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9 April 2008

To

The Controller of Patents
Office of the Controller General of Patents, Designs and Trademarks,
Boudhik Sampada Bhavan
Near Antop Hill Post Office,
S. M Road, Antop Hill
Mumbai-400037

Sub: Suggestions to improve the Draft Manual of Patent Practice and Procedure (2008)

Respected Sir,

Please find enclosed our suggestions to improve the Draft Manual of Patent

Practice Procedure (2008).

Thanking you,

Yours sincerely,

Dr K G Rajendran Head- Knowledge Cell

Encl: as above

SHORTCOMINGS OBSERVED AND SUGGESTIONS FOR IMPROVEMENT ON "DRAFT MANUAL OF PATENT PRACTICE AND PROCEDURE"

1) Clarity on the interpretation of definition of "new invention" with respect to "prior use" S.2 (1) (1): Definition of "New Invention" reads as follows:

"new invention means any invention or technology which has not been anticipated by publication in any document or <u>used in the country or elsewhere in the world</u> before the date of filing of patent application with complete specification, i.e., the subject matter has not fallen in public domain or that it does not form part of the state of the art." (Pg.18)

<u>Shortcoming:</u> The definition of "new invention" includes 'prior use in India or elsewhere in the world' which is not reflected in following explanations appearing in the manual:

-Pg.21 under 3.2.1, it reads as follows,

"General Principle: An invention or used in the country

ordoes not form part of the state of the art."

-Pg. 22-23 under 3.3.5, it reads as follows,

"The state of the art or by use in India."

-Pg. 24-25 under 3.4.3, it reads as follows,

"It was held was a public knowledge and that invention was in use publicly in India to establish their case."

-Grounds for opposition u/s 25 (1) (d) & 25 (2) (d) and for revocation of patents u/s 64 (1)

(e) and 64 (1) (f) also support invalidity of the patent claims based on "prior use in India".

<u>Suggestion:</u> Clarity on the scope of the term "prior use" whether limited to India or covers prior use 'elsewhere in the world' too.

2) Clarity on date to be considered to determine the novelty of the invention

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the date of filing of patent application with complete specification, i.e., the subject matter has not fallen in public domain or that it does not form part of the state of the art." (Pg. 18)

Shortcoming: Which date to be considered for novelty determination of the invention:
-date of filing of Provisional application?
-date of filing of patent application with complete specification?

-priority date?

<u>Suggestion:</u> Clarity required with respect to the date to be considered for novelty determination.

3) Clarity on requirements to satisfy the criteria of enhancement of efficacy u/s 3 (d)

Will improvement in solubility, flowability, stability qualify the efficacy criteria for polymorphs?

Suggestion: Include relevant cases citing rejections or grants of patent applications

- 4)Clarity on patentability of new forms like stereoisomers, polymorphs, metabolites
 - Explanations cited on Pg. no. 59, 60 of the manual for stereoisomers, polymorphs and metabolites clearly states that the same cannot be patented as compounds and only novel process for making the compounds is patentable.

Shortcoming: This explanation is not in conformity with Sec. 3 (d) which considers the above new forms patentable if they differ significantly in properties with regard to efficacy.

Suggestion: Include relevant cases citing rejections or grants of patent applications.

- 5) Illustrative examples on type of inventions covered under "method or process of testing"
- 6) Need to provide Indian classification in the manual for ready reference.
- 7) Explanation and interpretation of vague terms used in claims. e.g., "about", "substantial" etc.

8) Explanation of the phrases such as 'ordinarily within', 'within reasonable period' with respect to time lines.

- Remedy available to the applicant for patent office delays:
 - delay in publication of the patent application
 - delay in issuance of First Examination Report
 - delay in publication of the patent grant in the patent journal
 - delay in decisions by the Controller in pre and post grant opposition cases

Suggestion: There should be clear inviolable deadlines and if those deadlines are not met, then the applicant should get compensation as is practiced by USPTO

- 9) Clarity on the scope of 'Omnibus Claims'.
- 10) Examiner to quote relevant portions from the manual in the 'First Examination Report'.
- 11) Multitude of typographical errors to be corrected.