SEMESTER III

18BTU314A 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

Course Objectives: To understand the basic practical knowledge about planning of establishing a hypothetical biotechnology industry.

Course Outcomes: Students will able to know the filing the patent.

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: 18BTU314A **BATCH-2018-2021**

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	**PatentDrafting**	**GovernmentFee**
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. InvnTree 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 respectiveterritorial jurisdiction.

Office	Address	Territorial Jurisdiction
Mumbai	Intellectual Property Office, Boudhik SampadaBhawan, Near Antop Hill Post Office, S.M.Road,Antop Hill, Mumbai – 400 037.	The States of Maharashtra, Gujarat, Madhya Pradesh, Goa and Chhattisgarh and the

	Phone: 24137701, 24141026, 24150381, 24148165, 24171457 FAX :24130387 Email: mumbaipatent@nic.in	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 isprovided. Please note that, the fee mentioned is for E-filing only. The patent officecharges 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 Entity	Others except 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 sheetexceeding 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 thepatent 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 patentoffice 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 firstpage 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-3 PLANNING OF ESTABLISHING A HYPOTHETICAL BIOTECHNOLOGY INDUSTRY IN INDIA

Introduction

The biotechnology sector of India is highly innovative and is on a strong growth trajectory. The sector, with its immense growth potential, will continue to play a significant role as an innovative manufacturing hub. The sector is one of the most significant sectors in enhancing India's global profile as well as contributing to the growth of the economy.

India is among the top 12 biotech destinations in the world and ranks third in the Asia-Pacific region. India has the second-highest number of US Food and Drug Administration (USFDA)–approved plants, after the USA and is the largest producer of recombinant Hepatitis B vaccine. Out of the top 10 biotech companies in India (by revenue), seven have expertise in bio-pharmaceuticals and three specialise in agri-biotech.

India has no dearth of talent in biotechnology, as a number of institutions, both government and autonomous, provide the necessary opportunities for the students seeking to obtain a degree in this sector. The Government of India has provided adequate scope to this sector by providing facilities for Research and Development (R&D) in the field of biotechnology.

Market size

The Indian biotech industry holds about 2 per cent share of the global biotech industry. The biotechnology industry in India, comprising about 800 companies, is expected to be valued at US$ 11.6 billion in 2017. The government has to invest US$ 5 billion to develop human capital, infrastructure and research initiatives if it is to realise the dream of growing the sector into a US$ 100 billion industry by 2025, as per Union Minister for Science and Technology, Mr Harsh Vardhan.

Biopharma is the largest sector contributing about 62 per cent of the total revenue followed by bio-services (18 per cent), bio-agri (15 per cent), bio-industry (4 per cent), and bio-informatics contributing (1 per cent).

The high demand for different biotech products has also opened up scope for the foreign companies to set up base in India.

India has emerged as a leading destination for clinical trials, contract research and manufacturing activities owing to the growth in the bio-services sector.

Investments

India's biotech sector has attracted significant amount of attention over the past two decades. Several global companies have aggressively joined hands with Indian companies due to India's strong generic biotechnology potential. Some of the recent investments and developments in this sector are as follows:

- The Telangana state government's flagship pharma and biotech event - BioAsia 2017 attracted investments to the tune of Rs 3,382 crore (US$ 507.3 million).
- During the Vibrant Gujarat Global Summit-2017, 54 MoUs worth Rs 5,022 crore (US$ 736.1 million) in the biotechnology sector were signed by 37 companies.
- Syngene International Ltd, the contract research services arm of Biocon Ltd, is setting up a drug discovery and development center in Bengaluru for Amgen Inc., a biotechnology company based in the US.

Government Initiatives

A Network of Technology Centres and promotion of start-ups by Small Industries Development Bank of India (SIDBI) are among the steps taken by the Government of India to promote innovation and entrepreneurship in the agro industry proposed by the Ministry of Micro, Small & Medium Enterprises (MSME) in a new scheme. The Government of India has taken several initiatives to improve the biotechnology sector in the country as well as offer enough scope for research in this field. The Department of Biotechnology (DBT) along with other government funded institutions such as National Biotechnology Board (NBTB) and many other autonomous bodies representing the biotechnology sector, are working together in order to project India as a global hub for biotech research and business excellence. Some of the recent major initiatives are as follows:

- In the Union Budget 2017-18, the Department of Biotechnology (DBT) received Rs 2,222.11 crore (US$ 333.31 million), an increase of 22 per cent, to continue implementing the department's national biotech strategy and target increasing the turnover from the sector to $100 billion by 2025 from $7 billion in 2016.
- The Telangana government also inked an MoU with PE firm Cerestra to explore a 'Life Sciences Infrastructure Fund' with a corpus of Rs 1,000 crore (US$ 150 million) to create a sophisticated modular plug and play infrastructure for pharma, biotech and medical devices industry.

Road Ahead

With the country offering numerous comparative advantages in terms of R&D facilities, knowledge, skills, and cost effectiveness, the biotechnology industry in India has immense potential to emerge as a global key player.

India constitutes around 8 per cent of the total global generics market, by volume, indicating a huge untapped opportunity in the sector. Outsourcing to India is projected to spike up after the discovery and manufacture of formulations. Hybrid seeds, including GM seeds, represent new business opportunities in India based on yield improvement.

India currently has a marginal share in the global market for industrial enzymes. Hence, there is an opportunity in focused R&D and knowledge-based innovation in the field of industrial enzymes, which can innovatively replace polluting chemical processes into eco-friendly processes that also deliver environmental sustainability. Another interesting field of study is the area of bio-markers and companion diagnostics, which will enable to optimise the benefits of biotech drugs.

EX. NO-4 A CASE STUDY ON CLINICAL TRIALS OF DRUGS IN INDIA WITH EMPHASIS ON ETHICAL ISSUES.

Legal and Ethical Issues in Recent Clinical Research

It is true that India can provide a huge patient pool for CTs. However, the process of recruiting patients for CTs is questionable. Many a time, drug manufacturing companies prefer to recruit patients through local recruiters/agencies. A case study undertaken by Dateline shows that a pharmaceutical company paid $12 per patient for voluntary involvement in clinical trials (NBC, 2012).

Most of the patients are very poor and their average earning per day is 50 cent only (Hansen, 2012). Also, due to their economically poor background and lack of education, the patients are not aware of their involvement and the possible risk of injuries. Many a time they ignore the side effects like feeling weak or having body ache only because they are "monetarily compensated" for it. The payment works as an inducement. In fact, the patient can earn up to $400 depending on the length of study and this payment outstrips their general income (Dateline NBC, 2012).

The unethical practice of financial inducement—though seemingly an incentive—leads to enrolment of volunteers in more than one study at a time. This not only puts their lives in danger, but can also skew the accuracy of test results that pharmaceutical companies and regulators rely on to judge a drug's safety. Until now, many people have fallen sick and several deaths have occurred. The Indian government reports that across the country 13 more than 2500 people have died in clinical trials since 2005, many participating in studies for Western pharmaceutical companies. But it is unclear that how many people died or were injured due to their involvement in clinical trials because in many cases there are no proper systems of documentation of death registration. According to an affidavit filed by the Health Ministry in the Supreme Court in response to a petition by healthcare NGOs, there were 80 deaths due to clinical trials between January 2005 and June 2012. Further, between July 2012 and August 2013, nine more such deaths were reported (Biswas, 2013). However, compensation was paid only in 82 cases.

The Ministry of Health and Family Welfare also acknowledged that 2,644 people died during clinical trials of 475 new drugs between 2005 and 2012; and, 11,972 due to serious adverse events (excluding death) and out of which, 506 were said to have been caused by clinical trials (Biswas, 2013). There are several controversies regarding the number of deaths and injuries in CTs because different sources reported different numbers. According to the DCGI, there were 2,031 deaths during clinical trials between 2008 and 2011. Out of these, 668 had taken place in 2010, of which 22 were directly related to clinical trials. In these cases, the companies conducting the trials had paid varying compensations, but the DCGI was not aware of the amounts (Jain, 2013). Narayan (2013) has reported that since 2005, more than 2,800 patients have died during CTs and out of these, only 89 or about 3 per cent of the deaths occurred mainly due to the effects of the drugs under trial. Of these, 70 victims received compensation ranging from ₹1,80,000 ($3,000) to ₹4,20,000 ($7,000).

A study by The Tribune (2013) also reported that 666 deaths occurred alone in 2010; of these, 22 cases were attributed to deaths on account of clinical trials and the rest were attributed to past medical history of the trial participants. In 2011, this number reduced to 438, of which only 22 victims were paid compensation on account of clinical trials. In 2012, 436 deaths were recorded during clinical trials but compensation is yet to be paid with the government still ascertaining the number of deaths that have occurred due to trials (The Tribune, 2013).

Sources	*Year*	*Number of deaths*	*Number of injuries*	*Location*	*Compensation received*
Swasthya Adhikar Manch	2005–2012	89		All India	82
Ministry of health and family welfare	2005–2012	2,644	11,952	All India	NA
DCGI	2008–2011	2,031	NA	All India	NA
DCGI	2010	668	NA	All India	NA
Narayan (2013)	2005–12	2,800	89	All India	70
Bhatnagar (2013)	2004	14	NA	Bhopal, India	0
Bhatnagar (2013)	2005–10	32	NA	Indore, India	0

During clinical trial, a patient can die because of several reasons: life threatening diseases like cancer, cardio-vascular diseases like heart failure/stroke and other serious diseases that the

participant may have be suffering from in the past. Death can also occur due to adverse effects of the trials. However, there is no standard protocol for post-mortem mechanism to investigate it (Biswas, 2013).

The pharmaceutical companies conduct investigations only to ascertain the cause of death: whether it was the result of a clinical trial or simply because of a pre-existing disease. Compensation is to be given only if a death is said to have been caused due to clinical trial. Also, the amount of compensation varies across different companies. But now, the government is in the process of fixing a minimum compensation amount in case of death or injuries sustained during the course of the trials. The Ministry of Health and Family Welfare has authorised DGCI to determine the amount of compensation to be given in case of death or injuries sustained during trials (The Tribune, 2013).

Another unethical practice is the simultaneous conduct of Phase II and Phase III trials by CROs. Clinical trial laws were amended in 2005 to help familiarize India with international clinical research activities as well as allow for Phase II and Phase III trials to be conducted concurrently. Before 2005, Phase II and Phase III trials were allowed with a phase lag—that is, after their gross safety aspects were somewhat known abroad (Srinivasan, 2013). These concurrent clinical trials may have a serious adverse effect on the trial participants, for instance, causing disability or permanent damage or death.

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 labor (<=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 labor 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.

Ethical issues concerned with consent for intrapartum trials

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 bestevidence 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 wasshifted to ward at 11:30 P.M.
- Next day at 4:00 A.M patient complained of dizziness andpain 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 postoperative care result continue bleeding leading to shock culminating in death.

EX. NO-7 CASE STUDY ON HANDLING AND DISPOSAL OF RADIOACTIVE WASTE

The objective of this study is to provide an overview of the current management of radioactive and hazardous wastes. Its intended audience is policy makers and interested stakeholders. This work has two themes that compare:

• radioactive and hazardous wastes and their management strategies in general;

• the management of wastes arising from coal and from nuclear power generation in particular. These two themes provide two distinct perspectives.

The first illustrates that the disposal of radioactive waste is not a uniquely difficult issue, as is sometimes perceived.

The second compares the wastes arising from two of the probable low-carbon baseload electricity generating technologies to be used in the future: nuclear power and coal-fired generation with carbon capture and storage.

Neither technology is without its waste challenges, although they are very different, and both will rely to varying degrees on geological storage. The goal of these comparisons is to illustrate similarities and differences in these wastes and their management. Aspects of the wastes and their management that are examined include the inherent hazards of the waste, risks posed, regulatory requirements applied, treatment and disposal methods, risk communication, and social acceptance of disposal facilities and practices.

Both radioactive and hazardous wastes (a term used in this report for potentially dangerous non-radioactive wastes) are strongly regulated and safely managed. The principles applied to the management of both waste types are essentially the same.

The safe disposal of radioactive waste is not the uniquely difficult issue that is perceived by the media, much of the public and by many politicians: • Radioactive waste is produced in much lower quantities than hazardous waste. • Low-level and short lived intermediate-level wastes (LILW-SL) are already being disposed to repositories in many

countries. On a volumetric basis, some three quarters of all the radioactive waste created since the start of the nuclear industry has already been sent for disposal. • Whilst concern is expressed that some radioisotopes in waste decay so slowly that they remain potentially dangerous for very long periods of time, some hazardous wastes (e.g. mercury, arsenic) have infinite lives.

Radioactive wastes arise from the nuclear industry, from other industrial sources and from medical applications. The eventual safe disposal of all categories is a necessity with or without any further construction of nuclear power plants. There is a worldwide consensus amongst technical experts in the field that properly established deep geological disposal is an entirely appropriate management approach for high-level waste and spent nuclear fuel (HLW/SF). While facilities exist in many countries for LILW-SL there is, as yet, no facility for HLW/SF.

Theme 1 – Radioactive and hazardous wastes and their management strategies

The comparison between radioactive and hazardous wastes and their management strategies is intended to provide policy makers with a broad perspective on the similarities and differences between the waste types in the following areas:

• waste types: definitions, quantities and sources;

1. However, given the low volumes of waste, some three quarters of the radioactive waste from all sources so far generated has been sent for disposal.
   • risks and hazards;
   • ethics and management principles;
   • legislation and organisation;
   • waste management approaches before disposal;
   • management and disposal options;
   • licensing and safety assessment for disposal;
   • costs and financing.
   The scope of this theme is:

• the wide spectrum of solid hazardous wastes that arise in a modern industrial society;

• solid radioactive waste generated from civilian sources, primarily nuclear power production;

• developments in the management of mercury containing wastes, used as an example of a particular hazardous waste stream.

This theme neither includes gaseous or liquid effluents nor waste from military uses of nuclear power.

Theme 2 – Wastes arising from coal and from nuclear power generation

This theme is intended to provide policy makers with a broad perspective on the similarities and differences between management of wastes from nuclear and from coal generation in the following areas:

• waste quantities;

• waste properties and disposal;

• recycling waste to extract economic value;

• impact on climate change;

• economic issues;

• development status;

• safety; • regulation;

• stakeholder issues.

This report covers all types of radioactive waste generated in the civil nuclear fuel cycle and focuses in particular on the disposal of HLW/SF, which contains the vast majority of the radioactivity and is the most contentious. Wastes from the mining and milling of uranium ores are considered in terms of the quantities produced. The report does not deal with radioactive waste generated by military activities, although this is mentioned in some places for the sake of completeness. The report does not deal either with naturally occurring radioactive materials (so called NORM) which can be generated in significant quantities by other non-nuclear industries. 16 Nuclear power and coal generation with CCS are both seen in many countries as elements in a portfolio of technologies to reduce the impact of climate change. Comparison between wastes

arising from coal and from nuclear power generation should not therefore imply that nuclear power and coal generation with CCS are necessarily in competition or mutually exclusive; it is likely that both will be needed in considerable quantities to achieve the necessary reduction in emissions of climate change gases. It should be noted that both nuclear power and CCS depend for success on the implementation of geological disposal for their waste products albeit that carbon dioxide is not considered to be a hazardous waste.

Theme 1 – Radioactive and hazardous wastes and their management strategies

In volume terms, the global generation rate of hazardous waste is up to three order of magnitude higher than that of radioactive waste from the nuclear power industry; almost all industries and households generate hazardous waste, but most radioactive waste comes from a very few sources – primarily electricity generation.1 Taking the United States as an example, there are in the order of 100 times more large hazardous waste generators than radioactive waste generators. Radioactive wastes, particularly those generated by nuclear power plants, also have well-known constant characteristics, which is a considerable advantage in being able to predict their behaviour when disposed to a repository.

Waste characteristics, and therefore management strategies, are

1. Radioactive waste is also generated in very significant quantities by military activities, by research and development, medical applications and by various other non-nuclear industries. This report focuses on the civil uses of nuclear technology for the production of electricity. Some waste streams are both radioactive and toxic (so called mixed wastes), presenting management difficulties from both aspects. It should also be recognised that some radioactive waste streams contain lead and stable lead will ultimately be the natural decay product of some radio-nuclides. Lead is, itself, a hazardous material in waste. 10 fundamentally different between hazardous waste (which can have a range of hazardous characteristics making it flammable, oxidising, corrosive, reactive, explosive, toxic (including carcinogenicity) or ecotoxic) and radioactive waste which, in broad terms, has

only radioactivity (which can cause serious tissue damage or fatalities at high doses and which may cause cancer in the long term at lower doses) as a hazard.

Radioactivity decays predictably over time (albeit that for some isotopes this is over a very long timescale), so the hazard associated with radioactive waste continuously reduces. Whilst much hazardous waste can be fully treated to pose virtually no hazard before it is disposed, the intrinsic hazards in some hazardous wastes remain for all time. In this sense there is a parallel between the most difficult wastes arising from the two categories; longevity is not unique to radioactivity. The unit costs of managing hazardous waste are considerably lower than for managing radioactive waste. Hazardous waste management is generally carried out on a commercial basis with immediate payment for services received; for radioactive waste, funds are generally built up from electricity generation revenues to pay for future disposal in facilities that may not yet exist.

In most cases, market forces drive early implementation of hazardous waste management facilities in a way that is not seen for radioactive waste. The implementation time for hazardous waste management facilities is generally much shorter than for radioactive waste facilities; gaining socio-political acceptance for hazardous waste disposal appears easier than achieving acceptance for geological disposal of radioactive waste. This may be due to differing public perceptions regarding the risks posed by radioactive and hazardous waste disposal facilities. Theme 2 – Management of wastes from coal and from nuclear power generation. In 2007, about 40% of the world's electricity came from coal and 14% from nuclear generation. Globally, coal generation produces about 11 000 Mt/a (1 700kt/TWh) of wastes (including 10 500Mt/aof CO2; 1 600kt/TWh) and additionally some 20 000 Mt/a (3 000kt/TWh) of mining wastes. Nuclear generation, taking into account the wastes from plants that will eventually be decommissioned, produces

The management of mercury waste –

A case study Mercury is an example of a highly toxic, hazardous chemical.

The case study describes the production rates and sources of mercury and explains some of its hazard characteristics. The aim is to present a perspective on the management and eventual

geological disposal of highly toxic mercury waste streams. The annual global contribution to the mobilised pool of mercury has been estimated as 13 500 tonnes. To provide a perspective, this amount is in the same order of magnitude as the annual global HLW/SF arising from the world's nuclear power plants. Because the hazard from mercury does not diminish with time, when it is disposed of it must be isolated from man and the environment, effectively forever. In order to cope with safety requirements over long periods, without the need for monitoring and intervention, the trend for managing mercury waste is towards deep disposal.

The isolation needed for mercury wastes is therefore of a similar nature to, but even more demanding than those for high-level radioactive waste. Mercury waste provides a useful comparison with radioactive waste in that:

• It has a significant health impact if inappropriately managed.

• Mercury and mercury containing compounds will always remain toxic: they are typical of hazardous chemical substances requiring long term safe management and disposal – in this sense they present similar challenges to the management of radionuclides of especially long half lives.

• In a number of countries the management of mercury and similar wastes has adopted the same route as that proposed for long-lived radioactive waste: deep geological disposal. Health effects Mercury and its compounds can have a significant impact on health on local, regional and global scales since it can be highly toxic to humans, ecosystems and wildlife. High doses can be fatal, but relatively low doses can also have serious adverse impacts to the developing nervous system. There are indications of possible harmful effects on the cardiovascular system and the immune and reproductive systems, although there are exposure thresholds below which no adverse health effects are expected to occur. Mercury has not been found to be carcinogenic. Possible routes for intake and damage are connected to its chemical form, methyl mercury being the most hazardous. Inappropriate management of mercury has caused a variety of significant impacts on human health and the environment throughout the world.

As examples, the Minimata disease in Japan was caused by spilled mercury that bio-accumulated in fish and other seafood, a main source of food for local people; 3 000 people were affected. In Iraq mercury poisoning affected some 6 000 people due to consumption of seed that had been treated with fungicides containing mercury. Management of wastes containing mercury Some mercury can be recovered from waste for reuse. While many devices that have typically used mercury have been replaced with mercury-free alternatives (e.g., thermometers, switches, medical devices such as sphygmomanometers), there remain some legitimate uses for mercury, such as in lamp manufacture. Recovery and reuse of the mercury can reduce mining of new mercury to 37 supply these needs. The US waste regulations require mercury recovery for reuse from wastes containing more than 260 mg/kg mercury.

A programme on mercury waste and its environmentally sound management is being carried out under the Basel Convention, including production of draft technical guidelines to facilitate safe management. The United Nations Environment Programme is carrying out a comprehensive programme to understand mercury issues with a view to reducing risks for humans and the environment. The EU also has a strategy which includes looking for long term disposal solutions.12 Disposal strategies and technologies currently differ significantly between countries. Waste containing mercury has been disposed in specially engineered landfill, underground caverns and near surface pits.

Increasingly there is a trend to its disposal deep underground in stable geological formations. In 2005, Sweden was the first EU country to pass legislation requiring deep geological disposal for all waste with mercury content above 0.1%. Sweden is currently building a disposal facility in granite rock connected to a deep mine. Deep geological disposal of long-lived hazardous wastes is currently carried out in deep (700 m) salt formations in Germany where four mines are in use. Facilities are being developed in several countries to allow the long-term safety without the need for monitoring and intervention. Mercury and its compounds are highly toxic and present risks to human health and the environment over long periods that require some precautions that are similar in some ways to those needed for long-lived radioactive waste, particularly safe permanent disposal.