious and distressed due to labour pains which may be thought to interfere with the capacity to take decisions. Emphasis on these concerns will ultimately lead to exclusion of many eligible women in labour from intrapartum clinical trials.

The two main ethical issues regarding the consent process for intrapartum trials addressed in this case study are :-

1. Excluding women in established active stage of labour with cervical dilatation of more than 6 cms, on the grounds that she will be too distressed due to labour pains to provide informed written consent.

The ability of a woman in labour to understand new information and to make an informed decision varies widely. The nature of the intrapartum complication being studied in the trial also determines the time available for providing informed consent. Despite the arguments questioning the competency of laboring women to give informed written consent late in labour, there is evidence in the literature that most of the anticipated variables like labour pains, duration of labour, anxiety and opioid analgesics, may not interfere with the ability of women in labour to understand the information provided to them and make decisions.1 Many women with these conditions are still capable of giving their own consent, so it should not be assumed that they lack capacity. Hence denying women in labour to get included in the trial based only on the cervical dilatation cut off <= 6cms (early labour) seems scientifically and ethically incorrect. There is also a recommendation in the literature to consider the obstetric care provider (doctor/

midwife) as the "gatekeeper" to assess the physical and emotional state of the laboring woman and to determine her competency to provide consent2. This could be a novel alternative approach.

2. Audio-visual (A-V) recording of consent process for intrapartum clinical trials in India.

The issue of audio- visual (A-V) recording of the informed consent process is unique and applicable only in India. In 2015, the Drug Controller General of India (DCGI) amended the earlier regulation and made A-V recording mandatory only for trials involving vulnerable population and trials related to new drugs3. It has not been determined whether pregnant women constitute a vulnerable population in India. A-V recording might add to the anxiety and distress of laboring women and also may make them feel vulnerable with respect to maintaining privacy and confidentiality, thus discouraging women from participating in intrapartum clinical trials.

Conclusions and recommendations

There is a need to develop standard outline of the intrapartum consent process with optional elements that can be adjusted depending upon the type of the trial and the participants.

1. Intrapartum women who have received the relevant trial information and signed the informed consent antenatally, should be eligible to reconfirm and sign the consent during any stage of labour as long as they remain eligible and competent to provide consent. In acute circumstances, such women may also be allowed to provide oral consent at the time of complication supplemented by signing the written consent at a later stage4.

2. Intrapartum women who have not received the trial information antenatally, should be eligible to sign informed consent in early labour (<= 6 cms of cervical dilatation). Such women may still be allowed to sign informed consent even late in labour (>= 6 cms of cervical dilatation), provided they are considered competent to provide consent by the obstetric care provider (doctor/ midwife), taking into account their physical and emotional status on an individual basis.

EX. NO-6 CASE STUDY ON MEDICAL ERRORS AND NEGLIGENCE

Introduction

Recently, Indian Society is experiencing a growing awareness regarding patient's rights. This trend is clearly discernible from recent spurt in litigation concerning medical professional or establishment liability, claiming redressed for the suffering caused due to medical negligence, vitiated consent, and breach of confidentiality arising out of the doctor patient relationship.

Medical malpractice is professional negligence by act or omission by a health care provider in which the treatment provided falls below the accepted standard of practice in the medical community and causes injury or death to the patient, with most cases involving medical error. Back in 1984, the extrapolated statistics from relatively few records in only several states of the United States estimated that between 44,000-98,000 people annually die in hospitals because of medical errors. From all causes there have been numerous other studies, including "A New, Evidence based Estimate of Patient Harms Associated with Hospital Care" by John T. James, PhD that estimates 400,000 unnecessary deaths annually in hospitals alone. Less than one quarter of care takes place in hospitals. Across all care settings the numbers are higher. Another study notes that about 1.14 million patient-safety incidents occurred among the 37 million hospitalizations in the Medicare population over the years 2000-2002. Hospital costs associated with such medical errors were estimated at $324 million in October 2008 alone. Between 15,000 and 19,000 malpractice suits are brought against doctors each year.

Negligence is simply failure to exercise due care. The three ingredients of negligence are as follows:

1. The defendant owes a duty of care to the plaintiff

2. The defendant has breached this duty of care

3. The plaintiff has suffered an injury due to his breach. And in case of medical negligence mostly the doctor is the defendant. Negligence is predominantly a theory of liability concerning allegations of medical malpractice, making this type of litigation part of the Tort Law.

Civil Liability and Medical Negligence

Negligence is the breach of a legal duty to care. It means carelessness in a matter in which the law mandates carefulness. A breach of this duty gives a patient the right to initiate action against negligence. Persons who offer medical advice and treatment implicitly state and undertake to have the skill and knowledge to do as under: To undertake particular job.• To decide whether to take a case or not , To decide the treatment suitable for particular case• To administer that treatment.

This is known as an "implied undertaking" on the part of a medical professional. However, no human being is perfect and even the most renowned specialist could make a mistake in detecting or diagnosing the true nature of a disease. A doctor can be held liable for negligence only if one can prove that she/ he is guilty of a failure that no doctor with ordinary skills would be guilty of if acting with reasonable care. An error of judgment constitutes negligence only if a reasonably competent professional with the standard skills that the defendant professes to have, and acting with ordinary care, would not have made the same error. Doctors must exercise an ordinary degree of skill. However, they cannot give a warranty of the perfection of their skill or a guarantee of cure. If the doctor has adopted the right course of treatment, if she/ he is skilled and has worked with a method and manner best suited to the patient, she/ he cannot be blamed for negligence if the patient is not totally cured.Certain conditions must be satisfied before liability can be considered. The person who is accused must have committed an act of omission or commission; this act must have been in breach of the person"s duty; and this must have caused harm to the injured person. The complainant must prove the allegation against the doctor by citing the best evidence available in medical science and by presenting expert opinion.

Criminal Liability and Negligence

Indian Penal Code 1860 sections 52, 80, 81, 83, 88, 90, 91, 92 304-A, 337 and 338 contain the law of medical malpractice in India. A physician can be charged with criminal negligence when a patient dies from the effects of anesthesia during, an operation or other kind of treatment, if it can be proved that the death was the result of malicious intention, or gross negligence. Before the administration of anesthesia or performance of an operation, the medical man is expected to follow the accepted precautions.In such cases, the physician should be able to prove that he used reasonable and ordinary care in the treatment of his patient to the best of his judgment. He is, however, not liable for an error judgment. The law expects a duly qualified physician to use that degree of skill and care which an average man of his qualifications ought to have, and does not expect him to bring the highest possible degree of skill in the treatment of his patients, or to be able to guarantee cures."Gross Lack of competency or gross inattention, or wanton indifference to the patient's safety, which may arise from gross ignorance of the science of medicine and surgery or through gross negligence, either in the application and selection of remedies, lack of proper skill in the use of instruments and failure to give proper attention to the patient."

Case Report

- A 30 year old female from rural area was admitted with labour pain at 7:45 P.M., on clinical and ultrasonic examination, diagnosed as full term pregnancy with oligohydromnios.
- She was advised for cesarean section because of delayed labour with oligohydromnios. Patient attendant gave consent for operation at 9.00 P.M.
- Patient was operated and LSCS was done and patient was shifted to ward at 11:30 P.M.
- Next day at 4:00 A.M patient complained of dizziness and pain in lower abdomen, for this complaint she was given some injection by nursing staff.

- On repeated complaint she was not attended by any specialist Doctor and in the mean time she collapsed. At about 6:30 her attendant was informed that she died due to cardiac arrest.
- Patient attendant complained foul play and lodged FIR nearby police station, after conducting inquest police sent the body for postmortem examination.

Autopsy Examination

External Examination

Bloody vaginal discharge otherwise no specific finding.

General Examination

Patient look pale otherwise no specific fining.

Internal Examination

All viscera and vital organs are appeared pale.

- Heart was normal in size. Cardiac chambers contained few• ml of fluid blood, great vessels normal and coronaries patent.
- Both lungs were normal in size and cut section pale. No evidences of petechial hemorrhages or features suggestive of fat embolism.
- Stomach contained 60 ml of white colored fluid with semi digested food, with no specific odor, mucosa pale.
- Liver, spleen and kidney: normal in size and pale on cut section.
- Urinary bladder was empty.
- Uterus showing during postmortem examination with empty, enlargge and flabby and sign of recent delivery of baby by cesarean section are present.
- Hematoma in lower abdomen was found involving an extent of 19x16 c.m. covering both sides of lower abdomen and weight about 1500 gram.

- No evidences of petechial hemorrhages or features• suggestive of fat embolism.
- Skull and brain was found to be intact.

Discussion

- On the basis of history and examination of deceased, there was no adequate & timely monitoring of vital status and bleeding continued resulted to shock.
- In this case even though the cause of death is cardiac arrest, the treating doctor thought it is a case of death due to cardiac arrest.
- Failure to give proper postoperative care is included as instances of medical negligence.
- Thus by avoiding medical negligence we can bring improvements in monitoring care to a great extent possible and thereby preventing valuable human life from being a prey to accidents.

Opinion

Cause of death "hemorrhagic shock due to iatrogenic bleeding."

Conclusion

Due to failure proper post operative care result continue bleeding leading to shock culminating in death.