Comparative Study on the Patent Filing Procedure in India, Europe and USA

A THESIS

SUBMITTED IN PARTIAL FULFILLMENT

OF THE REQUIREMENTS FOR THE DEGREE OF

MASTER OF PHARMACY

IN

DRUG REGULATORY AFFAIRS

By

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Annexure I

INDIA'S LARGEST UNIVERSITY

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Discipline: M. Pharm (Drug Regulatory Affairs)

PROJECT/DISSERTATION TOPIC APPROVAL PERFORMA

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PROPOSED TOPICS

1. Preparation of Patent Application for a New Pharmaceutical Product in India
2. A Comparative Study on the Patent Filing Procedures in India, Europe and USA
3. Drafting and Filing a Patent in India for a Pharmaceutical Product

Signature of Supervisor

*Guide should finally encircle one topic out of three proposed topics and put up for approval before Project Approval Committee (PAC)

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DECLARATION BY THE CANDIDATE

This is to submit that this written submission in my thesis entitled "Comparative Study on the Patent Filing Procedure in India, Europe and USA" represents original ideas in my own words and where others' ideas or words have been included, I have adequately cited and referenced the original sources. I also declare that I have stuck to all principles of academic honesty and integrity and integrity and have not misrepresented or fabricated or falsified any idea/ data/ fact/ source in my submission. I understand that any violation of the above will be cause for disciplinary action by the school and can also evoke penal action from the sources which have thus not been properly cited or from whom proper permission has not been taken when required.

Patents related to API, process, product, method and equipment, if any, have been examined to ensure non-infringing approach to the existing patents.

This thesis encompasses the information generated by me based on experimental work carried out in the Institute. I assure and hold full responsibility for its genuineness.

_____

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Forwarded Through

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CERTIFICATE

The work described in this thesis entitled "Comparative Study on the Patent Filing Procedure in India, Europe and USA" has been carried out by Pankaj Sharma under my supervision. I certify that this is his bonafide work. The work described is original and has not been submitted for any degree to this or any other university.

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TO WHOMSOEVER IT MAY CONCERN

This is to certify that **Mr. Pankaj Sharma**, a student of M. Pharmacy (Regn. No. 10903393) of Lovely Faculty of Applied Medical Sciences, Lovely Professional University, Phagwara, Punjab has interned with us from January 02, 2015 to March 31, 2015.

During the period of internship, he ably assisted in drafting patent specifications and conducting patent searches. He also studied and researched about patent filing procedure and practice in India, Europe and the United States of America.

He is diligent and hardworking.

We wish him good luck for all his future endeavours.

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DEDICATED TO……

MY FAMILY

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Lastly, but not least, I would like to thank all those who were directly or indirectly assisted in completion of this work.

Pankaj Sharma

ABSTRACT

Patent is a legal right for grant of patent to the patentee for his new idea, method, product etc. for a limited time period by the government. In this work the patent law for patent grant in India, Europe and USA were compared. The patent law is quite similar in these countries. The difference is mainly in the patent filing procedure. The patent system is divided into two parts, first is patent filing procedure and second is the patent grant procedure. The procedure starts with the filing of application for the grant of patent. This is followed by the second step which includes the search, publication and examination. If the application fulfils all the requirement of the patent law then the patent is granted. A detailed comparison of patent filing procedure in India, Europe and USA on the basis of language, type of patent, independent claims, grace period, patent term, number of additional sheets etc. is contained in this work. Some case studies related to the patent law have also been incorporated.

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LIST OF ABBREVIATIONS

Abbreviation	Description
ADS	Application Data Sheet
AIA	American Invents Act
AIPS	American Inventors Protection Act
BDP	Bacterial Diarrhea Proteins
CFR	Code of Federal Regulation
CIP	Continuation in Part
CMC	Carboxy Methyl Cellulose
EPC	European Patent Convention
EPO	European Patent Organisation
FER	First Examination Report
HPMC	Hydroxyl Propyl Methyl Cellulose
HYPM	Hydroxylated Polymethacrylate
IDS	Invention Disclosure Statement
IPEA	International Preliminary Examining Authorities
IP	Intellectual Property
IPO	Indian Patent Office
ISA	International Searching Authorities
ISR	International Search Report
MPEP	Manual of Patent Examining Procedures
NARA	National Archive and Records Administration
PCT	Patent Co-operation Treaty
RCE	Request for Continued Examination
SF	Stability Factor
SISA	Supplementary International Searching Authorities
TSM	Teaching Suggestion Motivation
USC	United State Code
USPTO	United State Patent and Trademark Office
WIPO	World Intellectual Property Organisation

CHAPTER 1

INTRODUCTION

Chapter 1

INTRODUCTION

Patent is a legal right for any discovery, ideas approved for a narrow period of time to the patentee by the government in exchange of his discovery. Patent gives safety to the patentee for his new discovery. The safety is approved for 20 years. Patent safety means the other person cannot manufacture and distribute the product without taking permission from the patentee. When the patent time limit expires the protection also comes to an end and the patentee no longer holds the right to the discovery. Any discovery, related to the product and process that is useful for industrial application and is new can be patented. The patent filing procedures differs from one country to another. [1]

1. Patent Filing Procedure in India

1.1 What is invention- Section 2(1)(j) of the Patents Act, 1970 ('the Act') defines the inventions as **"**invention means a new process and product which is non-obvious and useful for industry".[2]

1.2 What is novelty- Section 2(1)(l) of the Act defines new inventions as "new invention means any technology and invention which is not available in any country or any published document before the filing of patent application" is known as novelty.[2]

1.3 What is inventive step- Section 2(1)(ja) of the Act defines inventive step as "inventive step means a feature of an invention that involves technical advance as compared to the existing knowledge or having economic significance or both and that makes the invention not obvious to a person skilled in the art".[2]

1.4 What is industrial applicability- Section 2(1)(ac) of the Act defines industrial applicability as "industrial applicability means that any method or technology being made which is useful to industry".[2]

1.5 Invention not Patentable[3]- Section 3 of the Act mentions different types of inventions which will not qualify for a patent even if they satisfy the requirements of section 2(1)(j) of the Act, namely:

a) Any invention which is against the natural law
b) Any invention which produce harmful effect to plant, animal or human life

c) Any discovery related to abstract theory and scientific principle
d) A technique of agriculture
e) Any method for the surgical, medicinal or other care of human beings
f) Presentation of information
g) Topography of integrated circuits
h) A dramatic, cinematography, literary, television production and musical artistic.
i) A numerical or business techniques
j) Method, scheme and rules for performing mental acts, programs for computers
k) Visual creation

Any "invention falling within subsection (1) of Atomic Energy Act, 1962 (33 of 1962)" are not patentable under section 4 of the Act

1.6 Types of patent application

Application for patents can be of following types:

1. Ordinary application
2. International/PCT application
3. Convention application
4. Application for addition
5. Divisional application

Ordinary application[4]

It is also called non-provisional application. This application contains the claims and the complete specification. It is submitted in the patent office without any reference to other application. In the patent application, name and address of first and true inventor must be given.

The important documents of the patent application are:-

- Form 2 "Complete or provisional specification"
- Form 3 "Statement and Undertaking"
- Form 5 "Declaration as to inventor ship"
- Priority document
- Power of attorney

International/PCT application[5]

PCT application is also known as international application. It was introduced in the year 1970. The main purpose of this application is to give safety to the inventor for his idea or discovery in the world. In PCT, there are 148 countries. Instead of filing several regional or national applications the applicant can file a PCT application and protects his invention in these 148 countries.

In PCT national phase application the applicant must attach a complete specification which include title, drawing, abstract description and claims. 31 months time period is fixed for entering into the national phase from the priority date. PCT national phase application can be examined any time before this time limit.

IPO as Receiving Office[6]

- The receiving office sends the search copy of the application to the ISA.
- An applicant can file an international application in a language other than the language which is accepted by the ISA for carrying a search. In this case the applicant will have to provide a translation of the application into the following languages:
  - a dialect acknowledged by the ISA
  - Publication language
  - a dialect acknowledged by the receiving office under Rule 12.1(a), unless the global application is documented in a published language.
- The office is competent only if the international search has been carried out by Swedish Patent office or by Austrian Patent and Registration Offices.

IPO as ISA (International Searching Authorities)[6]

- ISA notifies the applicant that the search copy has been received in Form PCT/ISA/202 and sends a copy of the notification to the International Bureau (IB).
- The language accepted for international search is English.

The other important points are:

- The topics indicated in subsections (i) to (vi) of PCT Rule 39.1 are not searched.
- There is no need to submit the separate power of attorney.
- ISA must create the international search report (ISR) and written opinion within 3 months from the date of receipt of the search copy.

- Once the written opinion and ISR are created then the ISA transmits one copy to the applicant and International Bureau on the same day.

IPO as IPEA (International Preliminary Examining Authorities)[6]

- International preliminary examination (IPE) is a non-compulsory part of the processing of an international patent application which is performed when the applicant files a 'demand'.
- Its primary objective is to formulate questions related to the invention which the applicant claims to be novel, has an inventive step or has an industrial application.
- The second objective is to identify whether there are any problems in the contents of the application.
- The result of the IPE is recorded by IPER and copy of the report is sent to the International Bureau.
- The International Bureau communicates the report to each elected office.

Convention application Section 135 of the Act[7]

According to the Act, convention application is defined as the application filed by the applicant in one or more convention country. After filing the application in convention country the applicant again files the same application at the patent offices of India within 12 months.

Application for Addition Section 54 of the Act[8]

The application is filed by the applicant in the IPO if any improvement or modification is made to the invention. The time period is the same as time for granting the patent and it is not extended.

Divisional application Section 16(1) of the Act[9]

This application is used when the applicant claims more than one invention and law does not allow multiple patents in one invention. The applicant sends a request application to the patent office before the grant of patent and divides the applications in two parts. Following this approach, it is not mandatory for the applicant to submit the complete specification in the first part of application. In the second part of application the applicant must submit the complete specification within the specified time period. If the applicant does not submit the complete specification in a given time period then the application is rejected by the IPO.

1.7 Person entitled to apply for patents Section 6 of the Act[10]

a. According to the section 134, application seeking the grant of patent can be filed by the following persons:

- First and true inventor of the invention
- First and true inventor assignee a person who represents the invention on his/her behalf
- Legal representative of the inventor

b. Under sub-section (1) of the Act, the applicant can make a patent application either alone or joint with other persons.

1.8 Types of Patent Specification

There are two types of specifications

1. Provisional specification section 9 of the Act
2. Complete specification: section 9 of the Act

Provisional specification[11]

This is filed when the applicant feels that his discovery/idea has reached the stage that it can be disclosed in the form of a written report. In this case provisional application is submitted to the patent office and it helps to preserve the priority date of the application. After receiving the provisional specification, the patent office gives an application number to the patent application.

Complete specification[11]

It is very important document in a patent application for the grant of patent, the applicant must submit it within 12 months from the date of filing of provisional application. In this application, applicant gives a complete description of his invention. The submission of complete specification period can be extended by 3 months.

1.9 Content of specification Section 10 of the Act[12]

1) **Title:** The title of the patent should describe the subject matter in the patent application.
2) **Field of invention:** The field of invention is a general wide statement telling about the technology of the invention.
3) **Background:** The background is used to describe the statement of the technology, the known prior art, the disadvantages/needs that are being overcome before the invention

described in the patent. The background identifies the key features of the invention that were lacking in the prior art.

4) **Summary:** The inventions are represented in a summarized form in this section. The information in this section is related to the steps taken to solve the problem which was discussed in the background of invention. This section also describes the advantages of the invention.
5) **Description:** It starts with the background of previous invention and also includes information about the present invention like process and products or its parts. It must be written in detail as per the rules of the Act.
6) **Claims**

- Claims must be clear and brief.
- It must describe the technical features of the invention.
- Important features of the invention must be stated in the independent claim.
- Only one independent claim should be present in the same category of the application.
- Independent claim should be followed by one of more dependent claims.
- Use Arabic numerals for numbering the claims
- The wording used in claim should be such way that it does not produce any doubt between the descriptions and claims.

7) **Abstract:** It is a short summary of invention and its uses. It should preferably be written in 150 words and should consist of the following.

- Invention description
- Description of the important component and their work

8) **Drawing:** The drawing of a patent specification describes the invention by using chemical or mechanical structures, charts and graphs and detailed relationship of features. The drawing contains references as (numeric and alphabetic) that relate the features described in the specification to the corresponding features or portion shows in the drawing.

1.10 Forms[13]

There are total 28 forms. The important ones and the information to be provided in their form are given below:

1. **Form 1**- Application for the grant of patent section 7, 54 and 135 and rule 20(i)

Form 1 is filed for the proof of right. It gives information about first and true inventor and declaration by the inventor that the applicant is the legal representative or assignee of the inventor. It is filed in duplicate within 6 months from the date of filing of the application.

2. **From 2**- Complete and provisional specification section 10 rule 13

An applicant attaches the complete specification report with Form 2 in which he gives the complete information about the invention. The content of the specification are title, background of the invention, description of the invention, drawing, claims or abstract.

3. **Form 3**- Statement and Undertaking under section 8(1) section 8(2)and rule 12

Section 8(1) and section 8(2) of the Act "requires an applicant to furnish details of the corresponding applications filed outside India on Form 3 at the time of filing an application in India or within 6 months from the date of filing. The Controller would be informed to applicant in writing from time to time regarding the detailed particulars of every other application relating to the same or substantially the same invention, if any filed in any country outside India".

4. **Form 5**- Declaration as to Inventorship section 10(6) and rule 13(6)

This form is filed at any time before the expiration of 1 month from the date of filing of application.

5. **Form 18**- Request for Examination of patent application section 11B and rules 20(4)(ii) and 24B(1)(i)

- Applicant must file a request of examination within 48 months from the date of filing of application.
- In case no request of examination is filed by any interested person or applicant within 48 months from the date of filing or date of priority, the application shall be treated as withdraw by the applicant.

6. **Form 9**- Request for publication section 11A(2) and rule 24A [optional]

The applicant may in form 9 request the Controller to publish the application at any time before the expired of 18 months time period and such application will be published within 1 month from the date of request.

7. Form 26 Authorisation of Agent Section 127, 132 and rules 135

In this form "give an information about the agent of any document relating to any proceeding or matter under the Act or these rule shall be deemed to be service upon the person so authorising him and communication directed to be made to a person in respect of any proceeding or matter may be addressed to such agent".

1.11 Fees[14]

There are two types of filing and that are e-filing and physical filing. The fees are based on the type of filing:-

For e-filing*:

Table 1.1 Patent filing fees in India

Number of entry	On what payable	No. of form	For natural person(S)	For person other than natural person(S) either alone or jointly with natural person(S)	
				For small entity	For other except small entity
			Rupees	Rupees	Rupees
1.	On application for a patent under sections 7, 54 or 135 and rule 20(1) accompanied by provisional or complete specification	1	1600	4000	8000
	(i) For each sheet of specification in addition 30		(i) 160	(i) 400	(i) 800
	(ii) For each claim in addition to 10		(ii) 320	(ii) 800	(ii) 1600

2	On filing complete specification after provisional upto 30 pages having upto 10 claims. (i) For each sheet of specification in addition to 30 (ii) For each claim in addition to 10	2	No fee (i) 160 (ii) 320	No fee (i) 400 (ii) 800	No fee (i) 800 (ii) 1600
3	On filing a statement and undertaking under section 8	3	No fee	No fee	No fee
4	Declaration as to inventorship	5	No fee	No fee	No fee
5	On request for examination of application for patent (i) Under section 11B and rule 24(1) (ii) Under rule 20(4)(ii)	18	(i) 4000 (ii) 5600	(i) 10000 (ii) 14000	(i) 20000 (ii) 28000

10% surcharge on physical filing

1.12 Publication[15]

After filing the application form, the applicant is required to publish a journal which contains name, address, abstract and procedure of invention to the patent office. This should be done within 18 months after filing the application form or from the date of priority, to the patent office. After this procedure the patent application is open for public inspection. Before publication it is not open for public inspection.

1.13 Examination[16]

The applicant who has filed for the patent undergoes the procedure of examination in which all the documents, application forms, claims forwarded by the applicant are tested. After testing of the reports, a First Examination Report (FER) is published and sent by the

patent office to the applicant or his agent stating the objections to which the applicant or his agent has to reply within 6 months. In case the applicant fails to reply to the report and an extension of 6 more months is given to the applicant.

1.14 Opposition to the patent[17]

After the FER the patent office searches for the same patent type in their offices to ensure that the patent applied for invention is valid there is no other claim or there is no other patent holder of that invention already in the past.

1.15 Grant of patent[18]

When all the criteria are met the patent is issued to a person for 20 years. If there is opposition to the patent another person can file within a year of publication of patent.

1.16 Drafting of a Patent Specification[19]

First step: Information/document required from Inventor, Invention Disclosure Form (IDF) which should include all information.

Second step: Prepare strategy for drafting and figure out the relevant method of drafting such problem - solution, could- would, Teaching Suggestion Motivation (TSM) etc.

Third step: Confirm your understanding with the inventor.

Fourth step: Prepare claims of the specification and confirm the scope and technical disclosure with inventors.

Fifth step: Draft the description, abstract, drawing/s of the specification

Sixth step: Share the full petition with the inventor to confirm

Seventh step: File a patent application based on the drafted patent specification

By taking an example of aceclofenac

In this draft, problem solution approach has been adopted. Technical problem has been mentioned in the background section and the solution to the said problem has been described in the following sections of the specification.

TITLE: Bilayered Tablet dosage form of Aceclofenac and method of preparation.

FIELD OF THE INVENTION

The present invention provides a bilayered tablet dosage form comprising a) first layer which was formulated by 30% Aceclofenac with Betacyclodextrin and pharmaceutically accepted excipients. b) Second layer was formulated by 70% Aceclofenac with pharmaceutically acceptable excipients.

BACKGROUND OF THE INVENTION

Aceclofenac is an analog of diclofenac. It is a non- steroidal anti-inflammatory drug (NSAIDS). It is used for providing relief from the pain and inflammation in rheumatoid arthritis and osteoarthritis. There are many analgesic- antipyretic drugs that have maximum effectiveness only for a few hours like 4 to 6 hours. So, such medicines have to be taken at least 2 to 3 times in a day which is undesirable. Aceclofenac is insoluble in water so we need suitable solublizers to improve its bioavailability. Aceclofenac bilayer tablet is prepared by different pharmaceutically acceptable ingredients. In this the first layer is immediate release which releases aceclofenac into the blood stream to initiate and achieve peak level concentrations as desired, within 5 minutes, and second layer is the sustained release. The purpose of the present invention is that release of the therapeutically active agent occurs such that blood level of it is maintained within a desired therapeutic range over an extended period of time. The dissolution and disintegration requirements are conducted by the using the equipment and test which is specified in the United State Pharmacopeia XXII. In the formulation of first layer, total 30% aceclofenac is used and for formulation of second layer, total 70% aceclofenac was required. The pharmaceutical acceptable excipients selected were PVP, hydroxyl propyl methyl cellulose (HPMC), carboxy methy cellulose (CMC), glyceryl monosterate poloxamer and surfactants based on hydrogenated castor oil (PEG-60, PEG-40). The immediate layer was prepared by the dry granulation process and sustained release layer was prepared by the dry granulation method and the two grades of granules were compressed by using the C-300 or CTX II A Catmark Rotary Tablet Press. Betacyclodextrin is used only for the formulation of immediate release layer.

OBJECT OF THE INVENTION

Accordingly, the object of present invention is to provide uniform blood level concentration over 12 hours to 24 hours a day. A bilayer oral dosage form of the water insoluble drug is formulated with a first layer which offers immediate release. The second layer is for sustained release of drug due to which the therapeutic active agent is released

in blood and is maintained in its desired range upto 12 to 24 hours. The first layer is for immediate release of aceclofenac into the blood stream so as to initiate and achieve peak level concentration of aceclofenac within 15 minutes.

DESCRIPTION OF THE INVENTION

Aceclofenac being insoluble in water needs to be combined with the solublizers to improve its bioavailability. It is used for providing relief of pain and inflammation in rheumatoid arthritis and osteoarthritis. It is desirable to introduce patient friendly dosage forms that need to be taken only once a day and yet ensure uniform concentration of the drug in the serum for a 12 to 24 hour period. A bilayer oral dosage form of the water insoluble drug is formulated with a first layer which offers immediate release and a second layer which offers the drug from a sustained release matrix core over 12 hours to 24 hours a day. The first layer is for immediate release of aceclofenac into the blood stream so as to initiate and achieve its peak level concentration within 15 minutes as desired for satisfactory therapeutic effects.

The immediate release component was prepared by mixing 30% of total aceclofenac with betacyclodextrin along with pharmaceutically acceptable excipients and it is prepared by the solvent/water based dissolution followed by dry granulation process.

The sustained release component was prepared by mixing 70% of the total aceclofenac with pharmaceutically acceptable excipients selected amongst PVP, HPMC, CMC, glyceryl monosterate poloxamer and surfactants based on hydrogenated castor oil (PEG-60, PEG-40).

The two grades of granules were compressed by using a C-300 or CTX II A Catmark Rotary Tablet press. The dissolution and disintegration requirements were verified by conducting tests specified in the USP XXII

The highlights of this product are:

1. Rapid availability in bloodstream and hence early onset of relief.
2. Uniform plasma level concentrations of aceclofenac over prolonged period.
3. Lower frequency of dosage and hence better patient compliances.

EXAMPLE 1

Table 1: Composition of Aceclofenac bilayered tablet

No	Ingredients	% Composition
	Immediate release layer	
1	Aceclofenac	30%
2	Betacyclodextrin	5% to 10%
3	Pharmaceutical excipient	2% to 3%
	Sustained release layer	
4	Aceclofenac	70%
5	Hydroxyl propyl methyl cellulose	40% to 50%
6	1-venyl 2-pyrrolidone	50% to 60%
7	Pharmaceutical excipient	5% to 10%

Procedure: The immediate release layer is prepared by taking 30 gms aceclofenac and dissolving it in 50 ml solvent selected from acetone and ethyl alcohol and then mixing this solution with betacyclodextrin (50 gms) dissolved in 30 ml de-ionized water. The mixture is evaporated with moderate heating (40^{o}C to 50°C) to form a uniform paste of aceclofenac- betacyclodextrin complex. The complex so obtained is subjected to dry granulation by precompression followed by granulation and is then blended with lubricants.

The sustained release layer is prepared by taking 70 gms of aceclofenac and dissolving it in either 50ml of acetone or ethyl alcohol or a combination of 50gms of HPMC and 30 gms of Povidone, followed by addition 0.5gms of sodium lauryl sulphate and 50ml of deionized water. The resulting solution was spray dried to produce a solid powder using a standard spray dryer. The solid powder is subjected to dry granulation by precompression followed by granulation and is then blended with lubricants.

The granules of the immediate release layer and the granules of the sustained release layer are directly fed into the tablet compression machine to obtain a standard bilayer tablet. The tablet is subjected to standard tests such as disintegration, dissolution as well as bioavailability studies.

We Claim

1. A pharmaceutical composition, comprising:
   a first layer formulated by 30% of Aceclofenac with Betacyclodextrin and selected pharmaceutical excipients; and
   a second layer formulated by 70% of Aceclofenac and said pharmaceutical excipients.
2. A pharmaceutical composition as claimed in claim 1, wherein said pharmaceutical excipient are selected from the group consisting of PVP, HPMC, CMC, glyceryl monosterate poloxamer.
3. A pharmaceutical composition as claimed in claim 1, further comprises of surfactants based on hydrogenated castor oil (PEG-60, PEG-40).
4. A pharmaceutical composition as claimed in claim 1, wherein said first layer is prepared by mixing of aceclofenac with betacyclodextrin and pharmaceutical selected excipients by dry granulation process.
5. A pharmaceutical composition as claimed in claim 1, wherein said second layer is prepared by aceclofenac with selected pharmaceutical excipients.

ABSTRACT

BILAYERED TABLET DOSAGE FORM OF ACECLOFENAC AND METHOD OF PREPARATION

The present invention provides uniform blood level concentration over 12 hours to 24 hours a day. A bilayer oral dosage form of the water insoluble drug is formulated with a first layer which offers immediate release and a second layer which offers the drug from a sustained release matrix over 12 hours to 24 hours a day. The first layer for immediate release is formulated to release aceclofenac into the blood stream to initiate and achieve peak level concentration as desired within 15 minutes. The two grade granules were prepared by dry granulation process and these grade were compressed by using a C-300 or CTX II A Catmark Rotary Tablet Press. The tablet prepared by compression is subject to standard test such as disintegration, dissolution as well as bioavailability studies to determine that the desired blood level concentration over 12 hours to 24 hours of sustained release period is met as the preset of the objective of the formulation.

1.17 Flow chart of filing application in India[20]

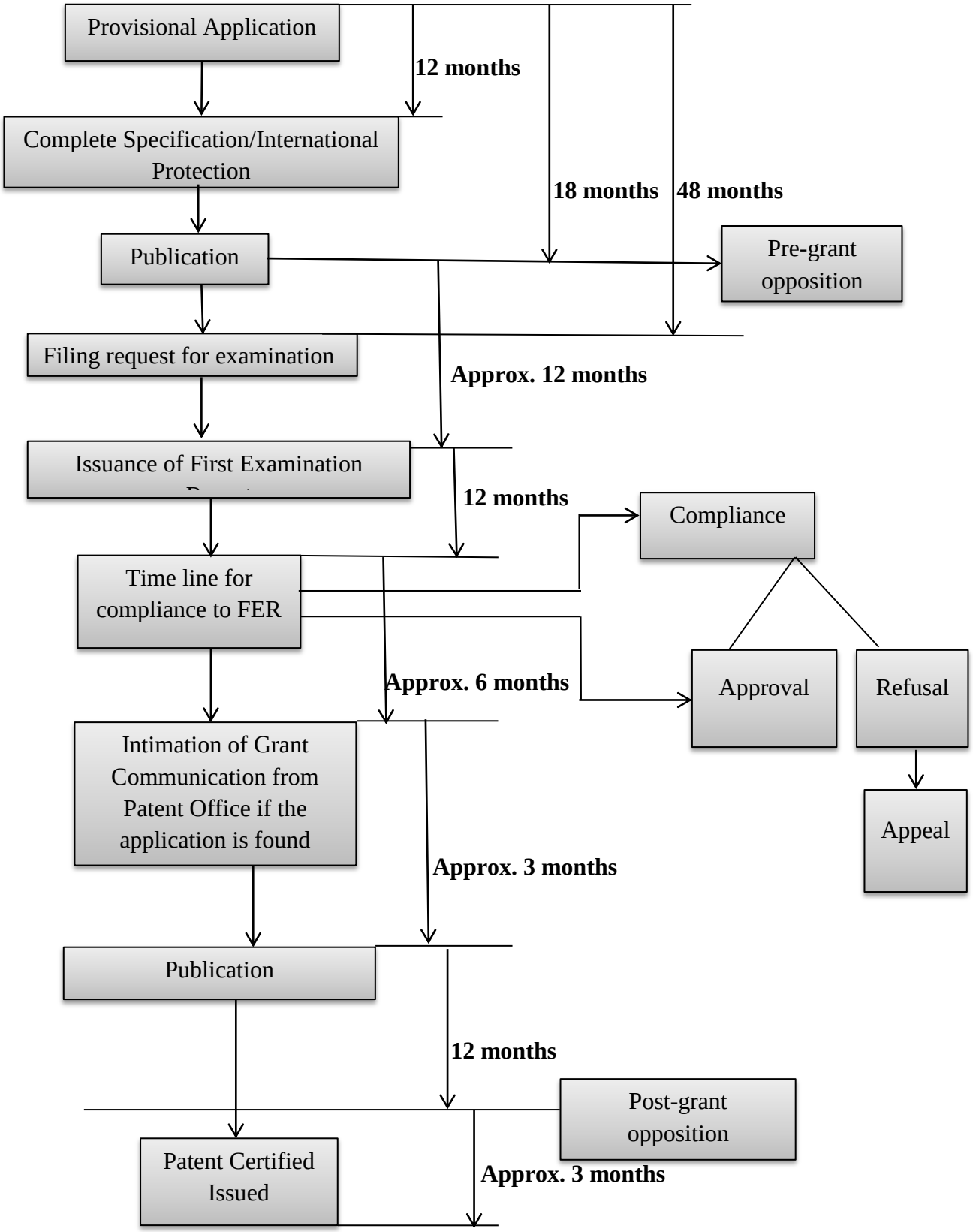

Figure 1.1 Patent filing procedure in India

2. Patent Filing Procedure in Europe[21]

The European Patent Convention (EPC) was created on 5th October, 1973. The main objective of EPC is to grant a patent to the true or the first inventor in a specific nation and for a certain interval of time. Furthermore, it helps to protect invention from those parties who abuse a creation for business purpose without authorisation.

- EPC has built a solitary patent strategy for grant of licenses based on single application.
- It made a uniform assemblage of substantive patent law intended to give simpler, less expensive and solid insurance for inventions in the contracting states. These states are Denmark, Greece, Norway, Austria, Belgium, Croatia, former Yugoslav Republic of Macedonia, Liechtenstein, Poland, Spain, Romania, Hungary, Slovakia, Iceland, Bulgaria, Cyprus, Albania, Latvia, Portugal, Serbia, Sweden, Czech Republic, France, Ireland, Malta, Italy, Turkey, Finland, Germany, San Marino, United Kingdom, Lithuania, Netherlands, Switzerland, Monaco, Slovenia, Luxembourg and Estonia.
- European patent term is 20 years from the date of priority or date of filing, whichever comes earlier.
- Patent term can be extended for medical or plant protection product patents.
- European Patent Organisation (EPO) has made a patent extension agreement with various states that are not the members of the EPC. Currently these states are Bosnia-Herzegovina and Montenegro.
- EPC has constituted a special agreement for the safety of industrial property which is known as Paris Convention.

2.1 Types of Patent Applications

Application for patents can be of following types:

1. National application
2. European application
3. International application (EURO-PCT application)
4. Divisional application

National application[22]

If an applicant intends to apply for patent in small number of European countries then it is better to select the national route and file the application at the IP offices of the countries in which the applicant is seeking protection.

European application[23]

When applicant wants protection of his invention in all the contracting states then he must file a European application. It is less time consuming as compared to filing an application in national or regional phase. This application can also be extended to the current extension states.

International application (EURO-PCT Application)[24]

When applicant wants a European patent he can decide between a EURO-PCT or the direct European route. The direct European route procedure is governed by the EPC alone. In the Euro-PCT route, the application is firstly checked by PCT and then checked by the EPC. Once an international application has entered the national stage before the EPO, it is said to be in the European stage. The maximum time duration is 31 months for entering into the European stage from the date of filing.

EPO as Receiving Office[25]

- An application has to be filed in a language accepted by the (ISA).
- The international application and request may be filed in English, French and German language.
- The Receiving Office does not accept the filing of international application with request in PCT-Easy format.
- The Receiving Office accepts the submission of international application in electronic form.
- In case the applicant is living or conducting his business in one of member state of the EPC, then no agent will be required by the receiving office.
- In case the aforesaid conditions are not met, then an agent will be required by the receiving office.
- In case, an agent is required then the separate power of attorney should be submitted in receiving office.

EPO as International Searching Authorities (ISA)[25]

- Search fee is Euro (EUR) 1,875.
- The language accepted for international search is French, German and English and the application is filed with the patent office of Netherland and Belgium.
- The authority requires that amino acid and nucleotide sequence listing should be electronic form.

European Patent Office as Supplementary International Searching Authorities (SISA)[25]

- The language accepted for Supplemental international search is French, German and English.
- The information specified in subsections (i) to (vi) of the PCT guidelines are not searched.
- The authority requires that amino acid and nucleotide sequence listings be submitted in electronic form i.e. CD-ROM, CD-R, DVD and DVD-R.
- 700 supplementary international searches will be conducted by authority in each year.

EPO as International Preliminary Examining Authorities (IPEA)[25]

- Preliminary examination fee is Euro (EUR) 1,930.
- The office accepts electronic filing via EPO online filing, the EPO-web-form filing service or the EPO case management system.
- The languages accepted for international preliminary examination includes English, German and French.
- The separate power of attorney is to be submitted to the authorities.
- The information specified in subsection (i) to (vi) of the PCT guidelines, is not searched.

Divisional application[21]

This application is used when the applicant claims more than one invention and law does not allow multiple patents in one invention. The applicant sends a request application to the patent office before the grant of patent and divides the applications in two parts. Following this approach, it is not mandatory for the applicant to submit the complete specification, in first part of the application. In the second part of application, the applicant must submit the complete specification within the specified time period. If the applicant does not submit the complete specification in the given time period then the

application is rejected by the European patent office. If the applicant submits the second part of application in a language other than the official language, than he must submit the translation of this application within 2 months from the date of filing the second part of the application.

2.2 Applications influenced by two factors

1. Legal factors
2. Economic factors

Legal factors[21]

- The European patent is granted after the examination of the application and it is checked that the application fulfils all the requirements of patentability as specified by the EPC.
- EPO department conducts an examination procedure. In this procedure each application has to go through three division of offices for examination.
  These are:-
  - Receiving section
  - Search division
  - Examination division
- In case the department decides against the application of applicant, then the applicant can file an appeal.
- Within 9 months from the date of grant of patent, any interested person can file Notice of Opposition.

Economic factors[21]

- The applicant has to pay the fees in every stage if he wants the protection of his invention.
- It depends upon the applicant if he wants to process his application faster at the substantive examination stage or search stage or both. Then the applicant should submit extra fees for the same in the patent office.
- The European search fee is refunded if the prior search report is prepared by the EPO on an international, national or European application.
- European procedure is conducted in French, German and English language and if the applicant files an application in a language other than these languages, then the

translation version of the application also has to be provided. However if applicant is from the contracting state then he/she gets the benefit on fees and language.

2.3 Stages of European patent application

It divided into 2 stages

First stage: it comprises of

1. **Formalities examination**[21]

In which authorities examine the important parts of the application such as content and form of the application, inventor designation and the payment of fee due.

2. **Search Report**[21]

The examination division make a search report after complete examination of the application includes claim, drawing, description, abstract. After the complete search the report is sent to the applicant and official gazette of EPC. They check whether the application fulfils the requirements of EPC.

Second stage: Substantive examination[21]

When an applicant files an application of request for examination then the EPO examines and make sure that the application of invention meets the requirements for the grant of patent according to the rules. The examining division consists of three examiners. One of these examiners maintains the contact with representative and the applicant.

2.4 Important Provision of EPC

Article 52 of European Patent Convention (EPC)

European patent are granted for invention that are non-obvious, original and useful for industrial purposes.

1. **What is invention-** Article 52(2) of EPC[26]

The EPC does not explain the “invention” but it provide a least of activities and subject matter that are not regarded as invention and cannot be patented.

It includes:-

1. Mathematical methods, discoveries and scientific theories
2. Visual creations
3. Methods, scheme and rules for performing mental acts, programs for computer and playing game or business

4. Presentation of information

Programs for computer- Article 52(2)(c),(3) of EPC[26]

Under Article 52 of the EPC, a computer program is not prohibited from patentability.

- Technical effects produce by a computer programs between hardware and software.
- The computer programs produce a technical effect to operate the computer device and its process.
- In a case when computer programs are not excluded, it is unimportant whether the program is claimed as part of a computer or as a method.

Method for treatment- Article 53(c) of EPC[26]

- The method like surgery, diagnostic and therapy which are performed on the animal or human body are expressly rejected from patentability but the rejection from patentability does not apply to substances, composition or product. For example, surgical machine or medicaments.
- Composition and substances are singled out for special treatment in the EPC as regards the novelty requirements and even a known composition and substance may be patented for further veterinary or medicinal uses gave that such utilization is inventive and novel.
- When a body tissue is removed from the animal or human body and the diagnostic method are developed on such tissue then they will be patentable only if tissue is not returned to same body.

Plant and animal varieties- Article 53(b) of EPC[26]

- The animal and plant varieties and the essential biological processes for the formation of animal and plant cannot be patented.
- A method for the formation of animals or plants is essentially biological, if it is based on sexual crossing of entire genomes and on the consequent selection of animals or plants and other technical steps relating to the preparation of animal and plant or treatment are present in the claim before or after the selection steps and the crossing.
- The exclusion does not apply to the products of such processes and microbial processes.
- The "biotechnological inventions are also patentable if they concern a biological material that is isolated from its natural environment or produced by means of a technical process".

Ordre public or morality- Article 53(a) of EPC[27]

Patents are not granted for "cloning human beings processes for modifying the germ line genetic identity of human beings, uses of human embryos for industrial or commercial purposes, or processes for modifying the genetic identity of animals that are likely to cause them suffering without any substantial medical benefit to man or animal, and also animals resulting from such processes".

2. **What is novelty-** Article 54, 55 of EPC[28]

- If an invention does not come under the state of the art then it is considered as novel.
- State of art means the product or items (invention) are available in the world anywhere like oral or written description before the filing of application.
- Any prior disclosure of the invention is non-prejudicial only if it occurred no earlier than six months before the filing of the European patent application or display in exhibition falling within the terms and condition of Paris Convention on international exhibition.

3. **What is inventive step-** Article 56 of EPC[29]

- An invention, not obvious to the skilled person in the light of state of art, will be included in inventive step.
- "problem-solution" approach is utilised for evaluation the invention.
- It depends upon various factors such as the method parameters, unpredicted technical result of an original combination of known components.

4. **What is industrial applicability-** Article 57 of EPC[30]

Any invention, which can be used in industry and would be useful for industrial purposes, will be included in this Article.

2.5 Preparing and filing a European patent application

1. **Formal requirements[31]**

- European patent application may be filed by any legal or natural person or anybody equivalent to a legal person by virtue of the law governing it.
- An application may also file by more than two applicants describing different contracting states and by joint applicants.
- European patent application may be filed in all the contracting states, Liechtenstein and Switzerland may only be designated jointly. The European patent application can

be extended to a number of states not member to the EPC. These states are Bosnia-Herzegovina and Montenegro.

2. **Languages for European patent applications-** Article 14 of EPC[32]

- EPO official languages are French, German and English.
- If an applicant files an application in a language other than official languages then the EPO gives a two months time period to the applicant to submit the translation of the same application into the official languages. If the applicant fails to submit the application within two months notification of invitation is given to the applicant and shall if he fails to submit the translation then the application is said to be withdrawn.
- If the language of applicant is other than the EPO official language but the residence or business place in the contracting state and if he files the application in one of the official state languages then he gets a benefit in fee of filing and examination but within 1 months from the date filing of application the applicant must submit the translation of same application in the EPO and if he fails to do then the application is rejected.

2.6 Content for the European patent application- Article 78 of EPC[33]

A European patent application consists of following important parts:

1. **Request for grant (EPO Form 1001)**

- The request for grant of patent filed in a form 1001 which is prescribed by the EPO. After completing the form, make sure that all the information given in the form meets all the requirements for the request for grant.
- The form must be properly signed by applicant or his/her legal representative.
- Page 8 of form 1001 (receipt for document) must be filed in quadruplicate or in triplicate, if filed with a national authority and if application is filed electronically no additional copies are necessary.

2. **Title:** The title of the patent should describe the subject matter of the patent application.

3. **Description of the invention**

It starts with the background of previous invention and also includes information about the present invention like process and products or its parts. It must be written in detail and as per the rules of the EPC.

This explained by taking an example of Biotechnology application:

- Amino acid and nucleotide sequences (unbranched sequences of ten or more nucleotides or four or more amino acids) are presented as a separate part of the description and the sequence listing must be filed in electronic form i.e. text format and if you file it on paper then you must submit a statement that the sequence listing in electronic form and on paper are identical.
- In case when inventor use a biological material in his invention whose preparation is not disclosed in patent application, so that it is not available to the public, then applicant must deposit the sample in the recognised depository institute (RDI).
- The applicant must mention the address and name of individual who submitted the biological material on behalf of the inventor.

4. Claims

- Claims must be clear and brief
- It must describe the technical features of the invention
- Important features of the invention must be stated in the independent claim
- Only one independent claim should be present in the same category of the application
- Independent claim should be followed by one of more dependent claims
- Use Arabic numerals for numbering the claims
- The wording used in claim should be such way that it does not produce any doubt between the descriptions and claims.

5. Drawing

- Drawing must not contain text matter and only use keywords which are absolutely indispensable like open, water, section on AB, stem and flow sheet diagrams or electronic circuits and block schematics and keywords in such a way that do not interfere with the lines of the drawing.
- Good quality drawings are very important for the correct disclosure of the invention. If the drawings are unreadable then the applicant is not allowed to file better quality drawing at a later stage.
- Colour photograph are scanned and made available in the electronic file in black and white.

- If the applicant files the application in electronic form then he has the advantage that the original quality of the drawing will be available to the EPO and "No Deficiency" communication would be issued

6) Abstract: It is a short summary of invention and its uses. It should preferably be written only in 150 words and should consist of the following.

- Invention description
- Description of the important component and their work

2.7 Forms[34]

There are total 18 forms. The important ones and the information to be provided in their form are given below:

1. Form 1001- Request for grant

The request for grant of patent is filed in Form 1001 which is prescribed by the EPO. After completing the form it should be ensure that all the information provided meets all the requirements for the request for grant of patent. The form must be properly signed by applicant and his/her legal representative. Page 8 of form 1001 (receipt for document) must be filed in quadruplicate or in triplicate if filed with a national authority. No additional copies are necessary if application is filed electronically.

2. Form 1002- Designation of inventor

If the person is not an inventor himself or not the co-inventor then he must file the designation of the inventor in separate document which indicates the origin of your right to the European patent. The designated person must be mentioned in the European patent specification, in the European patent bulletin, in the published European application and in the register of European patents. If the details of the designated person are not given during the filing of the European patent application then additional 16 months after the date of filing of application, are given to correct the deficiency. If they cannot submit the inventor designation within the prescribed period of time then the application is rejected.

3. Form 1003- Authorization

This form gives complete information about the authorised person, such as professional representative or a legal practitioner who represents the applicant. The name and address of the party giving the authorisation and the state in which his residence or principal place of business is located are also provided in this form.

4. **Form 1010-** Payment of fees and expenses

This form gives complete information about the payer like name of the payer and address of the payer, mode of payment, and the amount of processing fees for the European patent application like filing fee, additional fee, claims fees, examination fees and other important fees.

5. **Form 1037-** Acknowledgement of receipt

When an applicant files a patent application in electronic form by using the EPO online software an acknowledgement of a receipt is generated immediately.

6. **Form 1200-** Entry into the European phase

Applicants file a request of examination within 6 months from the date when European patent office publishes the search report. If applicant fails to submit this form in the prescribed time period in patent office, then the application is rejected.

2.8 Fees[34]

Table 2.1 Patent filing fees in Europe

Number of entry	**Description**	**Amount (EUR)**
1.	Filing fee- EP direct- not online	210,00+
2.	Filing fee- EP direct- online	120,00+
3.	Examination fee	1.620,00+
4.	Fee for European search	1.28500+
5	Fee for international search	1.875,00+
6	Additional fee for 36^{th} and subsequent page	15,00+
7	Claiming fee- for the 16^{th} to 50^{th} claim	235,00+
8	Claiming fee- for 51th and each subsequent claim	580,00+
9	Fee for grant (not more than 35 pages) or fee for grant including fee for publication	915,00+

, symbol means dot in Europe

2.9 Search[21]

After filing the patent, a search request has to be initiated. The purpose of this search is to reveal any prior art which may be relevant to the patentability of the alleged invention.

After the search, a search report is published along with the application 18 months after the priority date of the application. This is a public document. The purpose of publishing this document is to help the applicant to decide whether he/she should pursue the application or not. The presence of a prior art related to the patent application can prevent the grant of the patent.

2.10 Publication[21]

After filing the application form, the applicant is required to publish a journal which contains name, address, abstract and procedure of invention to the patent office. This should be done within 18 months after filing the application form or from the date of priority, to the patent office. After this procedure, the patent application is open for public inspection. Before publication it is not open for public inspection.

2.11 Examination[21]

The applicant who has filed for the patent undergoes the procedure of examination in which all the document, application forms, claims forwarded by the applicant are examined. After examining the application, the report is prepared by examiner and sent to the applicant or his agent stating the objections to which the applicant or his agent has to reply within a specified time period. In case the applicant fails to reply within 3 months to the report then the application is rejected.[21]

2.12 Issue or grant[21]

When the application fulfils the requirements according to the patent law and there is no objection, then the European patent office sends a notice to the applicant notifying him/her regarding "Notice of Allowance" and fees regarding the issue of patent.

2.13 Format for drafting the technical application documents[35]

By taking an example of AB5-type proteins

In this draft problem solution approach has been adopted. Technical problem has been mentioned in the background section and the solution to the said problem has been described in the following sections of the specification.

TITLE: Stabilisation of AB5-type proteins

FIELD OF THE INVENTION

The present invention relates to separation and detection of AB5-type protein complexes and also relates to identifying solutions for stabilising AB5-type protein complexes and to stabilise their solutions themselves.

BACKGROUND OF THE INVENTION

Cholera is a communicable disease which is caused by the bacteria (*Vibrio Cholerae*). The bacteria release protein into the human intestinal tract which belongs to the family of Bacterial Diarrhoea Proteins (BDP). The major symptoms of cholera are diarrhoea and vomiting which causes severe dehydration and loss of electrolytes. BDP comprises three types of proteins and these are AB2, AB4 and AB5 in which one Alpha (A) and two, four or five Beta (B) subunits are present. Among these proteins, AB5-type protein are causative for cholera. AB5-type proteins are EcT (*E.- coli* –Toxin) and CvT (*Cholera-vibrio*-Toxin). The AB5-type protein is highly unstable and rapidly becomes non-functional. Non-functionality arises when the protein complex consisting of one A subunits and five B subunits disintegrates and loses its natural three dimensional structure. AB5-type protein fails to produce its natural biological effects and cannot be used for biochemical analysis when AB5-type protein is in disintegrated state. Therefore, this protein is usually stored in dried form. For use, the protein is dissolved in a standard saline solution, kept at 4^{o}C and quickly used. So, there is need to replace the standard saline solution currently used by a stabilising solution in which the AB5-type protein maintain their natural protein complex structure for a long period of time.

DESCRIPTION

The present invention describes a method in which AB5- type protein are stable for longer period of time and determines the proportion of AB5-type protein complexes in a sample.

For determining the proportion of AB5-type protein complexes in a sample, the sample is analysed by column chromatography which uses a Ultrahydrogel-250 column with a particle size of 6µm and porosity of 250nm with a High-Performance Liquid Chromatography (HPLC) column that uses hydroxylated polymethacrylate (HyPM) having free carboxylic groups used as the support material.

Tris-HCl and Na_2SO_4 buffer in a ratio of 2:1 and within pH range of 6.8-7.6 and more specifically at a pH 7.2 is used for the separation of disintegrated AB5-type proteins complexes.

During chromatography, the proteins were detected by using UV absorbance spectroscopy in which two peaks are detected, one corresponding to the B5 subunit and other corresponding to AB5 complexes which can be detected and quantified in its complexed state and disintegrated state.

The stability of the AB5-type protein may be expressed in term of Stability Factor (SF) which was calculated as the ratio of the amount of AB5-type protein complexes divided by the total amount of AB5 + B5 (in %). If SF was more than 70%, 80% or 90% the AB5-type protein was deemed stabilized.

The above method quantitatively measures the protein complex stability of AB5-type protein Therefore, by this method the process of finding the stabilising solutions was established that resulted in an enhanced stability of an AB5- type protein in comparison with the standard saline solution. The stabilising solution means an aqueous solution which contains one or more stabilising agents that helps to maintain the nature and biologically active form of the AB5-type protein.

The stabilising agents are selected amongst sugars, detergents or amino acids and the method must include the step of incubating the AB5-type protein in a test stabilising solution for measuring the stability of the AB5- type protein.

The incubation of the sample may last from hours to several days, weeks or months and the incubation may take place at lower temperatures (such as 4^oC) or at ambient temperature (between 20^oC and 25^oC) and the sample is either kept in static condition or may be shaken. The biological activity of AB5-type protein in a stabilising solution is measured by in vivo or in vitro test.

EXAMPLE 1

Separation of AB5 subunit and B5 subunit of CvT by chromatography

Procedure: The dried CvT was dissolved in the standard saline solution and incubated at 4^oC and 22^oC for 1 hour, 12 hours, 24 hours and 48 hours in the static condition and sample was loaded onto the HPLC-Ultrahydrogel-250 column, by using Tris-HCl 200Mm

buffer along with Na_2SO_4 100Mm buffer at pH 7 for eluting the protein. Then protein peaks were detected, quantified and the stability factor (SF) was calculated.

Table 1

Incubation condition	**Stability Factor (%)**	
	4°C	**22°C**
1 hour, static	75	56
12 hour, static	61	33
24 hour, static	45	23
48 hour, static	37	18

EXAMPLE 2

Screening for AB5-type protein stabilising solutions

The stabilising solutions were tested for measuring their effect on an AB5-type protein complex. CvT used as AB5-type protein and used at 0.8 – 2.0 mg/ml and incubated at 4°C for 12 hours in different stabilising solutions and the sample were analysed by the method stated in example 1. The solutions number.as 3 and 6 in Table 2 were found to be particularly effective in stabilising CvT

Table 2

Candidate stabilising solution		**Stability Factor**	
		Static	**Shaken**
1.	PBS	55	45
2	PBS, glactose 0.1 mM	61	55
3	PBS, 0.25 wt % CHAPS	95	89
4	Phosphate buffer, pH 7.4	65	54
5	Phosphate buffer, pH 7.4, glactose 0.2M	64	52
6	Phosphate buffer, pH 7.4, L-arginine 0.4M	88	82

EXAMPLE 3

Effect of L- Arginine and CHAPS on CvT stability

The stability effect was observed over a wide range of pH with the increase in the amount of L-Arginine till 50mM. Beyond this concentration there was no improvement in complex stability. Stability was obtained when at least 10mM of L-Arginine is used. The protein complex was stabilized if at least 0.05wt % CHAPS was present and better results are obtained when the amount of CHAPS was at least 0.15 and these effects are examined when the stabilizing solution no. 3 and 6 of table 2 are used

Table 3

Stabilising solutions	**Incubation time (days)**					
	1	**2**	**10**	**30**	**60**	**90**
Phosphate buffer, pH 7.4 + 50 Mm L-Arginine	86.5	87.5	88.8	87.0	85.5	84.0
Phosphate buffer, pH 7.4 + 100Mm L-Arginine	88.8	87.2	85.6	90.5	83.4	82.2
Phosphate buffer, pH 7.4 + 200 Mm L-Arginine	86.3	88.3	83.7	83.5	81.2	82.4
Phosphate buffer, pH 7.4 + 400 Mm L-Arginine	85.8	88.8	88.3	87.2	85.3	83.9
PBS + 0.05 wt % CHAPS	85.5	87.5	86.8	87.0	86.5	85.0
PBS + 0.15 wt % CHAPS	90.8	89.2	88.6	88.5	88.4	88.2
PBS + 0.25 wt % CHAPS	93.3	91.3	90.7	90.5	90.2	89.4
PBS + 0.35 wt % CHAPS	90.7	88.8	88.3	87.2	90.3	87.9

We Claim

1. A method of detecting and quantifying the amount of complexed AB5-type protein the method comprising:

a. a sample of the protein kept for column chromatography using hydroxylated polymethacrylate having free carboxyl groups as the support material;

b. eluting the complexed AB5-type protein and B5 subunit using a buffer comprising Tris-HCl 200 mM and Na_2SO_4 100 mM at pH 6.8-7.6;
c. detecting and quantifying the amount of complexed AB5 and B5 subunits by UV absorbance spectroscopy.

2. The method of claim 1, wherein a column of the column chromatography has a particle size of 6 µm and a porosity of 250 nm.
3. A method of screening for stabilising solutions of the AB5-type protein complex, the method comprising:

a. incubating the AB5-type protein in a test stabilising solution;
b. detecting and quantifying the amount of a AB5-type protein complexes compared to the disintegrated B5 subunit
c. calculating the stability factor (SF), which is the ratio of the amount of AB5-type protein complexes divided by the total amount of AB5 + B5 (in %)

4. The method of claim 3, wherein the incubation takes place at 4 °C.
5. The method of claim 3, wherein the incubation takes place at 20-25 °C.
6. The method of claim 3, 4 or 5, wherein the sample is kept in a shaking incubator.
7. The method of claims 1, wherein the AB5-type protein is CvT.
8. The method of claim 3, wherein the solution comprising:

a. phosphate buffer and at least 10 mM L-arginine;
b. PB5 + 0.05-0.20 wt.% CHAPS, or 0.30-0.35 wt.% CHAPS,

9. The method of claim 8, wherein the L-arginine is present at a concentration of 10-50 mM.
10. The method of claim 8 or 9, wherein the pH of the phosphate buffer and L-Arginine is 7.4.

ABSTRACT

Stabilization of AB5-type Proteins

The present invention relates to process of separation and detection of AB5-type protein complexes and also of identifying the solution for stabilising AB5-type proteins complexes and to stabilize solution themselves because AB5-type protein lose their natural dimensional structure when it is dissolved in a standard saline solution due to which it cannot be used for biochemical analysis. So, in this present invention standard saline solution used is replaced by a stabilizing solution ensuring that AB5-type protein

retains its natural protein complex structure for an extended period of time. The protein sample is stable when the pH of stabilizing solution is between 6.8 and 7.4.

2.14 Flow chart of filing application in Europe[21]

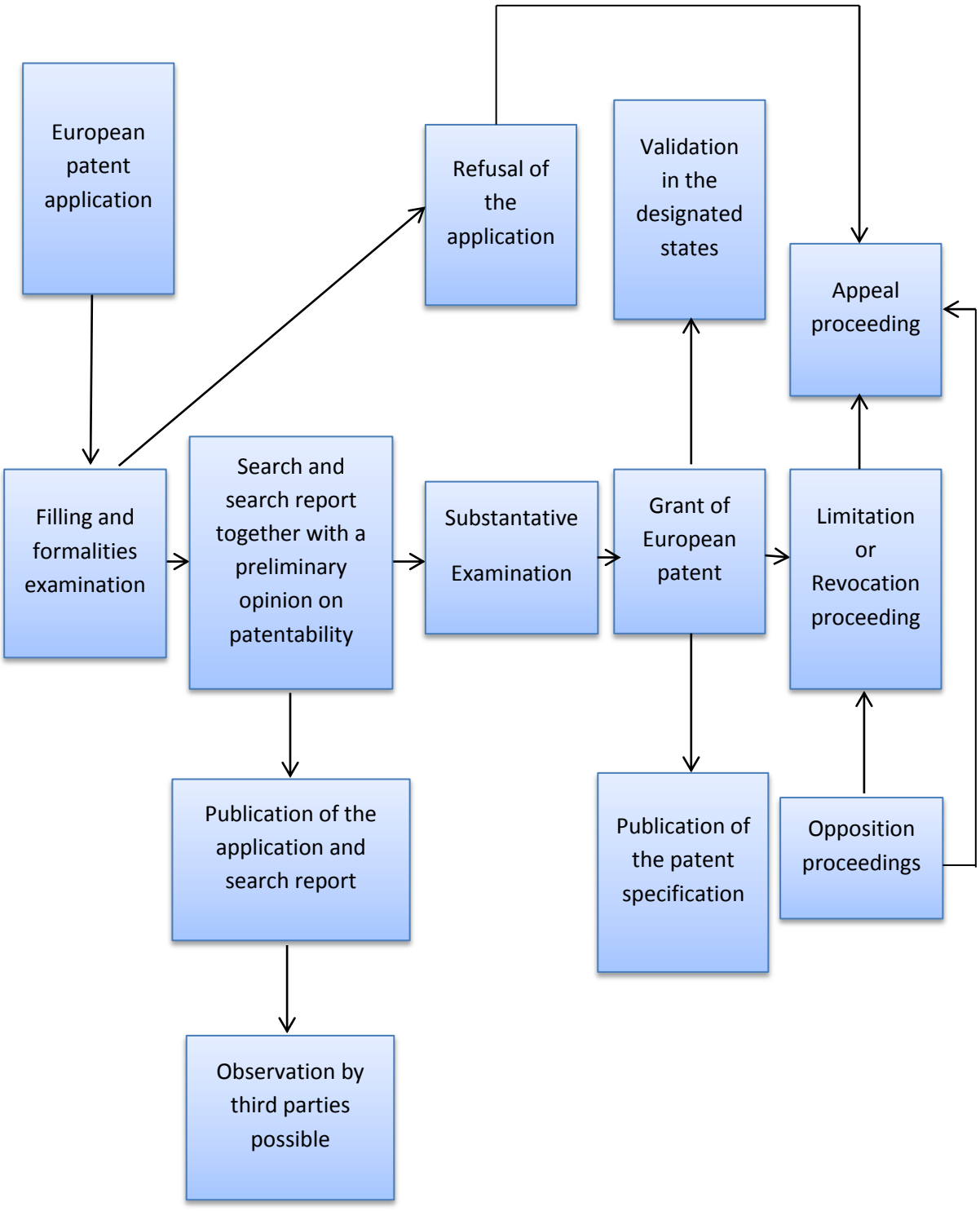

Figure 2.1 patent filing procedure in Europe

3. Patent filing procedure in USA[36]

- United State and Patent Trademark Office (USPTO) is an organisation of the U.S. Department of Commerce.
- The role of USPTO is to examine application and grant a patent on inventions. Other roles include maintaining the search files of U.S. patents, publishing and disseminating patent information, maintaining a search room for public use for examining issued patents and records assignment of patents.
- USPTO supplies copies of official records and patents to public.
- Patent is granted for 20 years in United States from the date of filing patent application.
- The granted patent is powerful only within U.S, U.S possessions and U.S territories.
- The law relating to patents in Article I, Section 8 by the United State gives power to congress to promote the science, arts and grant of patent.
- In 1790, the first patent law in USA was established.
- The first general modification in patent law was started on 19 July, 1952 but it became effective on 1st January 1953 with some modification. It is codified in Title 35 of United State Code (USC).
- American Inventors Protection Act of 1999 was introduced in 29 November 1999.
- From 1836 to 16 March 2013 "one who invents the piece of invention first was entitled to the grant of a U.S. patent but not for the first to file the application related to same invention".
- But after March 16, 2013 U.S. also follows 'First to file' principle.
- Leany- smith America Invents Act (AIA) is a U.S. federal legislation that was passed by congress and signed by the President of USA on 16 September 2011 and was implemented on May 16, 2013.
- The United States Code (USC), Code of Federal Regulation (CFR) and Manual of Patent Examining Procedures (MPEP) is published online by USPTO.
- USC is the compilation and codification of general and permanent government laws of the U.S. which is published by the Office of Law Revision Counsel of the House of Representatives every 6 years, which is divided into 50 Titles and all titles have sections. Title 35 of USC governs all aspects of patent law in U.S.
- CFR is the codification of general and permanent rules and regulation. It is also known as administrative law. It is published in Federal Register by Office of Federal

Register, an agency of National Archive and Records Administration (NARA). Any change in CFR is published every two days in e-CFR. CFR is divided into 50 titles or chapters. Chapter (title) 37 of CFR deals with patents, trademark and copyright rules. The revised volumes of CFR are issued once in year on 1st July.

- MPEP is published by USPTO and used by patent agent and patent examiners. It articulates the application of laws and regulations to a variety of situations with regards to the compliance of an invention to co-the statutory guidelines for patentable subject matter and criteria for patentability.

3.1 Types of Patents

There are 3 types of Patents:

1. **Utility Patents**[37]

Utility patent is that patent which "may be granted to anyone who discovers or invents any new and helpful methodology, machine, article of formation or structure of matter or any new and valuable changes".

2. **Design Patents**[38]

It is that patent which "may be granted to anyone who creates another unique design for an article of formation".

3. **Plant Patents**[39]

It is that patent which "may be granted to anyone who has discovered or invented a new method for the production of new plant varieties".

3.2 Patentable Subject Matter and Statutory Criteria for Patentability: 35 USC Section 101[40]

Any person who has discovered or invented any new and helpful methodology, machine, article of formation or structure of matter or any new and valuable changes thereof may get a patent.

The statutory categories of invention are:

- ✓ Process
- ✓ Machines
- ✓ Article of manufacture
- ✓ Compositions of matter

- Process and machines, are related inventions and can go for one patent.

- A patent means only one patent granted for each invention.
- The term “process” means sequence of steps for obtaining a result.
- The term “machine” means anything concrete having parts and components etc.
- The term “Article of manufacture” means any article prepared from a process of manufacture.
- The term “composition of matter” means composition of more substances or intermixing of two or more ingredients.
- The term “usefulness” means the invention disclosed has a useful purposes i.e. performs the function for which it is intended.

The judicial exceptions to patentability are:

1. **Law of Nature** like some equation f = ma, $E = mc^2$
2. **Natural phenomena** like electricity, sunlight, discovery a new mineral
3. **Abstract information** like software, geometrical algorithms.
4. **Business methods** like assignments, contract, legal agreements, legal rights. These documents cannot be patented.

How to obtain patent for software

Software can be granted a patent if you are able to strongly defend and prove the utility and show they are better than previous and brings technical advancement like efficient results, better speed.

- Claimed inventions that do not fall in co- statutory categories are not eligible for patenting. For eg. A claim to a bicycle may satisfy both machine and manufacture categories but may not have utility.
- Claimed invention that fall within statutory categories must still avoid the judicial exceptions.

Non-statutory invention (unpatentable): It is divided into two parts

Non-functional descriptive material: This includes music, literary work, data arrangements, rules to play games and legal agreements (e.g. an insurance policy).[40]

Functional descriptive material: This includes data structure, software per se, signal per se, logic or language per se.[40]

NOTE: For process also you have to show utility and technical advancements.

Case study: Diamond Vs Chakrabarty (1980) Landmark case on USC 101[41]

Patent no: US4259444: Patent for a bacterium capable of breaking down crude oil.

The patent was rejected based on the reason given below:-

1. Microbes are products of nature.
2. Under section 35 USC 101 living things are not patentable.

Chakrabarty again appealed to the Appellate Board's but the appellate board also rejected the application for patent grant. The appellate board is next authority Patent and Trademark office. Further, Chakrabarty appealed in U.S. Supreme Court.

Then US Supreme Court gave a landmark decision in the case:

- Reaffirms that the bacterium was not a handiwork of nature, rather it was Chakrabarty own invention.
- It got patent only on the ground of utility (i.e. breaking of crude oil).
- The relevant distinction was not between living and in- animate thing but between products of nature.
- Claims directed to encompassing a human organism are patent ineligible. (35 USC 101, Section 33(a) of AIA, 2011).

There are two approaches to give a reasonable utilization of legal special case:

1. Physical change
2. Produces a helpful, concrete and substantial result

The change of information (encoding or decoding) is not "physical change" or nor physical acts (new method of yoga or exercise) necessarily a "physical transformation. The example of physical change is 'fabricating a tyre by curing rubber'.

However, the claim still needs to be checked that whether it has utility as required under 35 USC 101

Useful result: utility of an invention has to be

I. Specific utility
II. Substantial utility
III. Credible utility

Specific utility[40]: It is when the invention which is claimed by the applicant provides specific advantages to the public.

Substantial utility[40]: It means "Real World Use". An application must show that an invention is beneficial to the public as disclosed in its first application not that it may demonstrate benefits at some future date after further application has been filed.

Credible utility[40]: It is that utility in which inventor understand about his invention and which regard an invention give a benefit to the public.

- Tangible result: It is that a claim must set forth a practical application of the judicial exception to create a true result.[40]
- Concrete result: The methodology or procedure should significantly deliver the same result again and again.[40]

3.3 Major Statutory Criteria for Patentability

Novelty: 35 USC Section 102[42]

35 USC 102(a)

As per the patent law, an invention must be new if the applicant wants grant on that patent and must not be described before in any way prior to filing of the application.

35 USC 102(b)

1. Disclosure made 1 year or less before the effective filing date of the claimed invention are not prior art if:

a. "the disclosure made by inventor or joint inventor or by another who obtained the subject matter disclosed directly or indirectly from the inventor or a joint inventor".

b. "the subject matter disclosed had before such disclosure been publicly disclosed by the inventor or a joint inventor or another who obtained the subject matter disclosed directly or indirectly from the inventor or joint inventor".

2. Disclosures appearing in application and patent does not form prior art, if the subject matter is disclosed.

a. "was obtained directly or indirectly from inventor or a joint inventor".

b. "by such subject matter was effectively filed under subsection (a)(2), had been publicly disclosed by the inventor or a joint inventor or another who obtained the subject matter disclosed directly or indirectly from the inventor or a joint inventor".

c. "claimed invention not later than the effective filing date of the claimed invention were owned by the same person or subject to an obligation of assignment to the same person".

35 USC 102 (c): Common ownership under joint research agreements

1. "the subject matter disclosed was developed and claimed invention was made by one or more parties to a joint research agreement that was in effect on or before the effective filing date of the claimed invention".

2. "the claimed invention was made as a result of activities undertaken within the scope of the joint research agreement".

3. "the application for patent for the claimed invention discloses or is amended to disclose the names of the parties to the joint research agreement".

35 USC 102 (d)

Determining whether a patent or an application is a prior art to claimed invention under subsection 102 (a)(2), such application will be considered to have been effectively filed.

1. "as an the actual filing date of patent application".

2. "if the application for patent is entitled to claim priority or to claim the advantage of an previous filing date based on any prior filed application".

Section 102, prior to the introduction of AIA, contained subsections 102 (e), 102 (f), 102 (g). But these are no longer valid post introduction of AIA.

Non-obviousness (Inventive Step): 35 USC Section 103[43]

In this section there are three types of application:

Pre-AIA application: The applications that were filed before 16 March 2013 and get priority/ benefit claims before16 March 2013 is called Pre-AIA application.

Transition application: The applications that were filed after 16 March 2013 but get a priority/ benefit claim before 16 March 2013 is called transition application.

Post-AIA application: The applications filed after 16 March 2013 and also get priority/ benefit claim after 16 March 2013 is called post-AIA application.

Important points:

- An ordinary skill person cannot make the invention non-obvious. Ensure that invention is an actual advance/step forward rather than more changes".
- Person having ordinary skill in the art is referred as phosita in U.S. The phosita test of obviousness is one of the largest area of US patent law".

- a fictional person
- neither a genius nor a lay person
- Considered to have normal knowledge in a particular technical area.
- To determine whether an invention is non-obvious or not while drafting and applying application. The patent agent/attorney is the phosita and during examination and fill time of grant the examiner is phosita.

3.4 Requirements of Section 103

1. What a prior art patent as a whole discloses?
2. What difference exist between prior art and the whole claimed invention?
3. The invention met on its merits, co-outstanding commercial success.

U.S. follows the **Teaching-Suggestion-Motivation (TSM)** test which helps to know "what is taught and suggested in prior art and motivates to make an invention".

The TSM test focuses on 3 points in the prior art:

1. Content and benefit of prior art.
2. Difference between prior art and claimed invention
3. "The level of common expertise in prior art (i.e. level of phosita)".

Analogous art (most relevant prior art)

1. The prior art to be modified/compared can be 'analogous' to the applicant's invention. i.e. it must

a. be related to field of the inventor's endeavour
b. be reasonable pertinent to the problem addressed

2. It is not necessary that prior art suggests the similar benefits or result as by the invention.

3. It is not required that any prior art references expressly suggest the modification or combination posted in 103 rejection".

3.5 Types of Patent Application

1. Provisional application
2. Non-provisional application
3. Continuation in part (CIP) application
4. Divisional application
5. Request for continued examination (RCE) application
6. Patent Cooperation Treaty (PCT) application

Provisional application[44]

It is that application where there is no examination process and no claim are required but it should include a satisfactory description and drawing of the invention. After the provisional application the applicant must submit a non-provisional application in patent office within 12 months from the date of filing of provisional application. In the provisional application filing fees are lower.

It includes:

- Specification
- Drawing
- Name of inventor
- Appropriate filing fees
- Cover sheet

Non-provisional application[44]

It is a very important application for the grant of patent in which applicant gives complete information about the invention like its method, process and uses of invention. These are included in title, claim, abstract, description and background. The claims are stated on a fresh page and the specification must be clear and brief. The applicant must submit this application within 12 months from the date of first file of temporary application,

Specification should have the following section, in order:

1) Invention title
2) Cross reference to related application
3) Statement of development/federally sponsored research
4) Sequence listing
5) Invention background
6) Invention summary

7) Drawing description of invention
8) Invention description
9) Claims
10) Abstract
11) Sequence listing (in any)

Divisional application[44]

This application is used when the applicant claims more than one invention and law does not allow multiple patents in one invention. The applicant sends a request application to the patent office before the grant of patent and divides the applications in two parts. Following this approach, it is not mandatory for the applicant to submit the complete specification, in first part of the application. The second part of application should be submitted within specified time period with the complete specifications in this application. If the applicant fails to do so then the application is rejected by the patent office.

Continuation in part application[44]

This application is filed when applicants forgets to add any topic or important word in the non- provisional application. So he/she can file a CIP application for adding some information in the application. Important here is that topic in which the additional information has to be added should have been mentioned in the provisional application. No additional topic can be introduced by filing a CIP application.

Request for continued examination (RCE)[44]

This application is filed when patent office rejects the patent application and sends the notice of rejection to the applicant. Then the applicant can file the RCE application with extra fees and request the examination department to re-examine his/her application once again. After 8 June, 1995 RCE has been discontinued.

Patent Cooperation Treaty (PCT) application[44]

PCT application is also known as international application. It was introduced in the year 1970. The main purpose of this application is to give safety to the inventor for his idea or discovery in the world. In PCT there are 148 countries are involved. Instead of filing several regional or national applications the applicant files a PCT application and protects his invention in countries participating in PCT.

3.6 Forms: In total there are 92, forms. Discussed below are the important forms that are used during the filing of application

1. Application data sheet[45]

An application data sheet (ADS) contains bibliographic data arranged in a specific format. It may be provided in case of provisional or non-provisional application. The use of an application data sheet is optional but preferred.

It includes:

- Applicant information
- Correspondence information
- Application information
- Representative information
- Domestic priority information
- Foreign priority information

2. Oath or Declaration[45]

- Each inventor must make a promise that he/she trusts himself/herself to be the true and first inventor of the application.
- When an applicant files a divisional or continuous application, then the patent office may accept the oath and declaration of first filed application for the same invention.
- It must be signed by the true or first inventor or by the other legal person who is equally representing the inventor on his/her behalf. In this form, full name and address of each applicant should be provided.
- When an applicant files this form in a language other than English then it is mandatory that the applicant must submit its translation within the time specified by the patent office.
- Declaration form PTO/SB/101-110. It is provided by USPTO.

3. Invention Disclosure Statement (IDS)[45]

IDS must be filed either within three months from the filing date and or before the mailing date of the First Office Action. The information in this form includes:-

- Invention title
- Invention description
- Technical explanation of the invention, including any drawing, data, etc. describing how to make or use

- General field of applicability
- Competitors and their related products processes
- Advantages of the invention over known prior art.

4. Request for continued examination (RCE)[45]

When patent office rejects the patent application and sends the notice of rejection to the applicant, then the applicant can file the RCE application with extra fees and request the examination department to examine his/her application once again.

5. Power of Attorney[45]

In this form, detailed regarding the agent, who has been authorized by the principal to act on his/her behalf are provided. So, any communication related to the patent can be addressed to directly to such an agent.

3.7 Fees[46]

Table 3.1 Patent Application Filing Fees

S.No	Description	Fees (Dollar's)	Small entity fee (Dollar's)	Micro entity fee (Dollar's)
1.	Basic filing fee- utility (paper filing)	280	140	70
2.	Basic filing fee- utility (electronic filing)	280	70	70
3.	Basic filing fee- Design	180	90	45
4.	Basic filing fee- Plant	180	90	45
5.	Each independent claim in excess of three	420	210	105
6.	Each claim in excess of 20	80	40	20
7.	Additional fee: for each additional 50 sheets that exceeds 100 sheets	400	200	100

Table 3.2 Patent Search Fees

S.No	Description	Fees (Dollar's)	Small entity fee (Dollar's)	Micro entity fee (Dollar's)
8.	Utility search fee	600	300	150
9.	Design search fee	120	60	30
10	Plant search fee	380	190	95

Table 3.3 Patent Examination Fees

S.No	Description	Fees (Dollar's)	Small entity fee (Dollar's)	Micro entity fee (Dollar's)
11.	Utility examination fee	720	360	180
12.	Design examination fee	460	230	115
13.	Plant examination fee	580	290	145

3.8 Office Action[36]

After the examination test, the decision should be notified to the applicant in writing through post or mail to attorney or agent. If the invention of inventor fulfils the criteria of patent then it is accepted and if the claim does not live upto the criteria of novelty then it may be rejected.

3.9 Applicant's Reply[36]

The applicant must request re-examination in writing. The applicant must reply to each and every objection of the USPTO office which is mentioned in prior office action. He/she must clearly point out that why their claims are patentable. After re-examination the applicant will be notified whether his/ her claims are rejected or objected.

3.10 Allowance and Issue of Patent[36]

After the re-examination of application the USPTO send a notice to the applicant notifying his/her regarding "Notice of Allowance" and fees regarding the issue of patent. If publishing is applicable, then it would be done within 3 months from date of notice.

3.11 Flow Chart of filing application in USA[47]

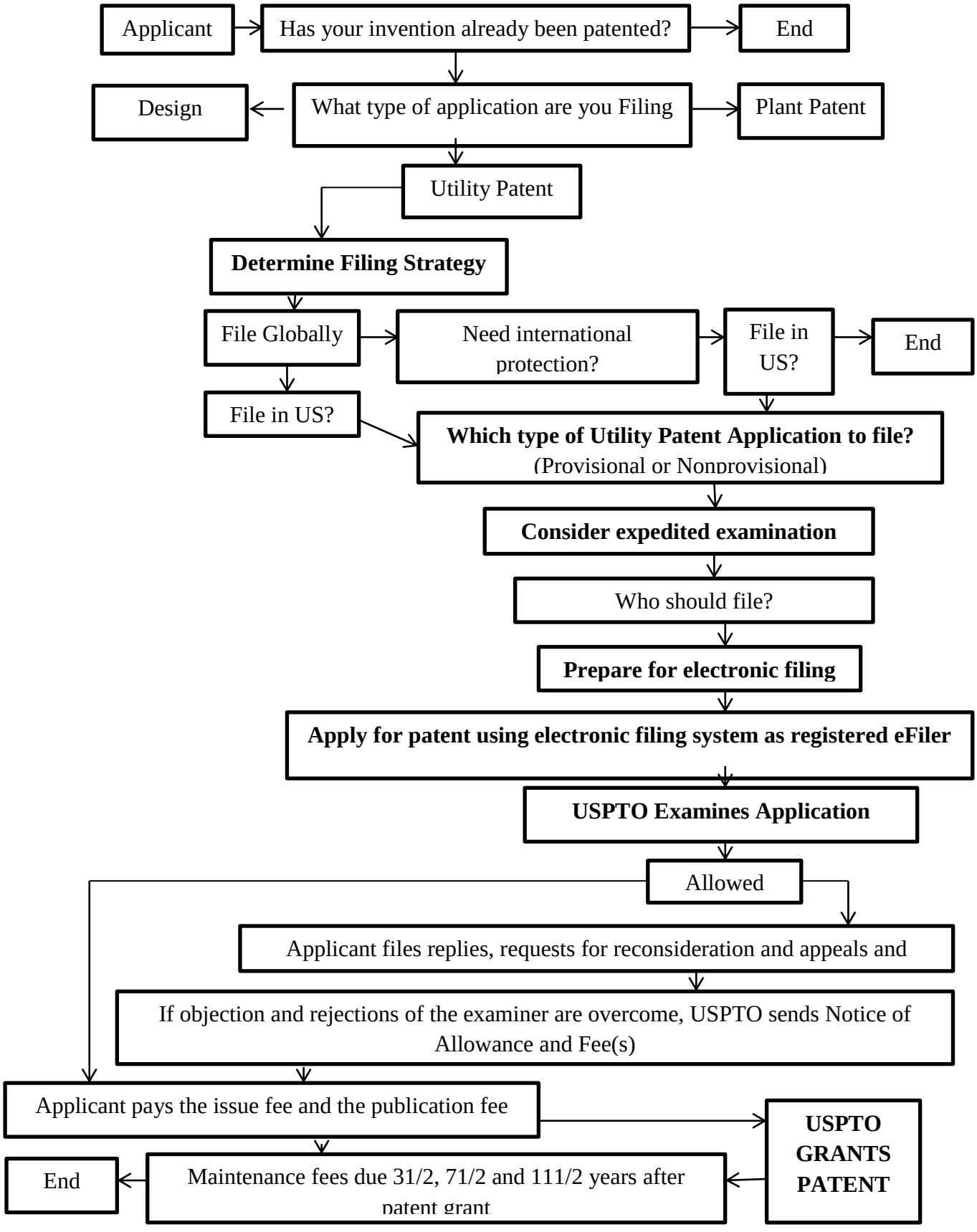

Figure 3.1 Patent filing procedure in USA

4. Comparison of Patent Filing Procedure in India, Europe and USA

The basic law for the patent grant is the above mentioned three countries is quite similar. The difference is mainly in the patent filing procedure. The patent system divided into two parts:

1. Patent filing procedure
2. Patent grant procedure

The patent grant procedure, which includes search, publication, examination and opposition, are the same in these countries and followed after filing the patent.

The patent filing procedure is compared based on parameters:-

These are

1. Language
2. Types of patent
3. Grace period
4. Inventive step
5. Independent claim
6. Number of sheets of specification
7. Number of dependent claims
8. Total number of forms
9. Invention not patentable
10. Patent grant term

Table 4.1 Comparison of the patent filing procedure in India, Europe and USA

Parameters	**India**	**Europe**	**USA**
Language	Application should be filed in English.	Application should be filed in German, French and English	Application should be filed in English.
Types of Patent	Process and product patent	Process and product patent	Design, utility and plant patent
Inventive step	"Problem-solution" and "could-would" approach utilised for find the difference between prior art	"Problem-solution" and "could-would" approach utilised for find the difference between prior art	Teaching-suggestion-motivation principle used for find the difference between

	and present invention	and present invention	prior art and present invention
Independent claim	One independent claim filed in same category of application	One independent claim filed in same category of application	Three independent claim filed in same category of application
Number of claim in specification	10 claims, if applicant claims more than 10, applicant pay extra fee for each dependent claim	16 claims, if applicant claims 16 to 50 than he has to pay as per fees rules.	20 claims, if applicant claim more than 20, he pay extra fee for each dependent claim
Number of sheets	30 sheets used in complete specification, if addition sheet used than extra charges are paid for each sheet.	36 sheets used in complete specification, if addition sheet used than extra charges are paid for each sheet.	50 sheets used in complete specification, if addition sheet used than extra charges are paid for each sheet.
Grace period	1 year grace period according to section 32,33	6 month grace period according to Article 55	1 year grace period according to section 102b USC.
Total number of forms	In total 28 forms but only 5 used for filing application	In total 18 forms but only 4 used for filing application	In total 92 forms but only 4 used for filing application
Invention not patentable	According to Section 3 of The Indian Patent Act 1970.	According to Article 52 of the EPC	According to Section 101,102 and 103 of USC.
Patent grant term	20 years	20 years	20 years for utility and plant patent but 14 years for design patent

CHAPTER 2

LITERATURE REVIEW

CHAPTER 2

LITERATURE REVIEW

The patent law in any country provides the safety to the inventor for his discovery. Patent safety means the other person cannot manufacture and distribute the product without taking permission from the patentee. In different countries there are different criteria for an invention to be a patentable but in all the countries the clause of novelty is there. This states that "the invention must be new" if your invention is already out you can't get patent despite criteria being accomplished such as Industrial application etc. The procedure for the grant of patent includes filling of the application form and submit it into the respective offices. The patent office in USA is United State Patent and Trademark Office (USPTO). In India the patent application is filed in the Indian Patent Office (IPO) where as in Europe the patent application filed in European Patent Office (EPO). In Europe when patent is granted the patent right is reserved into one of the 34 states i.e if someone applied for the patent in the Luxembourg the patentee will only have the patent right in the state of Luxembourg. After the filling of the application form the first examination is conducted by the respective offices after which all the clauses are checked. The application of patent undergoes the procedure of examination in which all the document, application forms, claims forwarded by the applicant are examined. After examination of the reports, a FER is published and sent by the patent office to the applicant or his agent stating the objections to which the applicant or his agent has to reply within 6 months. When the examination or claims fails, the office has to notify the applicant stating the reason of rejection. After receiving the notice from the examination office the applicant checks it and drafts an explanation and resends the application with the prescribed fee and requests for re-examination of the application. After the re-examination when the objections are clarified then the patent office sends a notice to the applicant notifying him/her regarding "Notice of Allowance" and fees regarding the issue of patent.

CHAPTER 3

OBJECTIVES OF THE STUDY

CHAPTER 3

OBJECTIVES OF THE STUDY

1. To study the patent filing procedure in India.
2. To study the patent filing procedure in USA.
3. To study the patent filing procedure in Europe.
4. Compare the patent filing procedure of India, Europe and USA.

Chapter 4

WORK METHODOLOGY

Chapter 4

WORK METHODOLOGY

1. The examination search report of two confidential inventions was compiled in which the first application was filed for the grant of patent in PCT and the other was for the grant of patent in Malaysia. On the request of examination of application, the examiner studies the application and searched for other prior art and relevant documents like published papers, articles and other published inventions. The ISR report was generated after search and was sent to the patent agent or the applicant. On receiving ISR report, the applicant replied to the ISR report. The maximum time limit to reply to the examination report is 3 months. The report is a proof that the invention is novel and different from the previous invention.
2. Patent search during examination phase was conducted by going through the different official sites of government of different countries like, Australia, Europe, USA, India, Singapore etc. Patent land scape show the company/applicant information related patent of one company or applicant that how many patent published at that time in the world was also prepared.

Different official sites from which the data regarding patent search was obtained are:-

i. www.ipindia.nic.in (India)
ii. www.uspto.gov (United State of America)
iii. www.epo.org (Europe)
iv. www.ipaustralia.gov.au (Australia)
v. www.ipos.gov.sg (Singapore)
vi. www.kipris.or.kr/ (Korea)
vii. www.myipo.gov.my (Malaysia)
viii. www.espace.net

If the applicant wants the advance search to be done then the site of espace.net should be used. Here search can be done based on patent number, title, publication number etc. or other such key points. This will help the applicant to ensure that the present invention is not relevant to the prior art.

Compilation of examination report of two confidential inventions:

A. Compilation ISR report

D1	Invention	CONCLUSION
This invention describes the method for the treatment of effluent (palm oil mill effluent). Palm mill effluent generally includes an aqueous solution or an aqueous phase having water-soluble components, an oleaginous or oil phase having oil soluble components, suspended solid phase having undissolved solids components and emulsifier having an emulsification activity. The method is used for reducing the emulsification activity of the emulsifier. The emulsifier activity is reduced by chemical modification, hydrolyzing the emulsifier and treating the emulsifier with a change in temperature, a chemical catalyst, an enzyme, an electrolyte and combination thereof. The emulsifier comprises hydrolyzing or	The present invention relates to a system for evaporating final discharged wastewater generated in a palm oil mill and the system comprises of removal of wastewater, equalization and stabilization of steam, evaporation, collection of condensed steam and water vapour and collection and distribution of clean water. In this invention available steam in the palm oil mill was utilized to evaporate the wastewater produced so that clean water would be recycled for boiler water, process water or general washing and cleansing purposes. The removal of wastewater grit further was conducted using a pump to transfer the wastewater into storage tank. The equalization and stabilization of steam was conducted using a vessel	In D1, it is not mentioned the steps that had been taken for the separation of the water from the effluent and they did not mention the use of components like condenser, evaporator, steam equalization vessel, water storage tank and the D1 only described the method for reducing the emulsification activity of emulsifier.

trans-esterifying less than about 50 percent of the triglycerides. The water separated from the clarified aqueous solution to form separate water and concentrated clarified solution and it would be separated by the evaporation, reverse osmosis, distillation and recycled back and reused by the oil mill (eg as boiler-feed water and process water). The concentrated clarified solution contained carbon source which produced the fermented product when fermenting the carbon source. The fermentation of product comprised at least one amongst ethanol, butanol, acetone, enzymes, amino acids, single-cell protein, carboxylic acids and their combinations therefore. A method for treating an aqueous effluent stream resulting from the extraction of palm oil and comprising of suspended matter, an oleaginous material and an	operating at temperature of 300^{o}C and pressure of 300 psig. The evaporation was conducted using a feed pump, an evaporation vessel, condensers for distillate and steam. The collection of condensed steam and water vapour was conducted using a heat-exchange system which helped in cooling down the water vapour to its condensation point and condensed the steam to liquid. The discharged wastewater generated in a palm oil mills was treated using anaerobic treatment system or aerobic treatment system or chemical treatment system or filtration treatment system. The steam was generated from steam boiler or turbine systems etc. The steam is utilized to evaporate wastewater for producing clean water. The steam is tapped from steam boiler, BPR and sterilizer relief system and operated at temperature ranging from	

emulsifier that may be hydrolyzed was developed The method consisted of: (a) hydrolyzing the emulsifier thereby reducing the emulsification activity of the emulsifier ; (b) separating the oleaginous material; (c) separating the suspended matter after hydrolyzing the emulsifier ; (d) separating water from the aqueous effluent stream after separating the suspended matter.	100 to 300^{o}C and pressure ranging from 40 to 300psig.	
D2	**Invention**	**Conclusion**
The wastes generated from "palm oil milling are returned to the field for cropland application, utilized in-house or in the plantation, or sold to third parties for value-addition. The entire spectrum of solid wastes, inclusive of solid wastes derived from air emissions and POME, has a utility function and none is wasted. However, the main criticism is the relatively low value-addition of such activities. Likewise, treated POME is utilized for	The present invention relates to a system for evaporating final discharged wastewater generated in a palm oil mill and the system comprises of removal of wastewater, equalization and stabilization of steam, evaporation, collection of condensed steam and water vapour and collection and distribution of clean water. In this invention available steam in the palm oil mill was utilized to evaporate the wastewater produced so	In D2, system or steps for the evaporation of wastewater and producing clean water has not discussed.

cropland application with the exception of independent millers that have no alternative but to discharge it into receiving waterways. The treatment technologies for POME allow for the above without breaching the EQA parameters. The addition of new technologies, replacement of old mills at the end of the mills' lifespan and the construction of new mills will reduce the carbon footprint. New technologies and new plants will contribute to higher level of resource utilization efficiency, higher oil recovery and lesser effluent. This, in turn, places the palm oil milling sector towards the path of sustainable production. Malaysia's strategic focus in developing renewable energy and the attraction of CER tax credit under CDM may prove to be the catalyst in the take-off of the biogas or biomass sector in the oil	that clean water would be recycled for boiler water, process water or general washing and cleansing purposes. The removal of wastewater grit further is conducted using a pump to transfer the wastewater into a storage tank. The equalization and stabilization of steam was conducted using a vessel operating at temperature of 300^{o}C and pressure of 300 psig. The evaporation is conducted using a feed pump, an evaporation vessel, condensers for distillate and steam. The collection of condensed steam and water vapour was conducted using a heat-exchange system which helped in cooling down the water vapour to its condensation point and condense the steam to liquid. The discharged wastewater generated in a palm oil mills was treated using anaerobic treatment system or aerobic treatment system or chemical	

palm and palm oil production chain. However, impediments like the low feed-in-tariff make the fuel value much lower than the required ROI. If the required ROI were attained, methane and biomass wastes would be transformed into a relatively higher value resource".	treatment system or filtration treatment system. The steam was generated from steam boiler or turbine systems etc. This steam was utilized to evaporate wastewater for producing clean water. The steam is tapped from steam boiler, BPR and sterilizer relief system and operated at temperature ranging from 100^{o}C to 300^{o}C and pressure ranging from 40psig to 300psig.	

D3	Invention	Conclusion
A process for the working-up of effluents and disposal of the loads and the effluent is concentrated in the first stage by a membrane process which consisted of a combination of at least two pressure permeation membrane processes in series which are selected from the group consisting of micro-, ultra- and nano-filtration, and the resulting concentrate is evaporated in the second stage, and incinerated in a third stage by gas phase oxidation. The first membrane process was worked up in the second membrane process and the concentrate of the second membrane process was either passed into the original effluent stream or passed, together with the concentrate of the first membrane process, to the second and third process stages. The membrane process of the first process stage consists of a combination of	The present invention relates to a system for evaporating final discharged wastewater generated in a palm oil mill and the system comprises of removal of wastewater, equalization and stabilization of steam, evaporation, collection of condensed steam and water vapour and collection and distribution of clean water. In this invention available steam in the palm oil mill is utilized to evaporate the wastewater produced so that clean water would be recycled for boiler water, process water or general washing and cleansing purposes. The removal of wastewater grit further is conducted using a pump to transfer the wastewater into storage tank. The equalization and stabilization of steam was conducted using a vessel operating at temperature of 300^{o}C and pressure of 300 psig. The evaporation was conducted using a feed	In D3, the steps of evaporating system were not defined. In this invention they did not use a condenser, evaporators, steam equalization vessel, wastewater grit removal system.

microfiltration and subsequent nanofiltration. While working-up of salt-containing effluents, the first process stage was carried out with membranes which possess the property of separating organic molecules with a molecular weight of more than 150 daltons from inorganic salts. The membrane process of the first process stage, symmetrical, asymmetrical or composite membranes were used which consisted of either organic or inorganic materials. The membranes used in the first process stage had on one side of the membrane support. An asymmetrical coating consisting essentially of at least one polymer layer which had been formed from an organic, film-forming, hydrophilic polymer and a monomeric ionic compound and/or a crosslinking agent, and of a thin, semipermeable, interfacially crosslinked film containing	pump, an evaporation vessel, condensers for distillate and steam. The collection of condensed steam and water vapour was conducted using a heat-exchange system which helped in cooling down the water vapour to its condensation point and condensed the steam to liquid. The discharged wastewater generated in a palm oil mills was treated using anaerobic treatment system or aerobic treatment system or chemical treatment system or filtration treatment system. The steam was generated from steam boiler or turbine systems etc. The steam was utilized to evaporate wastewater for producing clean water. The steam was tapped from steam boiler, BPR and sterilizer relief system and operated at temperature ranging from $100^{o}C$ to $300^{o}C$ and pressure ranging from 40psig to 300psig.	

ionic groups which are present on the upper side of this layer and are integrally bonded thereto, with the proviso that said films are not amphoteric, interfacially crosslinked films.		

D4	Invention	Conclusion
In this paper with the help use of case studies it is explained how evaporation and crystallisation technology may be used to treat effluent streams. This approach allows the production of valuable by-product that can offset the cost of effluent treatment. Crystallisation: Case study: 1. Vinasse concentration with depotassification 2. Vinasse concentration with depotassification and desalting 3. Production of fertilizer from straw fly ash Evaporation: Case study: 4. Integration of stream stripping with a black liquor evaporation. 5. Conversion of distillery waste evaporator from multi effect to MVR 6. Pot Ale (Malt Distillery Waste) evaporator using waste heat 7. Integrated evaporator treating two effluent	The present invention relates to a system for evaporating final discharged wastewater generated in a palm oil mill and the system comprises of removal of wastewater, equalization and stabilization of steam, evaporation, collection of condensed steam and water vapour and collection and distribution of clean water. In this invention available steam in the palm oil mill was utilized to evaporate the wastewater produced so that clean water would be recycled for boiler water, process water or general washing and cleansing purposes. The removal of wastewater grit further is conducted using a pump to transfer the wastewater into storage tank. The equalization and stabilization of steam is conducted using a vessel operating at temperature of $300^{o}C$ and pressure of 300 psig. The evaporation was conducted using a feed	In D4 a case study for treating an effluent stream is discussed. But it does not explain about the process for evaporating the wastewater generated from palm oil mill

streams	pump, an evaporation vessel, condensers for distillate and steam. The collection of condensed steam and water vapour was conducted using a heat-exchange system which helped in cooling down the water vapour to its condensation point and condensed the steam to liquid. The discharged wastewater generated in a palm oil mills was treated using anaerobic treatment system or aerobic treatment system or chemical treatment system or filtration treatment system. The steam was generated from steam boiler or turbine systems etc. The steam was utilized to evaporate wastewater for producing clean water. The steam was tapped from steam boiler, BPR and sterilizer relief system and was operated at temperature ranging from 100^0C to 300^oC and pressure ranging from 40psig to 300psig.	

D5	Invention	conclusion
This invention disclosed here is a process for treating a waste effluent discharged from a BCTMP process by producing water that is sufficiently clean for reuse in the BCTMP process or otherwise safe for dumping into an ambient environment. The effluent discharged from the BCTMP process contained water, organic and inorganic waste at low concentration including acetic acid. The effluent was evaporated by multi steps of evaporation each step produced at least some water condensate and increased the waste concentration of the effluent and burning the concentrated effluent in a recovery boiler and recovering smelt from the boiler. The smelt first dissolved into water and creating green liquor by adding at least some of the green liquor to the effluent prior to at least one of the multiple steps of	The present invention relates to a system for evaporating final discharged wastewater generated in a palm oil mill. The system comprised of removal of wastewater, equalization and stabilization of steam, evaporation, collection of condensed steam and water vapour and collection and distribution of clean water. In this invention available steam in the palm oil mill was utilized to evaporate the wastewater produced so that clean water would be recycled for boiler water, process water or general washing and cleansing purposes. The removal of wastewater grit further was conducted using a pump to transfer the wastewater into storage tank. The equalization and stabilization of steam was conducted using a vessel operating up to temperature of 300^{o}C and pressure of 300 psig. The evaporation was conducted using a feed	First thing is that D5 is for pulp mills not for palm oil mills and also used green liquor and caustic solution in it but in present invention no any used of any solution was used and they evaporated the wastewater by the use of steam and condensers and also defined that how the process was going on step by step.

evaporation. In this process using a separate evaporator for each one of the multiple steps of evaporation and all are connected serially and last evaporator in the series being a steam-driven concentrator evaporator and the green liquor is added to the evaporating effluent immediately prior to entry of the effluent into the last evaporator and evaporating the effluent until the waste makes up at least 65 percent of the effluent by weight. The process is same in next example but the only change is that adding caustic solution at the stage where green liquor was added.	pump, an evaporation vessel, condensers for distillate and steam. The collection of condensed steam and water vapour was conducted using a heat-exchange system which helped in cooling down the water vapour to its condensation point and the condensed steam to liquid. The discharged wastewater generated in a palm oil mills was treated using anaerobic treatment system or aerobic treatment system or chemical treatment system or filtration treatment system. The steam was generated from steam boiler or turbine systems etc. The steam was utilized to evaporate wastewater for producing clean water. The steam is tapped from steam boiler, BPR and sterilizer relief system and operated at temperature ranging from $100^{o}C$ to $300^{o}C$ and pressure ranging from 40psig to 300psig.	

B. Compilation ISR of PCT

D1: Formulation based on an extract of medicinal plants, coal tar pitch and salicylic acid for the effective control of psoriasis, method for obtaining said extract and forms of administration of the formulation:

This invention is relates to an herbal extract for the effective treatment of conditions, disorders and skin injuries resulting from skin disease such as psoriasis.

An herbal extract made from walnut, oregano, batamote, thyme, elderflower, rosemary, cress, saponaria, espinosilla, coal tar, salicylic acid and preservative at a concentration of 0.1%. The preservative is preferably paragon containing II (Methyl propyl parabens with DMDM Hydantoin).

In this formulation, the medicinal plants comprised an amount between 15 and 25g of each plant and preferably at 20g per 15 liters of water

The herbal formulation was prepared in various dosage forms such as ointment, liquid soap and solid soap.

The preparation of ointment dosage form included the use of petroleum jelly, BX-C04 complex, oat oil, olive oil, salicylic acid, aloe vera extract, tar coal based orange palm and lemon lime based HS and glycerine.

The preparation of liquid soap peg 150 dosage form included the use of cetiol HE, COSMEDIA GUAR Texapon KD, Paragon II, Dehyton KB, Euperlan PK extract aloe vera, BX-C02 complex, complex BX-C04, olive oil, oat oil, salicylic acid, coal tar based palm orange and lemon lime based HS.

The preparation of solid soap dosage form included surfabon, aloe vera extract, salicylic acid, oat oil, House club BX-C02, BX-C04 complex, based orange palm based HS lemon lime, coal tar, polyethylene glycol 6000 and peg- 150.

The process of obtaining the herbal concentrate consisted of the following steps:

a. A mixture of 20 g of each plant per 15 litres of water was boiled.
b. The heat was reduced to low and the volume was reduced to 1/5 of the initial volume.
c. The concentrated decoction was cooled.
d. The solution was filtered through a cloth to remove the remains of plants.

e. Paragon II at a concentration of 0.1% was added.

Process for preparing ointment dosage form:

a. 23.275kg petroleum jelly was heated at a temperature of 30^{o}C to 40^{o}C.
b. 755g of herbal concentrate and 135g extract of aloe vera were added to the heated petroleum jelly.
c. It was continuously stirred until they were dissolved completely.
d. In a container at a room temperature, 540g of coal tar and 600g palm orange base were mixed and added to the mixture of step c.
e. The mixture was stirred constantly at temperature 70^{o}C.
f. 270g lemon lime based HS was added and stirring was continued.
g. 330g of salicylic acid and 1345g of glycerol was added and mixed well.
h. The product was allowed to stand for a period between 18 to 24 hours. During this time the product solidified.
i. The mixture was melted and filled in container.
j. It was allowed to stand at room temperature until it solidified.

Process for the preparation of shampoo base:

a. 150g PEG 130 was diluted in sufficient quantity of water
b. 105g of COSMEDIA Guar was dissolved in sufficient quantity of water
c. The two solutions were mixed in the mixer and 90g cetiol HE was added and mixed.
d. Sufficient amount of water was added to make up 33.480kg of water.
e. 175g of paragon II, 7930g and 1590g KD Texapon of Dehyton KB were added and mixed.
f. Then 1500g of Euperian PK-771 was added and stirring was continued.
g. 1200g of shampoo base final volume was removed to continue the preparation of liquid soap.

Preparation of liquid soap:

a. 250g aloe vera, 400g of BX-4 complex, 400g of BX-2 complex, 350g of olive oil, 1400g of herbal concentrate and 600g of salicylic acid were added to the shampoo base in the mixer.
b. The mixture was continuously mixed.

c. To 1100g of coal tar 1000g of orange palm basis mix was added. This mixture was added to the contents of the mixer and stirred continuously until a homogenous mixture was obtained.
d. 350g lemon lime base HS was added and was allowed to stand for 24 hours before filing.

Preparation of solid soap:

a. 16.660g of surfabon was heated at a temperature of 75^{o}C,.and to it 113g of aloe vera extract, 226g of salicylic acid, 607g of herbal concentrate, 113g of oat oil, 113g of BX-04 complex and 113g of complex BX-02 were added and mixed till homogenous mixture was obtained.
b. 481g of base mix orange palm was mixed with 435g of coal tar and 340g lemon lime based HS in a container at room temperature.
c. The product obtained in step b was added to mixture prepared in step d and mixed it.
d. 2040g polyethylene glycol 6000 and 340g PEG-150 were mixed continuously until smooth.
e. The mixture was transferred into a rectangular mold and was allowed to solidified, finally cut into square portions of 150g.

D2: Cosmetic composition comprising at least one anti-dandruff agent and also oxyethylenated sorbitan monolaurate and cosmetic treatment process using the said composition:

"A cosmetic composition comprising of an aqueous medium at least one anti-dandruff agent other than 2 pyridone derivatives and at least one oxyethylenated sorbitan monolaurate comprising of 2 to 25 oxyethylene units" was prepared. The anti-dandruff agent is chosen from: pyridinethione salts, trihalocarbamides, triclosan, azole compounds, antifungal polymers, selenium sulphides and sulphurs in its various forms, cadmium sulphide, allantoin, coal tar or wood tar and derivatives thereof, salicylic acid, undecylenic acid, fumaric acid and allylamines. The pyridinethione salts were chosen from calcium, magnesium, barium, strontium, zinc, cadmium, tin and zirconium salts and the azole compound are chosen from climbazole, ketoconazole, clotrinazole, econazole, isoconazole and miconazole.

The antifungal polymers were chosen from amphotericin B or nystatin and selenium sulphides were chosen from those of formula $s_xse8_{x,,}$ wherein x ranges from 1 to 7. The anti-dandruff agent is present in the composition in an amount ranging from 0.001 to 10%, 0.1 to 5%, and 0.2 to 2% by weight relative to the total weight of the composition. The at least one oxyethylenated sorbitan monolaurate was chosen which had 2 to 25 oxyethylene units and it was present in the composition in an amount ranging from 0.5%, 0.5 to 10% or 2 to 9% by weight relative to the total weight of the composition.

The composition at least one ether having two fatty chains chosen which is solid at a temperature 30^oC and at least one ether having two fatty chains is distearyl ether. The two fatty chains are present in the composition in an amount greater than or equal to 0.5%, 1 to 5% and 1.3 to 2% by weight relative to the total weight of the composition.

The composition further had at least one fatty alcohol comprising at least 12 carbons or 12 to 30 carbons atoms. At least one fatty alcohol was chosen from the cetyl alcohol, stearyl alcohol, behenyl alcohol, lignoceryl alcohol, montanyl alcohol and it was present in the composition ranging from 0.5% to 10% or 1 to 5% by weight relative to the total weight of composition.

The composition further comprised of at least one surfactant chosen amongst anionic surfactant, cationic surfactant, amphoteric or zwitterionic surfactant which was different from the oxyethylenated sorbitan monolaurate which consisted of 2 to 25 oxyethylene units. The anionic surfactant was present in the composition at a concentration of 4 to 20% by weight relative to the total weight of the composition.

The aqueous medium is chosen from water and mixture of water and at least one cosmetically acceptable solvent.

The composition further comprised of least one solvent chosen from C_1–C_4 lower alcohol and polyols.

In this composition at least one additive was chosen from anti-hairloss agents, oxidizing agents, ceramides, pseudo-ceramides, vitamins, provitamins, plant, animal, mineral and synthetic oil, waxes, sunscreens, colored or non-coloured inorganic or organic pigments, dyes, thickeners, antioxidants, hydroxyl acids, fragrance and preserving agents.

D3: Method for using compositions containing dichlorophenyl imidazoldioxolan to treat serborrheic dermatitis, dandruff, psoriasis and acne and composition thereof

This invention relates to compositions such as body and hair cleansing product in particular shampoos, comprising dichlorophenyl imidazoldioxolan and method for using such compositions to alleviate the symptoms associated with dandruff, seborrheic dermatitis, acne and psoriasis.

The composition comprised of dichlorophenyl imidazoldioxolan and therapeutic components which are salicylic acid and piroctone olamine. The dichlorophenyl imidazoldioxolan and said therapeutic component are present in quantities effective for inhibiting the growth of fungi. The dichlorophenyl imidazoldioxolan is present in an amount based upon the weight of the composition from 0.25% to 2% and said therapeutic component is present in an amount ranging from about 0.5% to 3%. In this composition, one or more following components were used, at a surfactant, a foaming agent, thickener agent, preservative, anti-oxidant and an acid or a base or buffer sufficient to give the shampoo a pH of 3 to 8.

In this composition one or more surfactant were selected from the group comprising sodium C14- 16 olefin sulfonates, sodium lauryl sulphate, sodium laureth sulphate, cocamidopropylamine oxide, lauryl amine oxide, lauramido DEA, cocamidopropyl betaine, lauryl dimethyl betaine, cocodimethyl sulphopropyl betaine, sodium cocoyl sarcosinates, disodium oleamido MIPA sulfosuccinate, disodium cocamido MIPA sulfosuccinate, disodium laureth sulfosuccinate, cocoamphocarboxy-glycinate, disodium oleamido MEA sulfosuccinate, amine glycinates, amine propionates and amine sultaines or mixture thereof and is comprised of from 4% to 12% of an anionic surfactant and from 3% to 10% of an amphoteric surfactant.

The anionic surfactant is consisted of sodium olefin sulfonate, sodium lauryl sulphate, sodium laureth sulphate and amphoteric surfactant comprised of cocamidopropylamine oxide, cocamidopropyl betaine.

The foaming agent was selected from fatty acid mono and di alkanolamides comprising cocamide MEA, cocamide DEA, oleamide MEA, oleamide DEA.

The antioxidant used was butylated hydroxytoluene, butylated hydroxyanisole, ascorbic acid, N-acetyl cysteine, sodium metabisulfite. One or more pearlizing agents were used and these were consisted of ethylene glycol distearate, ethylene glycol monosterate.

Process for preparing a body and hair cleansing formulation:

a. Anionic surfactant and deionized water were mixed under conditions sufficient to produce a first mixture.
b. Dichlorophenyl imidazoldioxolan and antioxidant were mixed with the first mixture under conditions sufficient to produce a second mixture.
c. The second mixture was cooled to a sufficient temperature before therapeutic component was added to it.
d. Addition of the therapeutic component to the cooled second mixture under the desired conditions produced a third mixture.
e. Finally a buffer and an amphoteric surfactant were added to the third mixture under conditions sufficient which led to the fourth mixture.

The formulation is used for inhibiting the growth of bacteria on the surface of skin and treating acne, tinea capitis and tinea corporis and also helps in relieving one or more of the following symptoms of the skin or scalp: itching, redness or erythema.

D4: Shampoo composition with increased deposition of polyacrylate microcapsules

This invention is related to shampoo compositions containing polyacrylate microcapsules, wherein the polyacrylate microcapsules have increased deposition onto hair.

The shampoo composition consisted of 0.001% to 10% of an anionic charged polyacrylate microcapsule, 0.01% to 2% of a cationic deposition polymer, 2% to 25% of a detersive surfactant and a carrier.

The anionic charged polyacrylate microcapsule is an anionic emulsifier and a polyacrylate microcapsule and the anionic emulsifier surrounds at least a part of the external surface of the polyacrylate microcapsule or is physically or chemically bound to the external surface of the polyacrylate microcapsule.

The anionic emulsifier and the polyacrylate microcapsule were mixed such that the weight ratio of the anionic emulsifier to the polyacrylate microcapsule ranged from 1.0:40 to 0.5:5. The anionic emulsifier was selected from the group consisting of:

Poly(meth)acrylic acid; copolymers of (meth)acrylic acids and its (meth)acrylates with C1-C22 alkyl; copolymer of (meth)acrylic acids and (meth)acrylamide and mixture thereof.

The anionic charged polyacrylate microcapsule and the cationic deposition polymer were mixed such that the weight ratio of the anionic charged polyacrylate microcapsule to the cationic deposition polymer was in the range of 1.0:0.01 to 1.0:10.

The anionic polyacrylate microcapsule has a particle size of from 2 microns to 80 microns. It has a core and a shell that encapsulates the said core. The core comprises of 6% to 99.9% of a benefit agent, anti-dandruff agent ZPT and the cationic deposition polymer which is a water soluble polymer with a charge density of 0.5 milliequivalents per gram to 12 milliequivalents per gram. The molecular weight of cationic deposition polymer ranged from 100,000 Daltons to 5,000,000 Daltons.

The anionic charged polyacrylate microcapsule is contained in agglomerate and the agglomerate comprises of materials selected from the group consisting of silica, citric acid, sodium carbonate, sodium sulphate, sodium chloride and binders such as sodium silicates, modified cellulose, polyethylene glycols, polyacrylates, polyacrylic acids, zeolites.

The shampoo composition is in the form of gel and the gel comprises less than 45% water and has viscosity in the range of 1,000cps to 10,000 cps.

Method of making a shampoo composition:

a. Coating a polyacrylate microcapsule with an anionic emulsifier to form an anionic polyacrylate microcapsule.
b. Combining the anionic polyacrylate microcapsule with a cationic deposition polymer to form a premix.
c. Adding the premix to a detersive composition comprising surfactant and a carrier.

D5: Tar Gel Formulation

A tar formulation is used in the treatment of skin disorders containing tar, propylene glycol, ethyl alcohol and a gelling agent e.g. Carbopol 940 and it is formulated using appropriate ingredients in appropriate percentage and these are:

a. 1% to 10% by weight of an organic solvent extract of Crude Coal Tar.
b. 25% to 65% by weight of propylene glycol.
c. 20% to 35% by weight of ethyl alcohol
d. 0.5% to 5% by weight of a gelling agent.
e. 5% to 35% water

The "organic solvent selected from the group consisting of isopropyl myristate, PEG-6-dilaurate, polyoxyethylene (4) lauryl ether, propoxylated (15 moles propylene oxide)stearyl ether, polyoxyethylene(10) oleyl ether, polypropylene glycol(5) cetyl ether and glycereth-7-coconate and the extract is formed from 60% by weight of solvent and 40% by weight of crude coal tar". In this composition salicylic acid was used in this formulation as a keratolytic agent and additionally a protein and emulsifing agent was also used in the formulation.

In this formulation organic solvent extract of crude coal tar was present a concentration of 2% by weight.

This formulation is used in treating psoriasis and applied to the effected skin area for about 5 minutes and then removed any excess of material. It also helps in treating chronic atopic dermatitis, lichen simplex chronic us or nummular eczema.

Patent Land Scape

GLOBE MOTORS PATENTS:

S.NO	APPLICATION NO	TITLE
1.	771/CHE/2007	Dual function holding device operable under a system power loss condition
2.	13/541982	Retention structure for heat generating component
3.	13/446099	Method of positioning a sensor within a motor assembly
4.	13/422112	Rotar including anti-rotation feature for multi-pole structure
5.	12/841601	Frameless electric motor assembly
6.	13/075248	Parallel wound stator

7.	12/616334	Method of controlling an automatic door system
8.	12/103402	Multiple track sense magnet assembly
9.	11/678777	Seat storage actuator
10.	11/678963	Dual function holding device operable under a system power loss condition
11.	11/478426	Steering system torque sensor
12.	11/390399	Method and apparatus for winding field coils for dynamo-electric machines
13.	11/347948	Winding machine including actuated collet
14.	10/196400	Winding tool for forming wire coils in a stator stack including radially movable forming members
15.	12/719954	Electrical door operators
16.	12/416622	Concealed electrical door operator
17.	12/009029	Method and apparatus for powder stator stacks
18.	12/103469	Multi-track sense magnet with reduced cross-talk
19.	D/282728	Rotary actuator housing
20.	10/942509	Horizontal winding machine
21.	10/436765	Machine for winding dynamo-electric stators
22.	08/682928	Method for forming a black adherent coating on a metal substrate
23.	08/552340	Laminated motor core for mounting permanent ring magnets
24.	08/939267	Composition for forming a black adherent coating on a metal substrate
25.	EP20130713281	Rotor including anti-rotation feature for multi-pole structure
26.	EP20110175112	Frameless electric motor assembly
27.	EP20070106696	Dual function holding device operable under a system power loss condition
28.	EP20050252531	Apparatus for stripping wire to be arranged on a

		machine for winding stators for dynamo-electric machines
29.	EP20040255740	Winding machine with a horizontal axis
30.	EP20010981594	Machine for winding dynamo-electric stators
31.	EP19960932332	Motor termination board
32.	1997041569	Multi-pole ring magnet for rotating electrical machines
33.	1996071181	Motor termination board
34.	US19780925173	Pressure controlled breathing apparatus
35.	US19460657390	Commutator and method of making same
36.	US19330656708	Compass
37.	US19570647614	Hydraulic pump or motor
38.	US19570634723	Electric motor
39.	US19560564167	Resuscitator valve assembly
40.	US19750547047	Vibratory apparatus with improved motor actuated door mechanism for closing the discharge outlet
41.	US19310515074	Resilient wheel
42.	US19300505149	Fluid brake
43.	US19740500354	Vibratory apparatus and method
44.	US19740450975	Vibratory apparatus with improved motor actuated door mechanism for closing the discharge outlet
45.	US19300447341	Disengageable fastener
46.	US19730394744	Combined resuscitator and inhalator apparatus
47.	USD3694968	Vibratory apparatus
48.	USD3630356	Vibrating screen with spring beam
49.	USD3448747	Dual container work processing device
50.	USD3425409	Resuscitator

51.	US19390249264	Shock absorber
52.	US19510232641	Coil forming method
53.	US19800185295	Breathing apparatus with connector system for supplying emergency air to another individual

Chapter 5

CASE STUDIES

Chapter 5

CASE STUDIES

5.1 Case Study 1

International application PCT-CN was filed by John on 5 October 2011 in Chinese with the Chinese Patent Office (SIPO). The publication of PCT-CN contained 40 pages of description and 2 pages of claims. In order to enter the European phase, John provided you with an English translation of the description of PCT-CN comprising 35 pages and an amended set of claims in English comprising 3 pages. These documents were submitted to the EPO by fax.

a. John wants to know what the amount of the filing fee will be.

Filing fee for Euro-PCT is 200 Euro when the application is filed by fax and the additional fee of Euros per page for each extra page. So, for the Euro-PCT application consisting of more than 35 pages i.e. 14 Euro per page would be charged for the 36^{th} and subsequent pages. The PCT-CN was published in China and the additional fee for excess pages was calculated on the Chinese description. The total number of pages were 44, 1 for abstract, 40 for CN description and 3 for replacement claims. The replacement claim means the new set of claims replacing the claims published by WIPO.

For the 9 additional pages fee due $9 \times 14 = 126$ Euro

Total filing fee = filling fee + additional fee

$200 + 126 = 226$ Euro

The total filing fee will be 226 Euro

b. What is the latest date for paying the filing fee without incurring additional fees?

PCT-CN was filed on 5 October 2011 and the filing fee was due 31 months from the date of filing of application.

31 months from filing = 5 October 2011+ 31M = 5 May 2014 is the last date to pay filing fee without any additional fee.

5.2 Case Study 2

Mr. Smith is sole applicant and inventor of an international application. This application, containing the prescribed request together with a separate power of attorney for an agent, was filed at the EPO as receiving Office. The request was signed by the agent. The power of attorney was not signed at all.

a. Is there a defect in the application in view of the requirements for signatures?

No, the request for an international application must be signed by the applicant or by agent. Therefore, an agent can sign request on behalf of applicant. The appointment of agent for PCT requires the applicant signed request or a separate Power of Attorney. In the EPO receiving office no Power of Attorney is required as EPO have waived this requirement. Therefore agent validly appointed as EPO can sign application and there is no defect in view of requirement for signature.

b. Who can withdraw the international application and what has to be done to this end?

- The applicant can withdraw the international application by signing the notice of withdrawal himself.
- The agent can sign the withdrawal but must first submit a signed Power of Attorney signed by the applicant because the requirement to file a separate Power of Attorney have not been not waived under R90.4(d) where an agent can submit a notice of withdrawal.

5.3 Case study 3

In January 2013, Mr B, who has his residence in Germany, filed the European patent application EP1 for subject-matter A without claiming priority. EP1 was withdrawn in May 2013. In July 2013 subject-matter A was disclosed in a scientific article.

Your client Ms M, who has her residence in Italy, recently learned about the filing of EP1. Ms M informed you that she can prove that Mr B has stolen her invention and that in fact she is entitled to the grant of a patent for subject-matter A. Ms M wants to have patent protection for subject-matter A through the EPO.

a. Which steps must she take?

- EP1 was filed by Mr B in Jan 2013 but EP1 was withdraw in May 2013 because he was too late to claim priority to EP1 when filing a new EP application. According to the article (art 87(1) EOC) the priority must be claimed within 12 months of filing date of EP1.
- Ms M cannot file a new application today as subject matter was disclosed in July 2013 means new filing directed to subject matter A was not novel nor inventive as disclosure state of art under Art 54(2) EPC.

- Not matter that disclosure evident abuse as greater than 6 months ago i.e. July 2013 + 6M = Jan 2014 latest date to file new EP of disclosure July 2013 to be non-prejudicial disclosure.
- Ms M can start entitlement proceedings against Mr B at German courts.
- Once she has the final decision she must within 3 months of decision recognising her entitlement file a new EP application.
- She must pay the filing and search fees within 1 month of filing the new application.
- She must pay the designation fee within 6 months of publication of Search Report for the new application.
- New application must meet the requirements and it must be filed in paper form at EPO in Hague, Berlin or Munich Offices.
- Must be filed in same language as EP1 and meet all other formal requirements.
- Jan 2014 and July 2014 disclosure are not prior art under Art 54(2) EPC and the invention are novel and inventive.

b. In which contracting states can she obtain protection?

- The States that recognise decision of German court under Protocol on Recognition.
- Decision by EP court may judge Ms M only as being entitled in some states - if that is the case she can only have protection in those states

5.4 Case Study 4

The applicant filed a European patent application containing an independent claim 1 and a dependent claim 2. During oral proceedings the examining division pointed out that the subject-matter of claim 1 lacked inventive step. However, the division indicated that claim 2 would fulfil the requirements of the EPC. The applicant nevertheless did not amend the claims. The application was refused by a decision dated 6 August 2013.

On 1 October 2013, the applicant filed a notice of appeal. On 4 October 2013 he paid the fee for appeal and requested reimbursement of that fee. On 28 November 2013 the applicant filed a statement of grounds of appeal together with a new single claim consisting of the features of previous claims 1 and 2.

Is the appeal admissible?

- For appeal to be admissible, the appellant must file notice of appeal within 2 months of notification of decision to be appealed i.e. must be filed by 16 October 2013 (6 August 2013 + 10 days = 16 August 2013 + 2 months = 16 October 2013). 10 days

are for oral proceeding but the held decision must be given orally which should be subsequently given in writing and notified to the parties.

- The applicant filed a notice of appeal on 1 October 2013 and paid fee on 4 October 2013. The appeal is deemed to be filed only when the appeal fee was paid.
- The applicant must submit the statement setting out grounds of appeal within 4 months of notification which means on 16 December 2013 (16 August 2013 + 4 months = 16 December 2013) but the applicant filed on 28 November 2013 with a new single claim consisting of the features of previous claims 1 and 2 and all information provided met the requirements of R99(2).
- Other formal requirements like name and address of applicant and define the subject matter of appeal should be as per R99(1)(c)EPC.

5.5 Case Study 5

On 29 December 2014 you received a decision dated 27 December 2014 refusing your European patent application. The last sentence of the decision reads as follows: "As all the features of the independent claim are known from the prior art document D1, the application is refused for the lack of novelty, Art. 56 EPC." On 26 January 2015 you received a correction of the decision according to Rule 140 EPC for the same application. The correction is dated 24 January 2015. Only the last sentence was changed to "As all the features of the independent claim are known from the prior art document D1, the application is refused for lack of novelty, Art. 54 EPC".

What will you advise your client?

- The original decision was in error because a lack of novelty falls under A. 54 EPC, not A. 56 EPC
- R. 140 allows for decisions to be corrected for obvious mistakes, which is clearly the case here.
- The timetable for filing appeal therefore depends upon which decision is appealed: 27/11/14 or 24/1/15.
- File Notice of Appeal: 2months from “decision” (i.e. 27 December 2014 + 10 days = 6 January 2015 + 2 months = 6 March 2015).
- Since today is the final day for filling notice of appeal then time can be saved by filing notice of appeal by fax.
- Appeal fee also needs to be paid by 6 March 2015 Client then has 4 months from decision to file grounds of appeal (6 January 2015 + 4 months = 6 May 2015).

Chapter 6

SUMMARY AND CONCLUSION

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The patent law in any country provides safety to the inventor for his discovery. Patent safety means the other person cannot manufacture and distribute the product without taking prior permission from the patentee. In different countries there are different criteria for an invention to be a patentable but in all the countries the clause of novelty is there. The clause novelty states that “the invention must be new” if your invention is already known you cannot get patent despite being fulfilled criteria, such as Industrial application and must be non-obvious.

The patent system is divided into two parts.

- Patent filing procedure
- Patent grant procedure

The patent filing procedure is first step in which the applicant drafts the specification which provides complete information about the invention. This includes title, drawing, description, abstract and claims. The patent application acceptance and rejection depends upon the drafting. The filing procedure of India, Europe and USA was compared on the basis of language, type of application, total number of claims, inventive step, type of patent, independent claims and total number of specification.

- The legal systems of U.S, Europe and India have certain features are common i.e., non-obviousness/ inventive step, novelty and utility.
- The patent protection term in India and Europe is 20 years from the priority date but in U.S. the patent protection term for utility and plant patent is 20 years and design patent is 14 years.
- U.S. has three types of patents: utility, design and plant patent where as in India and Europe there are only two type of patent which are product and process patent.

Patent grant procedure is the next step after the filing of application, in which includes search, publication, examination and opposition is common in these three countries.

Chapter 7

REFERENCES

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REFERENCES

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