

Drafting and Prosecuting Pharmaceutical Patent Applications

**Presented in Hyderabad for SSI IPR
Awareness Programme**

March 3, 2005

Different Phases

- **Pre-lodgment**
- **Lodgment**
- **Post-lodgment**

Pre-lodgment

- Search and analysis of Prior Art
- Drafting a Patent Specification

Why Preliminary Searching

- Patentability

Novelty of the Invention.

Non-obviousness of the Invention.

Usefulness of the Invention.

- Infringement

Prior Art Search in general

- Patent Prior Art
- Non-Patent Prior Art

Various Search Engine

<http://www.uspto.gov>

<http://www.epo.org>

<http://www.wipo.int>

<http://www.delphion.com>

<http://www.ipindia.nic.in>

<http://www.indianpatents.org.in>

<http://stneasy.cas.org>

<http://www.sciencefinder.co.uk>

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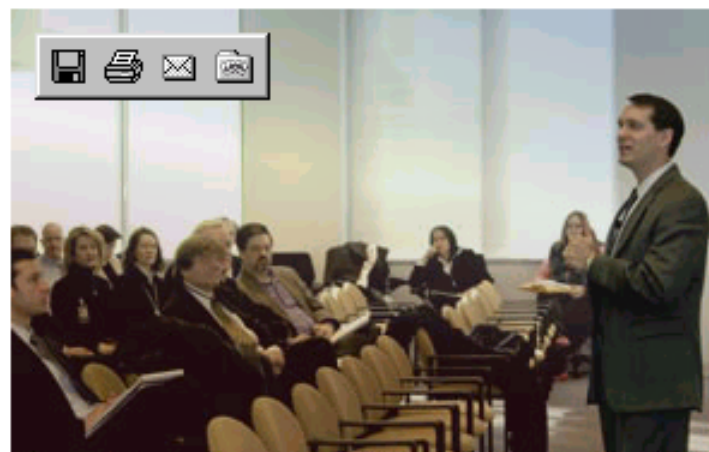
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Deputy Under Secretary of Commerce for Intellectual Property, Steve Pinkos addresses participants in USPTO-sponsored seminar on the Chinese criminal justice system for intellectual property offenses

China

On February 17, 2005 the Department of Commerce's United States Patent and Trademark Office (USPTO) sponsored a seminar on the Chinese criminal justice system for intellectual property offenses. The seminar was held to introduce the Chinese criminal justice system to U.S. industry, government agencies, intellectual property owners and legal practitioners so they may better understand the

USPTO Holds Seminar on Chinese Criminal Justice System for Intellectual Property Offenses

Continuing efforts to help U.S. business protect their

Deputy Under Secretary of Commerce for Intellectual Property, Steve Pinkos addresses participants in USPTO-sponsored seminar on the Chinese criminal justice system for intellectual property offenses

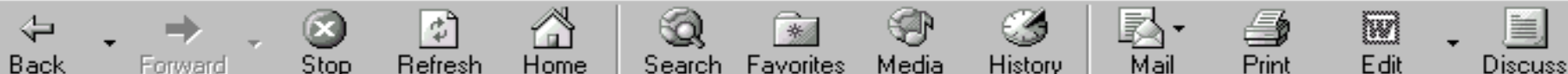
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(published since 15 March 2001)

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Information Applicable to Both Databases

Important Notices -- Please read!

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Patents from 1790 through 1975 are searchable only by Patent Number and Current US Classification!

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1976 to present [full-text]

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Patents from 1790 through 1975 are searchable only by Patent Number and Current US Classification!

Field Code	Field Name	Field Code	Field Name
PN	Patent Number	IN	Inventor Name
ISD	Issue Date	IC	Inventor City
TTL	Title	IS	Inventor State
ABST	Abstract	ICN	Inventor Country
ACLM	Claim(s)	LREP	Attorney or Agent
SPEC	Description/Specification	AN	Assignee Name
CCL	Current US Classification	AC	Assignee City
ICL	International Classification	AS	Assignee State
APN	Application Serial Number	ACN	Assignee Country

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Enter the patent number(s) you're searching for in the box below.

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Examples:

Utility : 5,146,634
 Design : D339,456
 Plant : PP8,901
 Reissue : RE35,312
 Def. Pub. : T109,201
 SIR : H1,523

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Patent Specification

“A Techno-legal document describes about technical aspects of the Invention in a manner to meet the requirements of the Patent law.”

Types of Specification In General

- **Provisional**
- **Complete**

Provisional Specification

- **Describes essential features of the Invention**
- **Does not require claims and abstract**
- **Secure the Prior right**
- **Liberty to develop the Invention**
- **Get time for testing commercial possibility of the Invention.**

Complete Specification

- **Is filed within 12 months from the date of the provisional application**
- **Include improvement associated with the subject matter of the provisional application**
- **Subject to examination**
- **Subject to acceptance & grant**

Contents of the Specification

Title

Field of the Invention

Background of the Invention

Summary of the Invention

Description of the Drawings

**Detailed Description of the
Invention**

Claims

Abstract

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Title of the Invention

- **Short & Precise**
- **Consistent with the Invention**

Field of the Invention

- **Indicates general class of the Invention**
- **Specificity of the Invention**

Background of the Invention

- **General State of the Art**
- **Related Art**
- **Problems associated with the Related Art**
- **Objective of the Invention**

Summary of the Invention

- Principal embodiment
- Preferred embodiment

Brief Description of the Drawing

Describes the Drawing figure

Detailed Description of the Invention

- **Explain the detailed nature of the Invention**
- **Explain the Principal embodiment**
- **Explain the Preferred embodiments**
- **Explain the drawings fig. & figure numeral**
- **Explain the complete experimental procedure**
- **Examples**

Claims

Introductory Phrase

Preamble

Transitional Elements

Body of the Claims

Dependent Claims

Multiple Dependent Claims

Omnibus Claim



What is claimed is:

A process for producing compound X, consisting essentially of :

reacting compound Y in the presence of a base and an aprotic solvent.....



**The process according to claim 1, wherein
the -----.**

**A process according to any of the
preceding claims and as substantially herein
described with reference to the description
and the examples.**

Abstract of the Invention

“ a short summary or condensed version of embodiments, which take out the essence of invention”

Conclusions

- Preferable to conduct a search for novelty from database and through other information sources.
- Analyze the complete prior art and clarify how the invention differs from the information known in the prior art.
- Each part of the specification should be described in brief.
- The utility and advantage of the invention should be clearly mentioned.
- Claims should sufficiently define the invention.

Types of Application

- Divisional Application
- Patent of Addition
- Continuation Prosecution Application
- Continuation in Part Application

Divisional Patent

“A divisional patent application is usually based on parent patent application, but contains claims that are different than those in the parent application. It is filed in response to a restriction requirement that is imposed by the Patent Office. “

- only can file while the parent application is pending

- cannot file once parent application issues as a patent or is abandoned
- will have to elect the patent claims that he or she wishes to pursue
- remaining patent claims may be pursued later in one or more divisional patent applications
- accordingly title and description should be consistent
term will be same as Parent application

Patents of addition

“An application is made for a patent in respect of any improvement in or modification of an invention described or disclosed in the Parent application”

- Patent shall not be granted as a patent of addition unless the date of filing of the complete specification was the same as or later than the date of filing of the complete specification in respect of the main invention.

- A patent of addition shall not be granted before the grant of the main patent.

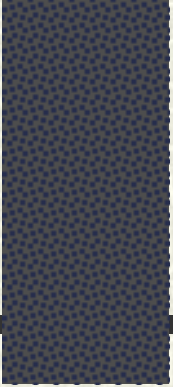
Term of Patent of Addition

- The term of a patent of addition would be equal to the patent for the main invention, or for the remaining term of the main patent as has not expired.
- If the main patent is revoked, upon making a request, the patent of addition shall become an independent patent for the remainder of the term for the main patent.
- No renewal fees is required to be paid for a patent of addition, but if such a patent becomes an independent patent, the same fee shall be payable as if the patent had been originally granted as an independent patent.

Continuation Prosecution Application

“A Continuation prosecution application filed during the lifetime of an earlier non-provisional application, repeating same description of the earlier non-provisional application with additional new claims.”

- only can file while the earlier-filed application is pending

- 
-
- cannot file once parent application issues as a patent or abandoned
 - include an appropriate reference to the prior application
 - have at least one inventor in common with prior application
 - using same text description with additional claims

Continuation in Part Application

“A Continuation-in-part is an application filed during the lifetime of an earlier non-provisional application, repeating some substantial portion or all of the earlier non-provisional application and adding matter not disclosed in the said earlier non-provisional application.”

- usually contains all of the same parts and must meet the same requirements as a parent application.
- only can file while the earlier-filed application is pending
- cannot file once parent application issues as a patent or abandoned
- include an appropriate reference to the prior application
- have at least one inventor in common with prior application

What does it mean by?

the earlier-filed application is pending---

A → Original Patent Application

B → 1st Continuation Application

C → 2nd Continuation Application

If A is still pending---

If A is issued but B is Pending ---

What does it mean by?

at least one inventor in common with prior application-

Application discloses : The New Compound 'X', The method of making the compound 'X' and use of the 'X' in antibiotic.

Application also discloses: The method of making the compound 'X' can be used to make structurally similar compound and that group of compound have some anti-inflammatory properties.

Original application claims: The New Compound 'X', The method of making the compound 'X' and use of the 'X' in antibiotic.

1st Continuation application claims: Method for making similar compound.

2nd Continuation application claims: Use the compounds as anti-inflammatory agents.

Substantive Amendments

(As per Ordinance 2004)

Product Patents for 'Food', 'Drug', and Pharmaceuticals'

Section 5 of the Indian Patents Act, 1970 has been deleted.

- Patents will be granted for all categories of inventions From January 1, 2005.

Product & Patentability

Types of products which fulfill the patentability criteria:

New drug molecules

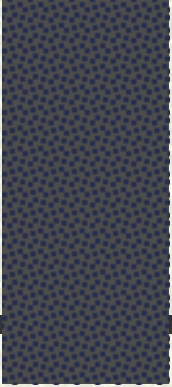
Synergistic combinations

Combination of new chemical entities with a known compound

Agrochemicals

New Chemical products, in general

Organometallic compounds



Optical glasses, semiconductors, Intermetallic compounds, Alloys

New food articles

New products resulting through biotechnological, microbiological or biochemical process

New product derived from natural resources

Patentable or not?

What will be the Patentability Criteria?

Structural Isomers:

Structure different and Properties same???

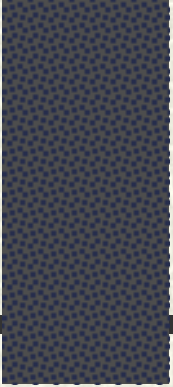
Structure different and Properties different???

Homologs

Stereo Isomers

Polymorphs:

New polymorph of same active with new properties???



new polymorph of same active by
new process???

Metabolites

Prodrugs

Hydrates

Acid addition Salt

Other derivatives

Restrictions on 'New Use' diluted

Sec.3(d);

“The mere discovery of any new property or new use for a known substance or of the mere use of a known process, machine or apparatus unless such known process results in a new product or employs at least one new reactant.”

The Ordinance says,

“The mere discovery of any new property or mere new use for a known substance or of the mere use of a known process, machine or apparatus unless such known process results in a new product or employs at least one new reactant.”

Lodgment & Post-lodgment

- ★ **Filing Phase**
- ★ **Examination Phase**
- ★ **Grant Phase**
- ★ **Opposition Phase**

Filing Phase

Convention Filing

PCT Filing

Convention Filing

- ★ Application Document

- Form 1

- ★ File the form without the Signature of the inventors – then file it within 3 months with inventors signatures

- Form 2

- ★ With specification

- Form 3

- ★ Section 8 obligations must be complied with. This is something that you may want to streamline

- Form 26

- ★ A general Power would suffice

PCT National Phase Filing

- ★ Additional documents for PCT National Phase Applications

- ISR

- PCT Request

- IPER (if available)

- Copy of the transmittal of PCT IB 304 (verified English translation of the priority document if not in English)

- ★ Agent can sign the verification

- Assignment – PCT Global Assignment would suffice

- Amendments under Articles 19 and/or 34

- The WIPO Publication Page

Form 3 – Section 8 Obligations

–Section 8 mandates the applicant to do the following:

- *File a statement setting out the details of all corresponding applications – at the time of lodgment;
- *File an undertaking that the Applicant will keep the Controller posted of the details of all corresponding foreign applications. This must be done within 3 months of filing such corresponding applications;
- *If the Controller asks, at the time of examination, typically, to furnish additional information regarding such applications – the additional information can include – search and examination reports

Late Filing

- *Late Filing of all forms/documents possible (including Form – 3)

- By submitting a petition Under rule 138

- If late filing leads to amendments of documents already filed, another petition Under Rule 137 is required

- As for PCT National Phase Applications, if priority document is not filed, the Patent Office will invite the Applicant to file it and in 3 months the Applicant must do so

Request For Examination (RFE)

- ★ RFE is introduced by the Patents Amendment Act, 2002 that came into force on May 20, 2003
- ★ There is a rather tricky timeline that an Applicant will have to keep a watch to compute the deadline to file RFE
- ★ I will explain this with the following flow charts

**REQUEST FOR
EXAMINATION FOR
CONVENTION APPLICATION**

CONVENTION APPLICATION

PRE 2005, JANUARY 1

**CONVENTION
PRIORITY DATE**

INDIAN FILING DATE

18 Months

PUBLICATION

**48 MONTHS FROM THE
FILING DATE**

**36 MONTHS FROM THE
PRIORITY DATE**

**WHICHEVER IS
LATER**

POST 2005, JANUARY 1

**CONVENTION
PRIORITY DATE**

INDIAN FILING DATE

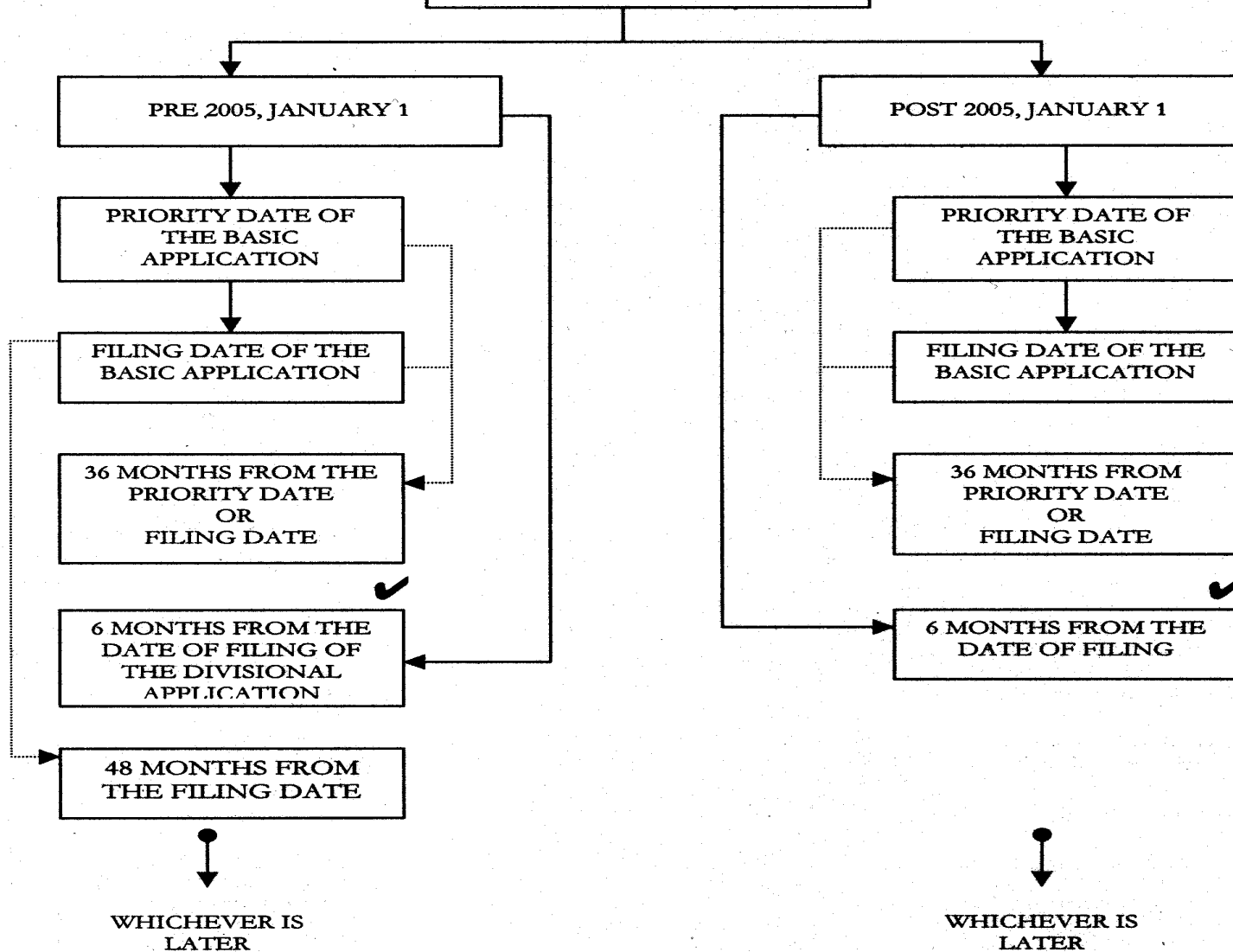
18 Months

PUBLICATION

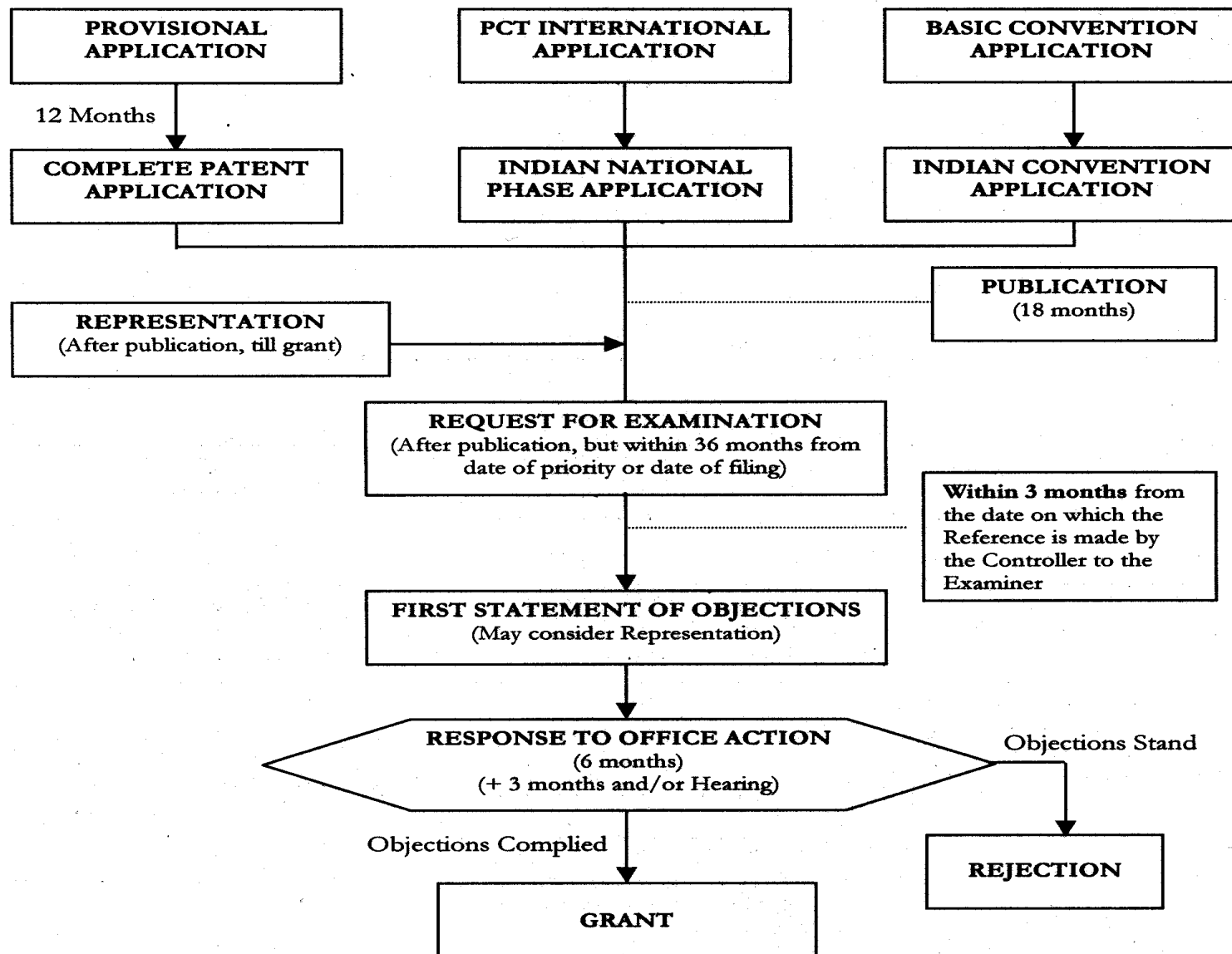
**36 MONTHS FROM THE
PRIORITY DATE**

**REQUEST FOR
EXAMINATION FOR
DIVISIONAL APPLICATION**

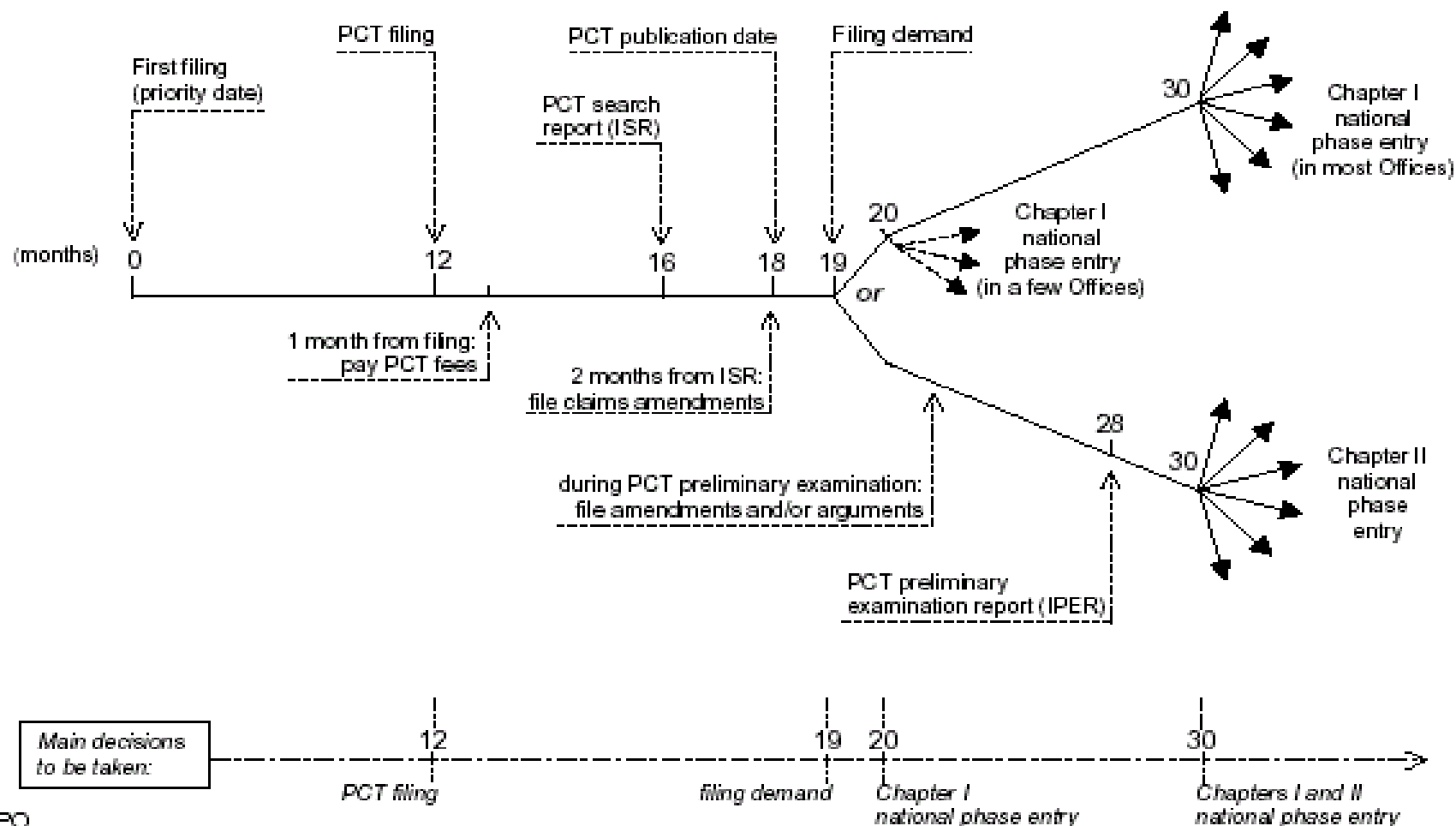
DIVISIONAL APPLICATION



PATENT PROSECUTION PROCEDURE - INDIA

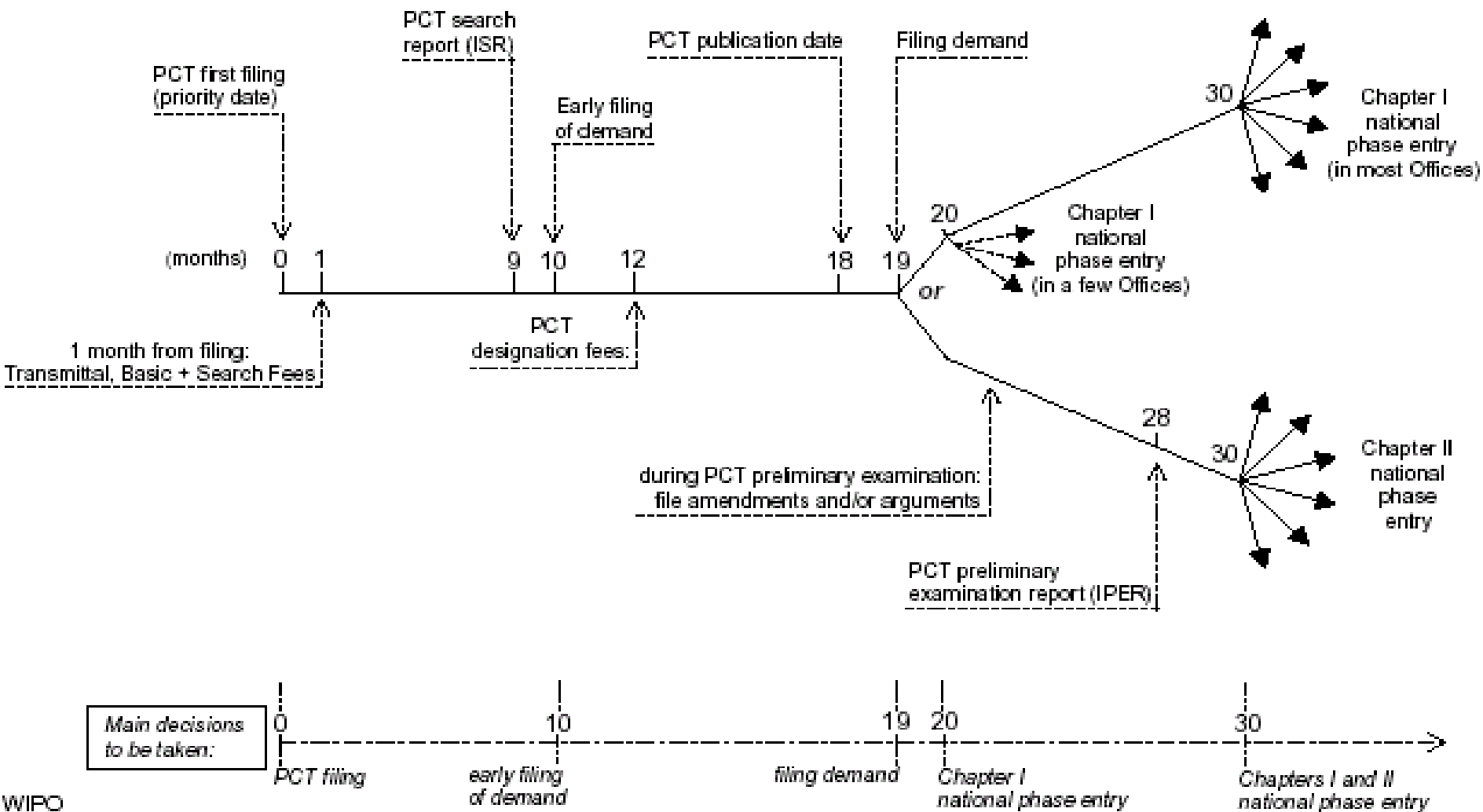


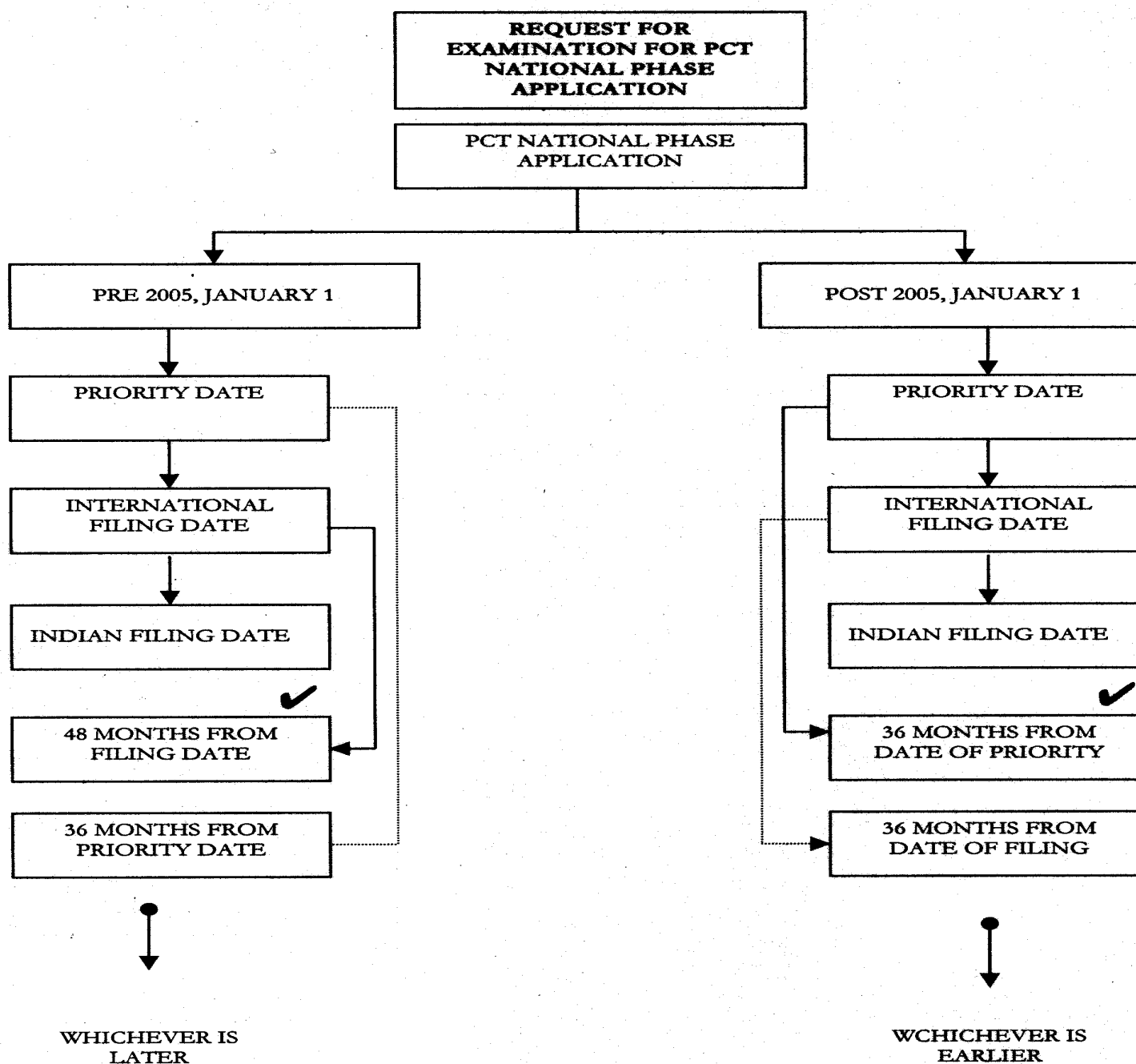
PCT TIMELINE A — PCT filing at the end of the priority year



WIPO
Timeline02-1
27.08.02

PCT TIMELINE B — PCT filing as first filing





Opposition Phase

Now post-grant opposition

The timeline to file notice of opposition has been increased to 1 year from the date of publication of grant of a patent. Earlier this period was 4 (+1) months from the date of publication of the acceptance of the complete specification.

Notice of Opposition must be filed in Form 7. The Notice must be filed within 1 year from the date of publication of the grant of patent.



Thank You