

Corrections / Suggestions from RANBAXY

and Procedure –India

Chapter I: Introduction

No suggestions/corrections

Chapter II: Preamble and definitions

Page 17, section 2.38

The term “discovery” has been used as synonymous with the term “invention”

Page 17, section 2.3.6 (ia) should be (i)

Chapter III: Patentable Subject Matter

Page 22, section 3.2.2

As the publication (a) may also be related on a number of cases the criteria to

Prior claiming is a provision in the Act, where a later patent publication (X) can act as an anticipatory prior art had it been filed prior to the filing date of the application in question (Y). It is similar to 102(e) in the US context, but with a critical difference i.e., if 'X' has to act as a prior art, the invention claimed in 'Y' should also have been claimed in 'X' – disclosure found only in the specification is not considered. This prior claiming concept raises many questions as to how the Examiner approaches such a prior art and they are not addressed in this draft. For example,

Prior claiming is only for novelty issue (anticipation), not for the inventive step issue. The entire discussion/explanation in the draft about the anticipation is restricted only to the disclosure in specification (description or examples) and it is silent about the disclosure in claims. Even if the inventions of 'X' and 'Y' are substantially the same, the claiming would be different in both the patents/applications as it depends on various factors and they would have been drafted by different persons/organizations. In this context, how will the broad claims fenced around the inventions be considered by the Examiner for establishing anticipation? Will the examiner consider single claim or multiple claims of 'X' against the claims of 'Y'? Will the examiner look into the specification along with the claims for finding any anticipation? What is the role of 'inevitable formation' (inherency in the US context) in case of prior claiming?

Draft is also not clear about the dates of the 'X' and 'Y', which are eligible for determining whether one patent/application can be a prior art for another patent/application. It is indeed complex as there can be multiple qualifying dates for PCT applications taking Indian priority or outside priority, patent of additions, etc. In case of US, the USPTO has developed a clear flow chart for determining the 102(e) date (<http://www.uspto.gov/web/offices/dcom/olia/aipa/102eflowchart.pdf>). Similar chart or guideline is absolutely necessary for patent examination procedure in India as well.

Page 32, Section 3.7.1 (iii) x and y should be in capital letters.

Page 32, Section 3.9.1

The statute defines inventive step as follows:

*"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. [Section 2(1)(ja)].*

The scope of the term "economic significance" has not been elaborated as to what contribution the concerned invention must make in terms of economic value. The cited cases explain inventive step with regard to conventional obviousness test. If the real case examples are not available then this term can be explained with hypothetical situations so as to get a fair idea about an invention having economic significance.

Page 34, Section 3.9.2 can be removed as the main heading Section 3.9 deals with Inventive Step.

Page 36, Section 3.11

Subheadings (e) and (h) are identical and in this case the latter one can be removed.

Subheadings (c) and (f) are to be compared to see if these are contradictory.

Page 42, Section 3.16.1

Subheading (c) and (d) are same and only one may be retained.

Section 3.17.1 subheading (a) with distance as the indicator for assessing inventive step for the subject matter of the invention and the prior art, the assessment of inventive step looks ambiguous. Perhaps, this can be explained meaningfully with an example or it should be replaced with the word "difference".

Page 49, Section 3.24.4

The cited case is appropriate for novelty rather than for assessing inventive step.

Chapter IV: Inventions Not Patentable

Page 54 Sections 3(d) and (e)

Words are missing and typographical errors to be removed given as below:

*d) the mere discovery of a new form of a substance which does not result in the enhancement of a **the** known efficacy of that substance or the mere discovery of a 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.

Explanation: For the purpose of this clause, salts, esters, ethers, polymorphs, metabolites, pure form, particle size, isomers mixtures of isomers, complexes, combinations and other derivatives of known substance shall be considered to be the same substance, unless they differ significantly in properties with regard to efficacy

(d)(e) a substance obtained by a mere admixture resulting only in the aggregation of the properties of the components thereof or a process for producing such substance;

Further the numbering of the subsections needs to be corrected.

Page 58, Section 4.5.3

The examiner makes comparison with regard to properties or enhancement of efficacy between the **known substance** and the **new form of known substance**.

In case the **new form** is further converted into **another new form**, the comparison is made between the already existing form and another new form but not between the base compound and another new form.

[Emphasis added]. The above paragraph is not clear.

The term "**another new form**" can be amended to "**new polymorph of new form**".

Let us consider the below hypothetical situation:

Amlodipine base [known substance] is known in the art and the applicant files a patent application claiming amlodipine besylate [new form of known substance - salt] showing enhancement of efficacy.

Now if the applicant file an application on amlodipine tosylate [another new form] which was prepared by converting amlodipine besylate, then as per the above guideline, the examiner need to make a comparison with regard to properties or enhancement of efficacy between amlodipine besylate [new form of known substance - salt] and amlodipine tosylate [another new form] and not between Amlodipine base [known substance] and amlodipine tosylate [another new form] and also not between all the three.

If the term "**another new form**" is amended to "**new polymorph of new form**" then the guideline would be in-line.

Now let us look in the following Hypothetical Situation:

Amlodipine base [known substance] is known in the art and the applicant files a patent application claiming amlodipine besylate [new form of known substance - salt] showing enhancement of efficacy.

Now the applicant files an application on amlodipine besylate polymorph A [new polymorph of new form] which was prepared by converting amlodipine besylate [new form of known substance], then as per the above guideline, the examiner need to make a comparison with regard to properties or enhancement of efficacy between amlodipine besylate [new form of known substance] and amlodipine besylate polymorph A [new polymorph of new form] and not between Amlodipine base [known substance] and amlodipine besylate polymorph A [new polymorph of new form].

According to Chapter III, 3.1.1, the criteria for an invention to be patentable in India are:

- (i) it must be novel
- (ii) it must have an inventive step
- (iii) it must be capable of industrial application

Further, the invention should not fall under any of the categories of "Inventions Not Patentable" mentioned under sections (3) and (4) of the Patents Act, 1970.

Thus, for an invention to be patentable in India it has to pass novelty test, inventive step test, industrial application test and, in addition, section (3) and section (4) test – specifically section 3 (d) and section 3 (e).

Section 3(d): We observe that the discussion of Section 3(d) in the Draft Manual has three major inconsistencies as mentioned below:

1) From the statute and Chapter III, 3.1.1 of the Draft Manual, it is clear that 3(d) test is additionally required apart from novelty, inventive step and industrial application. However, we observe that the parts in Draft Manual related to Section 3(d) discuss merely about the novelty and inventive step criteria. Section 3(d) has been elaborated in Chapter IV, 4.5.1 to 4.5.16, wherein Para 4.5.7 is critical as it gives guidelines with respect to the 'forms' of the known substances recited in Section 3(d) (salts, polymorphs, metabolites, etc). Ironically, the entire discussion in Para 4.5.7 is only into the novelty and/of inventive step criteria and away from the context of Section 3(d).

2) Section 3(d) inherently has another connotation in it. It says that mere discovery of new form of a known substance, which does not result in the enhancement of the known efficacy, is not patentable. If it is framed in the other way, the discovery of a new form of a known substance, which results in the enhancement of the known efficacy, is patentable (provided it satisfies the novelty, inventive step and application criteria). Explanation of Section 3(d) in Para 4.5.2 in the Draft Manual mentions that new forms shall also be considered as the known substance unless they differ in properties with regard to efficacy. However, the specific guidelines provided in Para 4.5.7 of the Draft Manual appears to eliminate certain new forms of the known substances from patentability even if they have enhanced efficacy.

3) The guidelines provided in Chapter IV, 4.5.7 discuss about the patentability of processes of preparing new forms (especially polymorphs, hydrates and purified compounds) and is silent about the patentability of the product per se. We understand that process of preparing so-called new forms are patentable in India even before the introduction of Section 3(d) in the Act. Section 3(d) has been introduced and exists to determine the patentability of the product, not the process. We are not able to grasp why the chapter of Draft Manual dedicated to Section 3(d) discusses about the patentability of the process, not exactly the product.

We are substantiating the above comments in the following paragraphs:

4.5.7 (i) Isomers: This Para defines the isomers and patentability of the isomers is discussed explicitly only in the context of novelty and inventive step/obviousness. There is no mentioning about efficacy at all.

4.5.7 (ii) Stereoisomers: Para 4.5.7 (ii) says, "In a case where an (S)-enantiomer of a compound, capable of exhibiting better efficacy over the (R)-enantiomer, for instance producing enhanced anti-diabetic effects is claimed, wherein the said claim is not allowable when the same chemical compound possessing anti-diabetic property is known from the prior art." This can reasonably be interpreted in such a way that the enantiomers are not patentable even if the efficacy criterion is satisfied – which is contradictory to Section 3(d).

4.5.7 (iii) Homologues: This Para defines the homologues and patentability of the homologues is discussed explicitly only in the context of inventive step/obviousness. There is no mentioning about efficacy at all.

4.5.7 (iv) Polymorphs: This Para defines the polymorphs and says that polymorphs are not patentable without any mention about the efficacy criterion. Further, patentability of the polymorphs is discussed only in terms of process of preparing the polymorphs.

We also noted that this Para mentions, "Such forms can be deemed within the prior art, and therefore, non-patentable if they were inevitably obtained following the process of the basic patent on the active ingredient or if they were covered by a previous product patent." The underlined portion appearing in the Draft seems to be a strange concept in determining the patentability of polymorphs. For example, if the 'previous product patent' has a claim, which 'covers' "A compound of Formula X and its salts and polymorphs thereof", then according to Chapter 4.5.7 (iv), the 'polymorphs thereof' covered by the 'previous product patent' cannot be patentable. It is possible for an Examiner or opponent to quote Chapter 4.5.7 (iv) to argue that any polymorph of Formula X is not patentable (despite having efficacy, novelty, inventive step and application) since it is 'covered' by a previous product patent. The quoted line also implies that the polymorph in question is not patentable if it is inevitably obtained following the process of the basic patent. The use of the term 'basic patent' in this context is misleading because there could be many other prior art publications (not only the basic patent), which may inevitably produce the polymorph in question.

4.5.7 (v) Metabolite: Para 4.5.7 (v) of the draft clearly rules out, "A metabolite is not patentable since giving the drug to a patient naturally and inevitably results in formation of that metabolite." This Para discusses only about novelty and there is no mentioning of efficacy at all. Does it mean that metabolites are not at all patentable or they are patentable if the metabolite claim is phrased with novelty tags like 'isolated' or 'pure'? If metabolite is not at all patentable despite having enhanced efficacy, then the draft guideline is contradictory to Section 3(d).

4.5.7 (vi) Prodrugs: This Para defines the prodrugs and patentability of the prodrugs is discussed explicitly only in the context of inventive aspects. There is no mentioning about efficacy at all.

4.5.7 (vii) Hydrates and other substances: This Para defines the hydrates, acid addition salts and other derivatives and patentability is discussed only in terms of process, not in terms of product. There is no mentioning about efficacy at all.

4.5.7 (vii) Purification compounds: The title of this Para itself is misleading – we believe it must be 'purified compounds' or 'purification of compounds'. ('Purification compounds' means the compounds, which are used for purification.) This Para discusses patentability only in terms of purification process, not in terms of product. There is no mentioning about efficacy at all.

Combinations: While the statute states that combination of active ingredients may be patentable if these combinations show efficacy, the manual has not provided any guidance to deal with inventions related to these combinations. Chapter III, Section 3.13, page 38 provides guidance for inventions dealing with combinations in terms of assessing inventive step. Guidance in relation to Section 3(d) for these combinations is required.

Section 3(e): This section should not be considered for judging the patentability of pharmaceutical compositions which are mixtures of active ingredient and pharmaceutically acceptable excipients. The preparation of a pharmaceutical composition involves complicated scientific experimentation and is not mere admixing or aggregation of properties of individual components. For example, any pharmaceutical composition is required to be stable for an intended period of use. The state of the art is not predictive regarding this aspect and involves innovation at every stage of development of these compositions. Not every pharmaceutical excipient can be formulated with every active ingredient. Another example can be that of extended release pharmaceutical compositions which are still more complicated as these involve another factor i.e. control of the release of the active ingredient in such a way that the therapeutic effect of the dosage is optimum and at the same time improve patient compliance which can be either due to reduced associated side effects or reduced frequency of dosing or both.

Chapter V: Applications

Page 112, Item iii:

Excerpt from this item:

Therefore, wherever possible, claims should not contain "Multiple independent claims in any one category, even if only one inventive concept is present".

Under these circumstances, a genus, a sub-genus, species and specific compounds claims, if claimed independently, may not be allowed. Examiner may reject or may ask the applicant to merge all in one independent claim, which are sometimes not advisable / acceptable for New Chemical Entities, and therefore, it may be deleted or modified.

Page 117, Item 5.8.10 (Markush – Type Claims):

Following points may also be highlighted:

- a. Examples depicting the Markush type claims drawn to compounds per se. To make it more clear and understandable, the manual should give a suitable example of a Markush-type claim drawn to the compound *per se*. Example: X-Y, wherein X is aromatic radical; Y is selected from halogen, hydroxy, amino, alkyl etc.
- b. Examination procedures / Searching requirement for Markush type claims drawn to compounds per se. The manual should also highlight whether the patent office will do the prior art search for the whole genus claimed or the genus of interest. There should be some suggestions in the manual as how the examination proceeding may take place for the Markush-type claims drawn to the genus *per se*. it should be clear whether the examination will be for the genus as claimed or for the elected species or both.
- c. Unity of Invention if Markush structure covering thousands of compounds has been claimed. Markush-type claim covers hundreds and thousands of compounds and the compounds within the genus may lack unity and therefore there may be some guidelines in the manual to establish the unity of invention within the genus claimed.

Page 119, Item (v) (b):

The term "modified drug" may be defined so as to make this clear and understandable .

Page 86, Section 5.2.4

"required to shall give" should be "required to give".

Page 96, Section 5.3.5, line 12 should read "filing of application in India the requirement of under section 135".

Page 97, Section 5.3.6

"Pr4ovisions" should be "Provisions".

Page 108, Section 5.7.3, subheading (c)

"dale" should be "date".

Page 121, Section 5.9.7, subheading (i)

"Ddescription" should be "Description".

Page 130, item (d)(i) line 8

"basis fee" should be "basic fee".

Page 138, Section 5.10.17, subheading (i), line 3

"whichever earlier" should be "whichever is earlier"

Chapter VI: Publication and Examination of Applications

Page 140: Section "11" should be "11A"

Page 141: '**Rule 24**': Request for publication - should be '**Rule 24A**'.

Page 142 Rule 27 line 4:filed in respect of the application may be inspected
al the appropriate office..... 'al' should be 'at'

Page 143 6.1.5 c) (j): '/' after parent application should be deleted.

Page 143-144 6.1.6: (iv) is missing the paragraphs (i)-(v)

Page 144 6.2: Section '11' should be '11B'

Page 145 Rule 24 B (1): numbering of paragraphs (i)-(v) is not correct

Page 147 paragraph (5): and may refuse to grant the **patent]** unless the
.....']' should be deleted.

Page 148 Section 15 paragraph:require the application, specification or
the. Other documents, as the case may be..... The full stop should be
deleted.

Page 150 6.2.2 i): "person interested" (section 2(1)9(t)..... '(' should be
deleted.

Page 152 b) Screening: numbering of a)-e) is not proper.

Page 153 f) ii.: (section 13(1)(b)..... '(' should be deleted.

Page 153 f) iii.: (section 13(2)..... '(' should be deleted.

Page 156 viii.: FER (S. 21 (1)..... '(' should be deleted.

Page 171 6.5.2 d.: (section 20(1)..... '(' should be deleted.

Chapter VII: Opposition Proceedings to Grant of Patents

Page 178, Section 7.1.3

The cited case is on Gleevac the matter of which is sub-judice as the applicant has appealed against the Controller's decision and the decision may reverse. At this juncture, this case should not have been cited.

Chapter VIII: Anticipation

Page 207, Rule 28, section (4) is missing or the numbering is to be checked.

Chapters IX to XVII

Chapter XI: Patents of Addition

Page 229, Section 11.1.8- The case provided in this part relates to lack of inventive step but does not provide any relation to patent of addition.

General observations:

1. This chapter does not provide any clarity on addition or deletion of the inventors (such as a clause on one common inventor)
2. There is no clarity on the number of applications for patent of addition can be filed.
3. No clarity regarding the newly added material- filing date, priority, any intervening prior art

Chapter XII: Amendment of Applications and Specifications

Pages 235-236

Court case provided under section 12.1.14 relates more to lack of inventive step rather than due to the amendments.

Chapter XVIII: Working of Patents and Compulsory Licenses

No suggestions

Chapter XIX : Use of Inventions by Government and Acquisition of Inventions by Central Government

No suggestions

Chapter XX: Suits concerning Infringement of Patents

Page 312 Section 20.4 Parallel Import:

Provision for Parallel import is provided in Section 107A(b) of the Act.

107A(b) reads, "importation of patented products by any person from a person who is duly authorized under the law to produce and sell or distribute the product shall not be considered as a infringement of patent rights"

However, the description of Section 107A(b) in Para 20.4 of the Draft Manual mention, "...importation of patented products by person authorized by the patentee will not be considered as an infringement." The phrases, 'person authorized under the law' and 'person authorized by the patentee' has different meanings, and we believe it is a critical error in Para 20.4 and requires correction. Para 20.4 further says, "...it is possible to import the patented products from the licensee of the patentee in any country without the permission of the patentee". No further description of Section 107A(b) is provided in Para 20.4 of the Draft Manual. We believe clear guidelines should be included in Para 20.4 in order to understand the implications of the Section 107A(b) with regards to parallel import.

Page 307 Section 106 "Power of court to grant relief in cases of groundless threats infringement proceeding of" may be corrected as "Power of court to grant relief in cases of groundless threats of infringement proceeding".

Numerical order in Section 113 (Page 309) and Section 114 (Page 310) is improper.

Chapters XXI to XXV

No suggestions

Thanks