Introduction

- Basic patentability requirements
- Novelty
- Obviousness (inventive step)
- Section 3 issues

- Divisional Applications
- Amendment on national phase entry

Fundamental EPO Requirements

- Article 52(1) EPC

- European patents shall be granted for any inventions, in all fields of technology, provided that they are new, involve an inventive step and are susceptible of industrial application.
**Fundamental EPO Requirements**

- Four Fundamental requirements:-
  - an invention
  - novelty
  - inventive step (non-obviousness)
  - industrial applicability

- Note the distinction between an invention and a patentable invention

**Fundamental EPO Requirements**

- Article 52(2)
  - The following in particular shall not be regarded as inventions within the meaning of [Article 52(1)]
    - (a) discoveries, scientific theories and mathematical methods;
    - (b) aesthetic creations;
    - (c) schemes, rules and methods for performing mental acts, playing games or doing business, and programs for computers;
    - (d) presentations of information.
  - Note the words “in particular” – this list is not exhaustive

**Fundamental EPO Requirements**

- EPO Boards of Appeal have deliberately avoided making a definition of what constitutes a (potentially patentable) invention. However...
  - an invention must have “technical character”

**Fundamental EPO Requirements**

- Must be an invention
  - Must have technical character
  - Not excluded by Article 52
- Otherwise there is no statutory restriction on potentially patentable subject matter
Novelty Art 54(3)

- Prior European Applications – Article 54(3)
  - A first European patent application:
    - filed before the filing date of a second European application
    - published after the filing date of the second European patent application
    - is part of the state of the art in respect of the second application
    - i.e. the first application can be cited for novelty purposes against the second application
    - For applications with a valid priority claims, the effective filing date is the priority date.
    - Applications of this type are not citable for inventive step

Novelty (Art54(3)

- International Applications
  - A PCT application designating the EPO becomes prior art under Article 54(3) only when
    - the PCT application enters the EP phase, and
    - the EP filing fee is paid
  - PCT applications which do not enter the EP phase are not prior art for the purposes of Art 54(3) EPC

Inventive Step (Article 56 EPC)

"An invention shall be considered as involving an inventive step if, having regard to the state of the art, it is not obvious to a person skilled in the art."

- Inventive step – India section 2j
  - "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.

Inventive Step (Article 56 EPC)

- At the EPO, an invention (whether or not it is a patentable invention) must have technical character
  - Inventive step is inherently a subjective question
  - To minimize subjectivity, at the EPO inventive step is assessed according to the "problem-and-solution" approach.
  - The problem-and-solution approach is based on the principle that every invention is the solution of a technical problem.
Inventive Step: Problem-and-solution approach

- determine the closest prior art
- determine the technical difference
- determine the inferred technical effect
- establish the objective technical problem to be solved
- check that problem was solved
- assess whether it would have been obvious to solve the objective problem by the claimed invention

Inventive Step (EPO)
Example 1 – polymorphic form of Atorvastatin

Amorphous form of Atorvastatin was known
- On appeal, claim was to one particular crystalline form of Atorvastatin

Inventive Step – Example 1
- Problem to be solved:
  - the problem to be solved in view of the prior art [amorphous Atorvastatin] lies in the provision of Atorvastatin in a form having improved filterability and drying characteristics.
  - The EPO Appeal Board agreed with this problem and agreed that the crystalline polymorphic form did solve the problem....but....

Inventive Step – Example 1
- ...would the solution to the problem have been obvious to the skilled person in the light of the prior art and common general knowledge?
- The Appellant said not obvious, because
  - the general knowledge of the person skilled in the art was that amorphous forms were generally more soluble and bioavailable than their crystalline counterparts. Therefore, the skilled person would have no incentive to look to crystalline forms as a solution to the problem.
Inventive Step – Example 1

• Also
  — Based on the cited prior art, the skilled person could not have predicted that the specific polymorphs claimed would show the improved properties demonstrated, which made them more amenable to large-scale processing.
  — However....

Inventive Step – Example 1

• The Appeal Board said
  — From his common general knowledge, the skilled person would firstly be aware of the fact that instances of polymorphism are commonplace in molecules of interest for the pharmaceutical industry
  — The skilled person would also have known it to be advisable to screen for polymorphs early on in the drug development process

Inventive Step – Example 1

• The skilled person would be familiar with routine methods for screening for polymorphs by crystallisation from a range of different solvents under different conditions
  — “It belonged to the routine tasks of the skilled person involved in the field of drug development to screen for solid-state forms of a drug substance”

Inventive Step – Example 1

• The Board also said
  — “In the absence of any technical prejudice, the mere provision of a crystalline form of a known pharmaceutically active compound cannot be regarded as involving an inventive step”
Inventive Step – Example 1

• The Board also asked itself:
  – whether there was an incentive for the skilled person to arrive at the present solution [the claimed crystalline form] in the expectation of achieving these improved characteristics.
• The Board noted that amorphous and crystalline forms were each known to have advantages and disadvantages. An advantage of crystalline forms was:
  – “Crystalline products are generally the easiest to isolate, purify, dry and, in a batch process, handle and formulate”
• and concluded from this.......

Inventive Step – Example 1

• Although this might not be true of every crystalline form obtained, it was nevertheless obvious to try this avenue with a reasonable expectation of success without involving any inventive ingenuity

Inventive Step – Example 1

• The appellant also argued
• that the presence of an inventive step was supported by the fact that a specific polymorph was being claimed rather than crystalline forms in general.
• The Board was not convinced
• “an arbitrary selection from a group of equally suitable candidates cannot be viewed as involving an inventive step”

Inventive Step – Example 1

Conclusions

• The solution to the technical problem was obvious – therefore no inventive step
• If the solution to the problem involves the skilled person just in routine activities, there is usually no inventive step – “obvious to try”
  – unless there is some technical prejudice or impediment which would prevent the skilled person from following the “usual” investigations
• If there is a range of equally plausible solutions to the technical problem, choosing just one of them is not inventive
• If one of a range of possible solutions to the technical problem offers some distinct advantage, there may be an inventive step – but still beware of “obvious to try”
• T0777/08
Inventive Step – India

Polymorphic forms of Rifaximin:

Cited Prior Art

D1 EP0161534 discloses rifaximin in crystallized form.
D2 US4341785 discloses new rifamicyn derivatives possessing antibacterial utility.

Controller’s views

- Citations do not contain a direct, unambiguous and enabling disclosure as regards the obtaining of the crystal form of rifaximin. Intention - To carry out the crystallization of rifaximin.
- No information as regards the details of the crystallization,
- No evidence that the process was successful and
- No evidence that the process as applied led to rifaximin beta as claimed in the present application.
- Crystalline forms of rifaximin not even mentioned in prior art citations. The existence of the crystalline form of rifaximin beta has only been known after the present invention.

Controller’s views

- New form of rifaximin having unexpected properties over those of the closest prior art.
- It was completely unknown that different polymorphic forms of rifaximin may exist, let alone that the present form beta of rifaximin may exist.
- It was not possible to study directly the crystallinity of Rifaximin and a surrogate compound, the bromo analogue, was necessary.

Controller’s views

- A compound known to have a uniform property in fact is comprised of various polymorphic forms of said compound having different properties in the term of absorption.
- No motivation to expect that a polymorphic form beta of rifaximin exists and that said form could be obtained by the specific process as claimed.
Controller’s views- absorption

- Pharmacokinetic parameters-
- Rifaximin β is negligibly absorbed.
- Another polymorphic form of rifaximin is well absorbed.
- These results show for the first time that "rifaximin" is, in fact, a mixture of compounds with different absorption kinetics.
- It was not to be expected that polymorphic forms of rifaximin and specifically polymorphic form β of rifaximin exists and, moreover, that said polymorphic forms have different absorption kinetics.

Section 3d - background

- Novartis case : Madras High Court
- An attempt was made to establish that the beta crystalline form demonstrates a 30% increase in bio-availability as compared with the imatinib free base. However, the court felt that this by itself does not demonstrate any therapeutic advantage in relation to the patient.
- Novartis Case : IPAB decision
- Novartis’s Beta Crystalline version may possess improved bioavailability, thermodynamic stability, improved flow properties and lower hygroscopicity, but this does not amount to an increase in "therapeutic efficacy".

Sec 3d

- Roche Case : post grant opposition (2010)
- The mono ester was demonstrated to have more bio-availability compared to that of bis ester of ganciclovir. The patent office did not consider it to be efficacy.
- Efficacy and bio-availability are two different concepts and are not the same.
- Definition of efficacy as therapeutic effect being independent of property (i.e. bio-availability)

Sec 3d

The mere discovery of a new form of a known substance which does not result in the enhancement of the known efficacy of that substance or 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 is not an invention.
Sec 3d – Quantum of Enhancement?

<table>
<thead>
<tr>
<th>Whole Blood Potency* – IC50</th>
<th>Bioavailability</th>
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</thead>
<tbody>
<tr>
<td>INVENTION</td>
<td>6.4</td>
</tr>
<tr>
<td>KNOWN COMPOUND 1</td>
<td>&gt;5.9</td>
</tr>
<tr>
<td>KNOWN COMPOUND 2</td>
<td>6.2</td>
</tr>
</tbody>
</table>

*WBP (IC50) = in vitro potency (IC50) x 100% free fraction.

Controller’s decision

- The difference in the properties of the prior art compounds and the instant compound under question is not so significant that it may pass the bar of sec 3(d) of the Patent Act.
- Further the same does not refer to the therapeutic efficacy.

Interpretation of Efficacy – 2012

- The enhancement in efficacy lay in the fact that the polymorph had an in vivo absorption level of about 100 times lower than the original form, resulting in reduction of the toxicity 100 times due to absorption.
- Controller’s opinion: same therapeutic value with 100 times less toxicity of the new polymorph of this invention was appropriate until someone interested proved contrary to it.

Interpretation of Efficacy - 2013

- Objection: Invention lacks inventive step in view of D1-WO/1999/005165, D2-GB2206879, D3-EP0135410, D4-EP0252720, D5-IN185120 and D6-IN166306 and claims attract Sec 3(d)
Applicant’s submissions

5185/CHENP/2007
Controller’s Decision, January 2013

• The technical problem to be solved by the present invention is to provide new streptogramin A derivatives particularly interesting as antibacterial agents.

• The in vitro and in vivo tests were conducted in order to compare the antibacterial activity on Staphylococcus aureus. The Minimum Inhibitory Concentration data shows that the compounds according to the invention have highest antibacterial activity in comparison to the compounds known in prior art.

Data provided

5185/CHENP/2007
Controller’s Decision, January 2013

Comparison of the antibacterial activity of the compounds of the present invention and of compounds of prior art.

<table>
<thead>
<tr>
<th>Examples</th>
<th>In vitro MIC activity ng (Staphylococcus aureus)</th>
<th>In vivo activity per oral mg (Staphylococcus aureus)</th>
</tr>
</thead>
<tbody>
<tr>
<td>1.076</td>
<td>0.15 - 0.4</td>
<td>18</td>
</tr>
<tr>
<td>1.078</td>
<td>0.35 - 1.6</td>
<td>60</td>
</tr>
<tr>
<td>1.081</td>
<td>0.9 - 3</td>
<td>120</td>
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<tr>
<td>1.083</td>
<td>2.1</td>
<td>25</td>
</tr>
</tbody>
</table>

Interpretation of Efficacy - 2007

841/DEL/1996
Pre-Grant Opposition, March, 2007

• M/s Astrazeneca UK Limited, UK ... Applicant
• M/s G M Pharma Ltd., India ... Opponent
• Applicant claimed surprisingly low ED50 values for invention which translate to the compounds having at least four folds and in some cases 16 fold potency as compared to the compounds of the prior art.
• IC50 values also compared.
**EPO Example 2**

**Claim Scope and Inventive Step**

- The EPO uses the problem solution approach to attack broad claims on the basis of inventive step (T0939/92) –
  - The application included a claim to a broad range of related compounds
  - The number of examples and activity data (herbicidal activity) was limited

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**Example 2**

**Claim Scope and Inventive Step**

- Without data showing activity across substantially the whole claim scope, it must be assumed that not all compounds within the claim had activity
- The problem asserted by the application was providing further chemical compounds with herbicidal activity
- This problem was not solved - not all the compounds had activity
- Since the problem is not solved, there is no inventive step
Example 2 - Conclusions
Claim Scope and Inventive Step

• Make sure that the problems addressed by the invention are realistic and are solved
• Try to avoid giving the EPO the opportunity to formulate a trivial problem with a trivial solution ("making alternative compounds")
• Make sure that claim scope is commensurate with available data
• Provide fall back positions to limit the claims if needed

Example 3 – Synergistic Compositions

• T0393/01 (by way of example – there are plenty of similar cases)
  – The claim related to a synergistic combination of two biocides, A and B
  – The claimed amounts of A and B were narrowly defined
  – The prior art taught a combination of A and C.
    • C was structurally similar to B
    • B was known in the art to be more active than C
    • One prior art document hinted at A + B, but did not suggest any amounts

Example 2 - Conclusions
Claim Scope and Inventive Step

• Check the claim language –
  – it might have been helpful to specify “herbicidal compounds of the formula…”, rather than just “compounds of the formula…” (but beware of Sufficiency objections, Art 83 EPC)
• It might be possible to include additional data on the application file to support activity (the applicant in T0939/92 didn’t do this)
Example 3 – Synergistic Compositions

- The Board is convinced that before using a biocide on a large scale, the skilled person would carry out routine experiments in order to optimise the amount of the active ingredients for economical and environmental reasons, so that he would inevitably end up with the amount disclosed in the contested patent without an inventive step.

Example 3 – Synergistic Compositions

- The Board added the more general point:
  - Enhanced effects cannot be adduced as evidence of inventive step if they emerge from obvious tests.

Example 3 – Synergistic Compositions

Conclusions

- Synergy – or other advantageous effects - are of no assistance for inventive step if the prior art points towards the components of the claim.

- Synergy may be useful if there is some impediment or difficulty which points the skilled person away from the general teaching of the prior art.

- Synergy might be established if the claimed composition ranges are very narrowly defined in relation to a much broader range in the prior art.
  - Where would the skilled person routinely look?

Synergy - Indian patent act

- Two different sections

- Inventive step : section 2ja

- Section 3 (e) : Synergy
- both independent of each other
European Divisional Applications

- Article 76 EPC
- 1) A European divisional application shall be filed directly with the European Patent Office in accordance with the Implementing Regulations. It may be filed only in respect of subject-matter which does not extend beyond the content of the earlier application as filed; in so far as this requirement is complied with, the divisional application shall be deemed to have been filed on the date of filing of the earlier application and shall enjoy any right of priority.
- 2) All the Contracting States designated in the earlier application at the time of filing of a European divisional application shall be deemed to be designated in the divisional application.

European Divisional Applications

- Rule 36
- 1) The applicant may file a divisional application relating to any pending earlier European patent application, provided that:
  - a) the divisional application is filed before the expiry of a time limit of twenty-four months from the Examining Division's first communication under Article 94, paragraph 3, and Rule 71, paragraph 1 and 2, or Rule 71, paragraph 3, in respect of the earliest application for which a communication has been issued, or
  - b) the divisional application is filed before the expiry of a time limit of twenty-four months from any communication in which the Examining Division has objected that the earlier application does not meet the requirements of Article 82, provided it was raising that specific objection for the first time.

European Divisional Applications

- This means:
  - A voluntary divisional application can be filed at any time up to two years from the EPO's first substantive examination report on any application in the "tree" of divisionals.
  - A mandatory divisional application – filed in response to an objection of non-unity – can be filed at any time within two years from when the non-unity objection was first raised.
  - The two year periods are not extendable.
  - In any case, the divisional must be filed before the parent grants or is abandoned.

European Divisional Applications

- There is no restriction on the subject matter of the divisional application provided that the divisional does not add new subject matter compared to the parent.
- A mandatory divisional application filed in response to a non-unity objection can still be in respect of any subject matter contained in the parent - not just the “non-unitary” subject matter.
European Divisional Applications

- A mandatory divisional might still be possible after the voluntary deadline has expired by amending the claims to “force” a non-unity objection – but very small chance of success

**Divisional Applications – India Sec 16(1)**

*A person who has made an application for a patent under this Act may, at any time before the grant of the patent, if he so desires, or with a view to remedy the objection raised by the Controller on the ground that the claims of the complete specification relate to more than one invention,*

**Controller’s Decisions – Divisional Applications 2012**

<table>
<thead>
<tr>
<th>Total No. of Controller’s decisions for Divisional Applications</th>
<th>No. of Granted</th>
<th>No. of Refused</th>
</tr>
</thead>
<tbody>
<tr>
<td>6</td>
<td>1</td>
<td>5</td>
</tr>
</tbody>
</table>

- **Divisional Applications- India**

A person who has made an application for a patent under this Act may, at any time before the grant of the patent, if he so desires, or with a view to remedy the objection raised by the Controller on the ground that the claims of the complete specification relate to more than one invention.

- **File a further application in respect of an invention disclosed in the provisional or complete specification already filed in respect of the first mentioned application**
Controller’s decision (2012) - divisionals

<table>
<thead>
<tr>
<th>Applicant</th>
<th>Application No.</th>
<th>Status</th>
<th>Field</th>
</tr>
</thead>
<tbody>
<tr>
<td>GIST BROCADES B.V.</td>
<td>1179/DEL/1999</td>
<td>Divisional Refused</td>
<td>Pharmaceutical</td>
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<tr>
<td>RESEARCH FOUNDATION, OSAKA UNIVERSITY</td>
<td>4663/DELNP/2005</td>
<td>Divisional Refused</td>
<td>Pharmaceutical</td>
</tr>
<tr>
<td>VERENIUM CORPORATION</td>
<td>3129/DELNP/2004</td>
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</tr>
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<td>PHARMACIA CORPORATION</td>
<td>4933/DELNP/2007</td>
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<td>CIBA SPECIALTY INC.</td>
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<td>Divisional Granted</td>
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<tr>
<td>SAMSUNG ELECTRONICS</td>
<td>315/KOLNP/2005</td>
<td>Divisional Refused</td>
<td>ELECTRONICS</td>
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</tbody>
</table>

IPAB decisions - divisionals

1191/KOL/2005
IPAB DECISION, 2011
LG ELECTRONICS, INC vs. THE CONTROLLER OF PATENTS

Patent Application No. 1191/KOL/2005 was filed by LG ELECTRONICS, INC, as a divisional application.


Appellants Contentions

• Under section 16, the applicant can file a divisional application any time before the grant of patent if he so desires or on the directions of the Controller.
• The appellant is entitled to file a divisional application voluntarily even if parent application DOES NOT contain more than one invention.
• The appellant submitted that the issue of more than one invention is applicable only when the Controller raises such objections.

Appellants Contentions:

• Section 16(1) to be interpreted as below.
• A person who has made an application for a patent under this Act may at any time before the grant of the patent, if he so desires,.......... file a further application in respect of an invention disclosed in the provisional or complete specification already filed in respect of the first mentioned application.”
• OR
• “A person who has made an application for a patent under this Act may ........with a view to remedy the objection raised by the Controller on the ground that the claims of the complete specification relate to more than one invention, file a further application in respect of an invention disclosed in the provisional or complete specification already filed in respect of the first mentioned application.”
IPAB decision

- We agree with the applicants arguments that the applicant can file an application as divisional application of his own before the grant of patent.
- However
- IPO is mandated by the law to ascertain that the divisional application so filed is on account of disclosure of plurality of distinct invention in the parent application.

IPAB decision

We are convinced that the phrase “if he so desires” used in Section 16 is not unconditional and it does not give the applicant an unqualified liberty to file a divisional application even when there is no situation of plurality of the distinct inventions contained in the mother application.

Appeal dismissed.

Cases 2 & 3 (IPAB)- Divisional

- BAYER ANIMAL HEALTH GMBH VS. THE CONTROLLER GENERAL OF PATENTS & DESIGNS (Decided: 29th OF OCTOBER, 2012)
- The basis of a divisional application is the existence of a plurality of invention.
- This is a sine qua non for seeking a division of an application.

- SYGENTA PARTICIPATIONS AG VS. THE CONTROLLER GENERAL OF PATENTS & DESIGNS. (Decided: 29th DAY OF JANUARY, 2013)
- ...The word “division” cannot mean split one invention into splinters, it can only mean splitting one application into more than one so that each application is for a separate invention. That is how the word “division” can be understood...

Amendment at the EPO

- Amendment is governed by Article 123 EPC
- (1) The European patent application or European patent may be amended in proceedings before the European Patent Office, in accordance with the Implementing Regulations. In any event, the applicant shall be given at least one opportunity to amend the application of his own volition.
- (2) The European patent application or European patent may not be amended in such a way that it contains subject matter which extends beyond the content of the application as filed.
- (3) The European patent may not be amended in such a way as to extend the protection it confers.
Amendment at the EPO

• Before grant Article 123(2) is key
  – The EPO takes a very very restrictive view of added subject matter
    • If the wording of the amendment is not present verbatim in the application as filed, EPO examiners will be very difficult to persuade that the amendment is allowable
  – Context can be very important
    • If a feature from the description is to introduced into a claim, the EPO will look closely at that part of the description.
    • Is the feature described in isolation, or only in combination with other features
    • If in combination with other features, the EPO will require those other features to be incorporated into the claims also
  – This can be a massive claim restriction
  – Take care to draft proper fall back positions in the description and claims

Amendment at the EPO

• The applicant has the right to make one voluntary amendment
  – Subsequent amendments are accepted at the discretion of the Examiner
  – The EPO keeps suggesting that if proper amendments are not made at an early stage (e.g. in response to the search opinion), discretion to amend may be refuse
    • Have never seen refusal of an amendment on these grounds – but beware!

Amendment at the EPO
– regional phase entry

• EPO wants to streamline prosecution
• “raising the bar” programme
  ➢ early grant or refusal
• New limitations on what you can do and when
  ➢ respond to objections at much earlier stage
  ➢ earlier issuance of summons to oral proceedings
  ➢ significant limitations on divisional filings
• All of the above require careful consideration of EP strategy
  • Advisable to review at EP phase entry

EP regional phase entry - EPO as ISA

- respond to WO/IPER
- file amendments
- pay excess claims fees
- waive right to Rule 161/162 communication

<table>
<thead>
<tr>
<th>Event</th>
<th>Time months</th>
<th>Action</th>
</tr>
</thead>
<tbody>
<tr>
<td>Rule 161/162 communication</td>
<td>31</td>
<td>file EP application</td>
</tr>
<tr>
<td>Art. 67(3) communication: publication details</td>
<td>6 months</td>
<td></td>
</tr>
<tr>
<td>Art 94(3) communication: First exam report issued</td>
<td></td>
<td></td>
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<tr>
<td>- responded to WO/IPER</td>
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<td></td>
</tr>
<tr>
<td>- file amendments</td>
<td></td>
<td></td>
</tr>
<tr>
<td>- pay excess claims fees</td>
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</tr>
</tbody>
</table>
EPO as ISA

- Obligatory response to negative WO or IPER
- Payment of excess claims fees
- Only opportunity for voluntary amendment
- 6 month response deadline
- Strategy:
  - reduce number of claims (as close to 15 as possible)
  - prioritisation of claims
  - combine dependent claims (where possible)
  - avoid multiple independent claims in the same category
  - remove non-patentable subject matter (methods of treatment, diagnosis or surgery)

EP regional phase entry

- EPO not ISA

<table>
<thead>
<tr>
<th>Time (months)</th>
<th>Action: file EP application</th>
<th>Event: Rule 161/162 communication</th>
<th>Rule 62a(1) communication: invitation to indicate one independent claim per category for search</th>
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</thead>
<tbody>
<tr>
<td>6 months</td>
<td></td>
<td>2 months</td>
<td>Rule 70(2) and 70a(2) communication: no meaningful search + invitation to indicate matter to be searched</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>2 months</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>confirm wish to proceed response to search opinion</td>
</tr>
</tbody>
</table>

- EPO not ISA

- Rule 161(2) EPC – Amendment of the application
- Applies where authority other than EPO is ISA or IPEA
- Payment of excess claims fees
- 1st opportunity for voluntary amendment
- No requirement to comment on WO or IPER
- 6 month response deadline
EPO not ISA

- **Strategy:**
  - Avoid multiple independent claims in the same category
  - Prioritisation of claims
  - Listing important claims first
  - Reduce number of claims (as close to 15 as possible)
    - Combine dependent claims (where possible)
    - Remove non-patentable subject matter (methods of treatment, diagnosis or surgery)

EPO not ISA – Rule 62a

- **Rule 62a EPC – Plurality of Independent claims**
  - An EP patent should only contain one independent claim in the same category – very limited exceptions
  - If claims not amended prior to search applicant asked to indicate independent claims to be searched
  - Only searched subject matter examined

- **Consequences:**
  - EPO will only search the first listed independent claim in any given category
  - No opportunity for the payment of additional search fees
  - Unsearched subject matter has to be deleted

EPO not ISA – Rule 63

- **Rule 63 EPC – No meaningful search possible**
  - Claims are deemed to lack clarity or are excluded from patentability
  - Prior to search applicant asked to file statement indicating subject matter to be searched
  - Only searched subject matter examined

EPO as ISA – Rule 63

- **Consequences:**
  - If do not respond, no search will be conducted
    - Then you have problem!
  - If you respond but do not address the problem, no search will be conducted
    - ...then you again have problem!

- **Strategy:**
  - Make sure claims are clear and can be searched
  - Remove unpatentable subject matter
  - Always respond to a Rule 63 EPC communication!
**EPO not ISA – Rule 70a**

- Rule 70a EPC – Invitation to respond to EESR
  - Applies where authority **other than EPO is ISA or IPEA**
  - Also applies to direct filed EP applications
  - 2nd opportunity for voluntary amendment (Euro-PCTs)
  - 1st opportunity for voluntary amendment (direct filed)
  - Obligatory response to Extended European Search Report
  - 6 month deadline. ([take care with deadline calculation](1))

**EPO not ISA – Rule 70a**

- Consequence:
  - If do not respond, application deemed withdrawn
- Strategy:
  - Take care with unity objections
    - Not a communication from the Examining Division
  - Need to be responsive
    - Extent of response needs to be considered
    - Speed of grant required / impact on divisionals

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**CLAIM AMENDMENTS - India**

**AMENDMENT OF THE INTERNATIONAL APPLICATION FOR THE NATIONAL PHASE**

- PCT applicants guide

- 6.013. May the applicant amend the international application for the national phase? The PCT guarantees that the applicant may amend the claims, the description and the drawings before any designated Office.

- Although he already has had the opportunity to amend the claims in the international phase, he may wish to make further amendments, which may be different for the purposes of the various designated Offices, in the national phase.
PCT applications involving Section 3

- INVENTIONS NOT PATENTABLE:
  - Sec 3 d: the mere discovery of a new form of a known substance, mere discovery of any new property or new use for a known substance.
  - Sec 3 e: (e) a substance obtained by a mere admixture.
  - Sec 3 I: treatment of human beings
  - Before July 2012, amended specifications and claims were filed by way of voluntary amendments at the time of national phase entry.

Claim amendments – PCT to Indian National Phase

- PUBLIC NOTICE by Indian Patent office on process of filing of PCT National Phase Applications in India, (2 July 2012)

- It is clarified that the IPO does not allow an Applicant to amend the specification or the related documents before he actually enters National Phase in India.

- (These instructions shall come into effect on 6th July, 2012.)

Controller’s decision – Claim amendments – PCT to Indian National Phase

- Application No. - 4387/CHENP/2006
- “A SYNERGISTIC IMMUNE RESPONSE STIMULATING COMPOSITION”
- Filed by
- INSTITUTO CIENTIFICO TECNOLOGICO DE NAVARRA.

Controller’s decision – Claim amendments – PCT to Indian National Phase

- CLAIM 1 (AS FILED IN THE PCT APPLICATION)
  - An immune response stimulating composition comprising nanoparticles based on a methyl vinyl ether and maleic anhydride (PVM/MA) copolymer.

- CLAIM 1 WHILE FILING IN INDIA (ARTICLE 19)
  - An immune response stimulating composition comprising nanoparticles based on a methyl vinyl ether and maleic anhydride copolymer (PVM/MA) as an adjuvant for the manufacture of a vaccine comprising an antigen or for the manufacture of an immunotherapy composition comprising an allergen.

- AMENDMENT AFTER ENTERING INDIA
  - An immune response stimulating composition comprising an allergen or an antigen and nanoparticles based on a methyl vinyl ether and maleic anhydride copolymer (PVM/MA) as an adjuvant.
Controller’s decision

• It is to be noted that the date of national phase application is reckoned from the date of international application filed in PCT. Therefore the contents of complete specification filed in PCT and the Indian national phase application shall be same.

• No amendment is allowed at the time of filing the application (National phase), but the same is allowed after filing the application.

Sec 59 - Controller’s decision

• Section 59 of the act does not refer to original claims, rather it refers to the claims of the specification before amendment.

• In the instant case, the claims before amendment are those claims with which applicant had filed the national phase application.

Section 59

• No amendment of an application for a patent or a complete specification shall be made except by way of disclaimer, correction or explanation, and

• No amendment thereof shall be allowed, except for the purpose of correcting an obvious mistake, and

• No amendment of a complete specification shall be allowed the effect of which would be

• That the specification as amended would claim or describe matter not in substance (i.e. matter) disclosed in the specification before the amendment, OR

• That any claim of the specification as amended would not fall wholly within the scope of a claim of the specification before the amendment.

Effect on Filing fees?

• The filing fees increase for each claim in addition to 10 claims.

• If the applicant has numerous use claims and if he wishes to amend/delete his claims at Indian National phase, but is not allowed to do so, then the applicant has to pay fees for claims which he is sure are not going to be granted in India.
Fees

- If the applicant makes a choice to delete some claims of the PCT application and then file the National Phase application with reduced claims, would the patent office reject the national phase application for non payment of fees?

An applicant had submitted a PCT application with 20 claims.
- National Phase - A fee of Rs.1000/- and an additional fee of Rs.200/- for each claim in excess of 10 claims. (Total fees Rs.3000/-)

PCT filed within 31 month deadline (on the last date)
- At the national phase entry stage three claims were cancelled.
- Fees paid for only 17 claims and not 20 claims.
- The applicant had planned to delete 3 claims in the national phase.

The Controller had returned the application on the ground that the fees were insufficient.

The Controller’s rejection of the application on the last date only on the ground of insufficient of fees appears to be unreasonable since the appellant has not been given an opportunity to rectify his mistake.
- The patent application may fail for other reasons but not because perhaps by a miscalculation or arithmetical error, the correct fees has not paid.
- We allow the appeal, the appellant can resubmit the application and indicate which of the 3 claims to delete.
- This is no amendment, only deletion.
- If any other fees payable, it must be paid within the time specified by the Controller.