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13/5/08

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INDIAN DRUG MANUFACTURERS' ASSOCIATION

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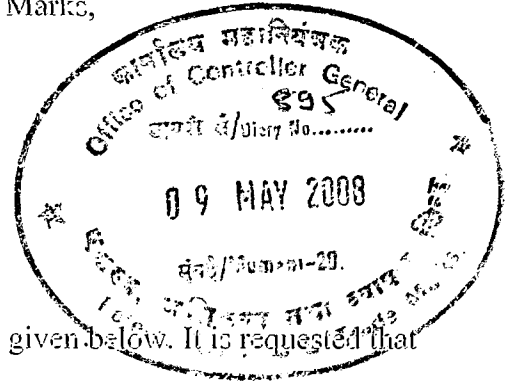
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PARTNERS IN GLOBAL HEALTHCARE

April 24, 2008

Office of the Controller General of Patents, Designs and Trade Marks,
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Sub: Comments/ Observations on the Patents' Manual

Dear Sir,

Our comments/ observations on some Paras of the manual are given below. It is requested that they may please be considered.

Point 1. A General Observation on Chapter III. Patentable Subject Matter

As a general rule, foreign case law should be used cautiously in India because our Patentability criteria differ substantially from the criteria adopted in industrially developed countries particularly USA. We should accept only those Filings which are not against the letter and spirit of the Indian Patents' Act 1970 as amended up to date. This is particularly important on issues relating to 1. Patentability, 2. Pre-grant Opposition, 3. Compulsory Licences; and 4. matters relating to Indian Traditional Knowledge.

Point 2

Determination of Novelty
Para 3.2 Novelty of Invention

Sub para 3.2.1: In the last line, the words "and has unrelated features" be added after the word "domain".

Para 3.3.7: In fifth line after the word "essential", the words "and unrelated" may be added.

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Point 3

Para 3.3.4 (Text)

3.3.4 In order to demonstrate lack of novelty, the anticipatory disclosure must be entirely contained within a single document. If more than one document is cited, each must stand on its own. The cumulative effect of the disclosures cannot be taken into consideration nor can the lack of novelty be established by forming a mosaic of elements taken from several documents. This may be done only when arguing obviousness (Ammonia's Application, 49 RFC 409). However, if a cited document refers to a disclosure in another document in such a way as to indicate that, that disclosure is intended to be included in that of the cited document, then the two are read together as though they were a single document.

Comments –

This judgment appears to bar taking recourse to more than one document indicating 'anticipatory disclosure' i.e. if there are two or more separate sources dealing in parts of the same one issue, they cannot be used to determine 'novelty'. But the case is different in India's Traditional Knowledge, where such references may be described partly in one book and partly in another ancient book. We must see things in totality. Therefore, this case law should not be used. This Para should be deleted.

Point 4.

Para 3.3.6 Text

3.3.6 Special care is taken when relying on dimensions derived from drawings. Although features shown solely in a drawing form part of the state of the art when a skilled person could derive a technical teaching from them without further description, it is generally not possible to derive a technical teaching by measuring dimensions in a diagrammatic representation and the dimensions under these circumstances do not, therefore, form part of the state of the art. [T204/83 (OJEPQ 10/85)]

Comments – Ruling in T 204/83 (OJEPQ) 10/85 relates to 'dimensions and drawings'. It applies to scientific inventions. But in our Traditional Knowledge where we use symbols more frequently than in Western countries, this decision does not hold good. However, since this decision applies mainly to scientific documents, a note can be given in the end of this Para to stress the point relating to Indian ancient text books.

Point 5

Para 3.3.12 Text -

3.3.12 The invention is taken as lacking in novelty if information about anything falling within its scope has already been disclosed. Thus, for example, if a claim specifies alternatives or defines the invention by reference to a range of values (e.g. of composition, temperature, etc), then the invention is not new if one of these alternatives, or if a single example falling within this range, is already known. Thus, a specific example is sufficient to destroy the novelty of a claim

to the same thing defined generically. For example, disclosure of a metal coil spring anticipates a claim to resilient means. On the other hand, a generic disclosure does not impugn the novelty of a more specific claim, so that an earlier reference to a metal coil spring cannot be used to attack the novelty of a claim specifying such a spring made of copper. In some cases, however, the disclosure of a comparatively small and restricted field of possible alternatives might properly be held to be a disclosure of each and every member; for example, 'fluid' may be taken to disclose both liquid and gas, if the context warrants it, and a reference to an electric motor may be regarded as disclosing the use of both series and shunt-wound types.

Comments -The sentence on Page 24 " On the other handspring made of copper" is suggested to be deleted because 'novelty' as we consider under the Indian law, would be affected by a 'generic disclosure' against a claim such as given in this illustration.

Point 6

Prior Public Use

Para 3.6.9 Text

3.6.9 If an article or a material is unconditionally supplied to a member of the public, possibly as the result of just a single sale (T482/89 OJEP0 11/92), it is regarded as making available information to the public if that information could be obtained by dismantling or analysing the article or material or even destruction of the article (G1/92 OJEP0 5/93).

Comments - In this illustration the Puling is that a single 'sale' would be construed as disclosure or "making available information to Public". Under our Patents' Law Sec 32 - "Anticipation by public working"... there is a grace period of one year during which the Patent Applicant can put the product to test by "working" i.e. supplying it to public. Therefore, this Para in the Manual needs re-drafting.

Point 7

Mosaicing Multiple Documents

Para 3.11.m Page 37. Text

3.11. m. Where an invention can be thought of as the result of a selection from a number of alternatives, to demonstrate that the invention is not obvious, it is usually only necessary to show that it solves a technical problem in a surprising or unexpected way.

Please delete word 'only' in '... it is usually only necessary' because this word is unnecessarily narrowing the import of the Paragraph. Use of terms, such as, "Surprising" or "Unexpected" prior to a distinctly obvious or frivolous invention, should be treated as disqualifying the invention for grant of a patent.

Point 8

Inventions not patentable

Section 3(d)

Para 4.5.3 Page 58 Text

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.

Comments and suggestion – This is an important para, but gives rise to many questions. It should be clearly indicated as to what the scope of comparison will be. Whether the base compound or the new form or both will be compared with another new form.

Point 9

Isomers Text -

4.5.7 Some of the examples of new forms are given below without limiting the scope of the application of the provisions of the Act.

*(i) Isomers: Isomers are different compounds that have the same molecular formula which may be broadly divided into two kinds, namely,
- structural isomers or positional isomers and,
- stereo isomers.*

Structural isomers or positional isomers may be structurally similar or dissimilar compounds. The simplest examples are butane and isobutane and ethanol and dimethyl ether. In the former case the compounds are having structural and functional similarity.

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However, In the second set of compounds, although they have the same molecular formula but are structurally and functionally different. Such isomers even having close similarity may be considered to be novel over the prior art. Isomers having the same empirical formula but having structural differences may be considered novel and may not normally offend "obviousness" as they are structurally different.

Example:

Cyclohexylstyrene is not considered prima facie obvious over prior art isohexyl styrene.

Para 4.5.7 (i) Isomers – ‘isomers’ are non-patentable unless they “differ significantly with regard to efficacy”. If Isomers which are structurally different are really therapeutically different then they can be considered for patenting. This para, therefore, needs some more clarifications.

Point 10

Contents of complete specification

Para 5.6.1 Text -

5.6.1 Complete Specification is required to have the following components:

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(a) Title

(b) Preamble of the invention

(c) Name, address and nationality of the applicant

(d) Field of Invention

(e) Use of Invention : A brief statement of the advantages of the invention

(f) Prior Art

(g) Problem to be solved

(h) Object of Invention(may be more than one)

(i) General statement of invention

(j) Detailed Description of Invention[with reference. to drawings , if any)

(k) Best method /example of working of the invention

(l) Statement of claims

(m) Signature with date

(n) Drawings

(o) Abstract

Comment 1 - As per Section 10.4. Proviso (ii) (D) of the Patents' Act the applicant must disclose the source and geographical origin of the biological material. Therefore this point should be added to the list

Comment 2 - They should also mention the details relating to the "Access and Benefit sharing Agreement" if any, with the Competent Authority under the "Biological Diversity Act – 2002".

Point 11

Para 5.9: Sufficiency of disclosure.

Sub para 5.9.2 deals with patent application where there is mention of biological material. This para needs to be expanded to provide for the requirement of agreement with the biological material supplier and agreement reached with him about benefit sharing.

Point 12

CHAPTER VII: OPPOSITION PROCEEDINGS TO GRANT PATENT

Page 178, para 7.1.2: Proceedings under pre-grant opposition.

Sub para (viii) provides for rejecting representation against granting of patent or allowing grant of patent. The decision of the Controller should have logical conclusion of allowing appeal to either party against the decision of the Controller.

Point 13

Para 9.3 Prohibition to apply Patent for invention outside India.

Page 215 sup para 9.3.3

In addition to the invention relevant for defence purpose and atomic energy, the invention relating to biodiversity material of India should also be incorporated for taking permission.

Point 14

Page 226, para 10.12 Term of Patent

Para 10.12.1

Reference to patent term which had not expired on 20th May, 2003 under Patents (Amendment) Act 2002, should be clarified as "process patent" instead of "patent" which may not be mistaken as 'product patent'.

Point 15

CHAPTER XIV: SURRENDER AND REVOCATION OF PATENTS

Page 252, para 14.2.5 Revocation of patent for non-working

There have been instances in the past when supplies of critical material/component were blocked at the instance of the concerned foreign government for important concerns. The instances of blocking of critical materials are after the atomic experiments at Pokhran. Under these circumstances, it would be appropriate for the government/Controller to revoke the relevant patent. It would be a challenge for the domestic enterprises to research and produce that particular material blocked by the foreign patent holder or the concerned government. This important aspect could also be added in this para.

Point 16 Page 295 para 18.2.11

The circumstances for extreme urgency could also be due to environmental causes viz. pollution of air, pollution of water or pollution of soil. It would be desirable to incorporate these important circumstances for notification by the Government the circumstances of extreme urgency and grant of compulsory licences immediately under Section 92 (3).

Thanking you,

Yours faithfully,
For Indian Drug Manufacturers' Association,



Gajanan Wakankar IFS (Retd)
Executive Director