ORGANISATION OF PHARMACEUTICAL PRODUCERS OF INDIA

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Tapan Ray
Director General

Ref.IPR-2008/ 169

April 10, 2008

Shri V. Ravi
Controller General of Patents, Designs & Trade Marks
Bhoudhik Sampada Bhavan
Near Antop Hill Head P.O.
S.M. Road, Antop Hill
Mumbai 400 037.

Dear Shri Ravi,

OPPI Comments on Draft Manual of Patent Practice & Procedure

Organisation of Pharmaceutical Producers of India **(OPPI)**, as you may be aware, is a premier association of research based international and large pharmaceutical companies in India and is not only an industry association but also a scientific and professional body.

The production of a revised edition of the Manual of Patent Practice and Procedure (MPPP) is very much welcomed to provide up to date guidance to the public and users of the patent system as well as to the officers of the Indian Patent Office administering patent procedures. This is all the more necessary following the recent changes to the law and rules governing patents in India which have introduced new provisions applying particularly to pharmaceutical and chemical inventions. The revised edition of the MPPP goes part way to clarifying things but does not succeed in a number of important areas. It is well understood that the MPPP is intended for guidance and has not the force of law. However it is in the public interest for this guidance to be as clear as possible without being prescriptive. The current draft does not yet achieve this as is pointed out in the detailed comments given in the attachment.

We have given our suggestions in the attachment on the specific paragraphs and chapters that may be further clarified during the finalisation of the Draft Manual. The specific para-wise comments/suggestions are divided into four parts covering the issues on Patentable Subject Matter (Chapters III); Inventions not Patentable (Chapter IV); Pre-Grant Oppositions (Chapter VII); and Working of Patents and Compulsory Licensing (Chapter XVIII).

We request you to kindly take these into consideration before finalising the MPPP.

If you need any clarification, we shall be happy to meet you at your convenience.

Thanks and regards,

TAPAN RAY
DIRECTOR GENERAL

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DRAFT MANUAL OF PATENT PRACTICE & PROCEDURE

OPPI Recommendations

I. PATENTABLE SUBJECT MATTER (CHAPTER III)

Para 3.2.1. at Page 21 Section 2 (Novelty of Invention)

Manual:

"General Principle: An invention is considered new (novel) if it has not been anticipated by publication in any document any where in the world or used in the country or prior claimed in an application for patent in India or form part of the knowledge, oral or otherwise, available within any local or indigenous community in India or elsewhere before the date of filing of patent application or date of priority, that is, the subject matter has not fallen in the public domain or that it does not form part of the state of the art."

Suggestions:

There is inconsistency between para 3.2 of the Manual and Section 2(1)(l), 13, and 29 to 34 of the Patents Act with regard to expression oral or otherwise, available within any local or indigenous community in India or elsewhere before the date of filing of patent application or date of priority.

The expression *"oral or otherwise, available within any local or indigenous community in India or elsewhere"* may be deleted considering the implementation problems likely to crop up during prosecution. Moreover, this goes beyond the Act.

Para 3.2.2 at Page 22 w.r.t. Section 2 (Novelty of Invention)

Manual:

"Although the term 'state of the art' has not been defined under the Patents Act, the following general principles are applied by the Patent Office to determine the novelty of an invention during the examination procedure by applying provisions of section 13, read with the provisions of sections 29 to 34

An invention is considered to be novel:

.....

***(c)** if it has been claimed in any claim of any other complete specification filed in India, which was filed before the date of application though published after the date of that application."*

Suggestions:

For the phrase "*... though published after the date of that application*", the phrase "*before the date of that application in order to be in public domain*" may be substituted.

Para 3.3.5 at Page 22 w.r.t. Section 2 (Determination of Novelty)

Manual:

"The state of the art in the case of an invention is taken to comprise all matter (whether a product, a process or information about either available in India or elsewhere) which has at any time before the priority date of that invention been made available to the public by publication of description or by use in India."

Suggestions:
Para 3.3.5 may be redrafted to read as:

"The state of the art in the case of an invention is taken to comprise all matter (whether a product, a process or information about either available in India or elsewhere) which has at any time before the priority date of that invention been made available to the public by publication of description "world wide" or by use in India."

Para 3.3.11 at Page 23 w.r.t. Section 2 (Determination of Novelty)

Manual:

"Prior publication does not however depend on the degree of dissemination. The communication to a single member of the public without inhibiting fetter is enough to amount to making available to the public (Bristol-Myers Co's Application, [1969] RPC 146). There is no need even to show that a member of the public has actually seen the document. For example, in Monsanto Brignac's Application, ([1971] RPC 153) , it was held that a company had published a document by supplying it to its salesmen, since it had been given to them with no restriction on disclosure; indeed it had been put into their hands with the intention that they should make the information available to the public."

Comments:
Irrespective of the quantum of claimed invention being in public domain, specific evidence needs to be adduced to support claim of invention being in public domain and thus to negate novelty.

Para 3.4.1 at Page 24 w.r.t. Section 2 (Illustrative Cases)

Manual:

"If the prior inventor's publication contains a clear description of, or clear instructions to do or make, something that would infringe the patentee's claim if carried out after the grant of the patentee's patent, the patentee's claim will have been shown to lack the necessary novelty, that is to say, it will have been anticipated."

Comments:

Whatever is not claimed is disclaimed and thus cannot destroy novelty. Reference may be made to Johnson & Johnston (Fed. Cir. 2002) where the plaintiff claimed the use of aluminum in its invention whereas the defendant used steel. The matter came up to be tested on the basis of Doctrine of Equivalence. Specification of the Plaintiff's patent disclosed "other metals, such as stainless steel or nickel alloys" but the same were not claimed. The Federal Circuit reversed the District Courts' judgment for willful infringement and held that no action for infringement can be sustained as use of Steel was not claimed by the Plaintiff.

Para 3.5.1 at Page 28 w.r.t. Section 2(Enabling Prior Art)

Manual:

"Establishment of anticipation by the prior art requires that the prior invention should be sufficiently disclosed so that a person skilled in the art is able to work the invention without undue burden of experimentation."

Comments:

In accordance with para 3.3.4 of the Manual, to determine novelty, the anticipatory disclosure must be entirely contained within a single document. Under such circumstances, contents of para 3.5.1 cannot be considered to negate novelty though it may make a case of obviousness

Para 3.6.1 at Page 28 w.r.t. Section 2 (Prior Public Use)

Manual:

"Prior public use of the invention in India before the date of filing of application destroys the novelty of the invention. However, there is an exception to this general rule. The Act provides that if an invention has been publicly worked in India within one year before the priority date by the patentee or applicant for the patent or by any third person from whom he derives the title or by the person who has obtained a consent to work the invention and such working of invention was only for the purpose of reasonable trial and it was necessary to effect such trial or working in public in view of the nature of the invention then such working of invention does not anticipate the invention (Section 32)."

Comments:
The Manual does not specify any benchmark for ascertaining prior public use. The cases cited in this para are not relevant for this purpose. Some yardstick to decide experimental use is required to be incorporated in the Manual to provide guidance for examination of patent.

Para 3.7.1 at Page 32 w.r.t. Section 2 (Prior Claiming)

Manual:
"In order to prove prior claiming of the invention, compliance with the following conditions is examined:

***(i)** that the application 'X' where the invention has been claimed prior to the application 'Y' claiming alleged invention, has been filed in India*

***(ii)** the application 'X' must have been filed earlier to the date of filing or priority date of application 'Y' in question*

***(iii)** the application(x) should have been published on or after the date of application(y) in question."*

Suggestion:
The language of (iii) may be substituted as below:

"(iii) the application(x) should have been published on or before the date of application(y) in question to be in public domain on the date of filing."

Para 3.10.1 at Page 34 w.r.t. Section 2 (Important Features of Assessment of Inventive Step)

Manual:

"The Supreme Court laid down the following criteria for assessing inventive step in M/s. Bishwanath Prasad Radhey Shyam Appellant v. M/s. Hindustan Metal Industries, "It is important that in order to be patentable an improvement on something known before or a combination of different matters already known, should be something more than a mere workshop improvement; and must independently satisfy the test of invention or an 'inventive step'. To be patentable the improvement or the combination must produce a new result, or a new article or a better or cheaper article than before. The combination of old known integers may be so combined that by their working interrelation they produce a new process or improved result. Mere collection of more than one integers or things, not involving the exercise of any inventive faculty, does not qualify for the grant of a patent." [AIR 1982 Supreme Court 1444]"

Suggestions:
Some yardstick to decide the improvement or the combination to produce a new result, or a new article or a better or cheaper article than before is required to be incorporated in the Manual in view of paras 3.10.2 and 3.10.3.

Para 3.14.1 at Page 38 w.r.t. Section 2 (Determination of Inventive Step)

Manual:

"The following aspects are looked into while determining inventive step in the alleged invention:

.....

B) Steps in Determination of Inventive Step

.....

***(b)** Assessing the technical result (or effect) and economic value achieved by the claimed invention;*

Suggestions:
The term "and" may be substituted by "or" in order to make it consistent with Section 2(1)(ja) of the Patent Act.

C) Assessing Inventive Step

In assessing an inventive step, mosaics is permissible, if it is obvious to do so at the time of filing or priority date of patent application, to the skilled person in the art, as stated in para. 3.11 supra. The applicant may, for example, have presented his invention as a combination of features A, B, C, and D which he admits as known in combination, with a further feature E which it would undoubtedly be inventive to add to the acknowledged combination. It may be that a prior document discloses the combination of features A and E, and that the addition of the remaining features B, C, D is then the most natural way of completing the disclosure in the prior document and therefore obvious.

Suggestions:
Guidelines for examining a process patent application and combination patent application with regard to change in sequence and process parameters is suggested to be incorporated as these could result into radical changes.

Para 3.18.1 at Page 43 w.r.t. Section 2 (Long Standing Problem)

Manual:
***"(ii)** It is also not inventive to respond to a change in economic circumstances. for example if a product has not been made from a particular material or by a particular process for reason of cost, and the material or process becomes cheaper or the market value of the product increases, it is not inventive to take advantage of this."*

Suggestions:
Economic significance should be considered as non-obvious and inventive in order to make 3.18.1(ii) in consistent with section 2(1)(ja).

II. INVENTIONS NOT PATENTABLE (CHAPTER IV)

Para 4.1 at Page 55 w.r.t. Section 3(a)

Manual:
3(a) "An invention which is frivolous or which claims anything obviously contrary to well

Suggestions:
3(a)* Typographical error: *"An invention which is frivolous or which claims anything obviously contrary to well established natural laws- the underlined portion is missing.

Para 4.3: at Page 56 w.r.t. Section 3(b)

Manual:

"Some examples are:
(i) *An invention, the use of which is contrary to the law which is in force, or use of which is prohibited such as,*

a. *Any device, apparatus or machine or method for committing theft/burglary,*
b. *Any machine or method for counterfeiting of currency notes,*
c. *Any device or method for gambling,*
d. *An invention the use of which can cause injury to human beings, plants and animals.*
.....
(iv) *An invention, the primary or proposed use of which would disturb the public order e.g. a device for house-breaking."*

Suggestions:
Guidelines provided for in the Manual relating to functional aspects of the devices (as in 4.3.iv) can also have utility for a good cause and therefore should be considered as patentable.

"An invention the use of which CAN cause injury to human beings..." is too narrow; many technologies have the potential to cause injury to humans if they are applied in a certain way but have benefits if they are applied in a different way . The language may be changed to indicate that only those inventions may be excluded from patentability if their use in normal course of nature is to harm human beings.

Para 4.4.3 at Page 56 w.r.t section 3(c)

Manual:

"A scientific theory is a statement about the natural world. These theories themselves are not considered patentable, no matter how radical or revolutionary an insight they may provide, since they do not result in a product or process. However, if the theories lead to practical application in the process of manufacture of article or substance, they may well be patentable. A claim for formulation of abstract theory is not patentable. For example, the fact that a known material or article is found to have a hitherto unknown property is a discovery and not an invention. But if the discovery leads to the conclusion that the material can be used for making a particular article or in a particular process, then the article or process could be patentable."

Suggestions:

After substantive human intervention, if a new property/applicability of any bio-tech, chemical or pharmaceutical substance, involving technical advancement or economic significance and societal benefit is arrived at, the said substance with respect to said new property/applicability should be considered as patentable.

Para 4.4.4 at Page 57 w.r.t section 3(c)

Manual:

"Finding out that a particular known material is able to withstand mechanical shock is a discovery and therefore not patentable, but a claim to a railway sleeper made of the material would not fall foul of this exclusion, and would be allowable if it passed the tests for novelty and inventive step. Similarly, finding of a new substance or micro-organism occurring freely in nature is a discovery and not an invention e.g. in Kirin-Amgen v. Hoechst Marion Roussel [2005] RPC 9]."

Suggestions:

Any new substance or micro organism or genetic material isolated from its natural environment thereby decreasing disadvantages of the associated material and increasing the known or new efficacy should be considered as patentable, e.g. beneficiation of biosphere leading to isolation of micro organism in its pure form for specific applicability may be patented particularly in view of 3(c) 4.4.2.

Para 4.5.1 at Page 57 w.r.t Section 3(d)

Manual:

"Mere discovery of a new form of a known substance which does not result in the enhancement of the known efficacy of that substance is not patentable. According to the proviso to this sub-section, a known substance in its new form such as amorphous to crystalline or crystalline to amorphous or hygroscopic to dried, one isomer to other isomer, metabolite, complex, combination of plurality

of forms, salts, hydrates, polymorphs, esters, ethers, or in new particle size, shall be considered same as of known substances unless such new forms significantly differ in the properties with regard to efficacy."

Suggestions:

Section 3(d) discriminates against chemical/pharmaceutical inventions from other fields of technologies and so violates TRIPs Art 27(1). The example of "hygroscopic to dried" is unhelpful since "hygroscopic" and "dried" do not describe different forms: a "hygroscopic" compound does attract water, i.e. if there is water around, the compound will be damp or wet, and if the water is removed (e.g. by drying) the compound becomes dry. Whether the compound is dry or wet is a question of the environment of the compound, it is not an intrinsic property of the same. However, any substance which can be prevented from going back to its natural hygroscopic property through an innovative process may be considered patentable.

It is presumed that combination of plurality of forms include "other derivatives", which is missed out from 4.5.1.

Para 4.5.2 at Page 57 w.r.t. Section 3(d)

Manual:

"In order to be patentable, any salts, esters, ethers, polymorphs, metabolites, pure form, particle size, isomers, mixtures of isomers, complexes, combinations and other derivatives of known substance, they must differ significantly in the properties with regard to efficacy. The requirement here that namely the new form must result in enhancement of known efficacy of known substance and that in order to be distinct from the known substance, the new form must differ in the properties with regard to efficacy."

Suggestions:

Efficacy should be given a broad interpretation such as including better stability, advantages in handling of a chemical compound etc. and should not just be clinical superiority. It is pertinent to mention that at the time of filing of Patent Application particularly, the one filed before the Patents (Amendment) Act, 2005 came into effect, data with regard to *in-vivo and in-vitro* behaviour of a claimed substance is ordinarily not generated and included in the specification. Moreover, it is rather difficult to predict efficacy of a substance with the change in substituents of a core compound. One can only disclose a difference in the properties particularly, the physical properties such as stability, solubility, penetrability and its bio-chemical behaviour, which may help in prediction of the efficacy of a substance. It is rather difficult, and not required to quantify efficacy. We suggest that the data generated with regard to *in-vivo and in-vitro* behaviour of a claimed substance, after filing the application, may be taken on record for deciding enhanced efficacy and determining the patentability of the substance. Further, such data should also be considered while dealing with disputes.

Para 4.5.3 at Page 58 w.r.t. Section 3(d)

Manual:

"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."

Suggestions:

From the word "or", it is apparent that the examiner will consider either significant difference in properties or enhancement of the efficacy while comparing prior art and the substance of the subject application. Further, it is also apparent that the comparison is made with the latest prior art.

Para 4.5.4 at Page 58 w.r.t. Section 3(d)

Manual:

"The comparison with regard to properties or enhancement of efficacy is required to be made at the time of date of filing of the application or priority date if the application is claiming the priority of any earlier application but not at the stage of subsequent development."

Suggestions:

As indicated above, data with regard to *in-vivo and in-vitro* behaviour of a claimed substance is ordinarily not generated at the stage of patent filing and hence not included in the specification filed. More so, in case of Applications filed prior to 1.1.2005 when Section 3(d) in its present form was not there. Further, if clinical data is required to be submitted, such data would have to be collected in studies, which likely will expose the new form to the public in a manner, which may take away novelty from the claimed new form (hence, you only have the choice, whether you wish to fail by lack of novelty or under Section 3(d).

As an established principle of patent examination all over the world, a distinction is made between data that need to be provided in the patent filing and data that can be delivered later for marketing approval. Data that needs to be included in most countries is such data that enables the person skilled in the art to work the invention satisfying basic criteria for patentability. For instance, if a new chemical compound is employed, the Applicant has to describe how to obtain this new chemical compound. The other type of data discussed during patent examination is data showing that the claimed invention is inventive compared to the prior art. Such data can always be provided by the Applicant during the prosecution. The point is that the Examiner first has to decide what kind of data is required to show an inventive step.

Para 4.5.6 at page 58 w.r.t. Section 3(d)

Manual:

"In regard to 'efficacy' in pharmaceutical products, the Madras High Court observed: "going by the meaning for the word "efficacy" and "therapeutic"

... ..., what the patent applicant is expected to show is how effective the new discovery made would be in healing a disease/ having a good effect on the body? In other words, the patent applicant is definitely aware as to what is the "therapeutic effect" of the drug for which he had already got a patent and what is the difference between the therapeutic effect of the patented drug and the drug in respect of which patent is asked for."
"Due to the advanced technology in all fields of science, it is possible to show by giving necessary comparative details based on such science that the discovery of a new form of a known substance had resulted in the enhancement of the known efficacy of the original substance and the derivatives so derived will not be the same substance, since the properties of the derivatives differ significantly with regard to efficacy." (Novartis AG v.
Union of India W.P. 24760/06)."

Suggestions:
Above citation is rather inappropriate at this juncture since the instant case specifically involved a pharmaceutical invention and by citing such a specific case law, the manual tends to equate the term efficacy with therapeutic efficacy or otherwise generalize patenting benchmarks which are typical for certain pharmaceutical inventions to all products across the fields of technology.

Para 4.5.7 at Page 58 w.r.t. section 3(d)

Manual:

"Some of the examples of new forms are given below without limiting the scope of the application of the provisions of the Act.
(i).....

(ii) Stereo Isomers
Stereo isomers are prima facie obvious. Once a compound having a chiral center is known, its enantiomers are obvious because a person skilled in the art knows that a compound having a chiral center exists in two optically active forms. Hence, a product patent may not be granted for the enantiomer form. However, when a new compound is claimed having chiral center(s) for the first time, such a new compound may be patentable.

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.

Suggestions:

Separation of individual enantiomer from a racemic mixture usually results in reduction of unwanted enantiomer thereby increasing efficacy and reducing harmful side effects. This conforms with the requirements stipulated under 3.8 and hence may be considered for the grant of patents.

"(iii) Homologues:

Homologues normally display add-on property. They are structurally similar and provide the example of Structure –
Function linearity and may lack inventive step. However the cases are to be decided on case to case basis."

Suggestions:

It is well understood by the persons skilled in the art that the change in bonds between two atoms and attachment of a particular moity at a specific position results in change in dissociation factor and cleaving ability of the substance displaying add on properties and increased efficacy. As rightly indicated above, patentability of homologues may be decided on case to case basis rather than painting all the inventions with a single brush.

"(iv) Polymorphs

Some compounds are present in polymorphic forms, i.e., they crystallize in diverse forms. Such forms can be deemed within the prior art and therefore not patentable. However, process patent may be allowed for the new polymorph, if the polymorph is prepared by novel process involving inventive step. Some therapeutically active ingredients, present in polymorphic forms, may have different properties that are more or less significant in terms of their therapeutic use. 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."

Suggestions:

Polymorphs exist in two or more crystalline forms due to different arrangement and/or conformation of molecules in a crystalline lattice. Further, when crystals of a compound are forming (e.g., crystallizing from a solution), solvent molecules get entrapped or bound within the crystal lattice. The presence of the entrapped solvent molecules does affect the three-dimensional crystal lattice that eventually crystallizes thereby exhibiting different physical properties and chemical behavior and in turn pharmaceutical's performance such as dissolution rate, solubility, bioavailability, level of toxicity, crystal habit, mechanical strength. The molecules even behave very differently in in-vitro studies, in-vivo preclinical studies and clinical studies different phases. It may be noted from herein above disclosure that the polymorphs differ in their physical properties which reflect in their efficacy and hence may be considered to satisfy the explanation to 3(d).

(v) .....

"(vi) Prodrugs

Prodrugs are inactive compounds that can produce an active ingredient when metabolized in the body. Hence prodrugs and metabolites are interlinked. When metabolyzed in the body, inactive compounds (pro-drug) can produce a therapeutically active ingredient. It must be determined whether the patent on the compound covers the prodrug and the extent to which claims relating to certain compounds should also be allowed to include their prodrugs. The inventive aspects of a prodrug may be decided based on the merits of the case."

Suggestions:

As rightly indicated above, inventive aspects of prodrug should be decided on the merit of the case. Additionally, the change in precursor may change the mechanism in which the metabolites are formed in the body, patentability of such compounds may be considered on case to case basis. Further, composition/formulation of prodrugs may be considered for grant of patents.

"(vii) Hydrates and other Substances:-

Hydrates, acid addition salts and other derivatives, which are routinely prepared, prima facie lack an inventive step. However, where there is a problem like stability, absorption etc., and there is a long standing problem in preparing the derivatives, patentability of such process may be considered."

Suggestions:

Hydrates or Solvates regulate impurities present in the final compound and also solve the problems like stability, absorbability. Considerable reduction in impurities and improvement in stability will result in meeting ICH Guidelines proving the substance with increased efficacy. This is also applicable to the purified compounds with reduced impurities/toxicities.

Para 4.5.10 at Page 61 w.r.t. Section 3(d)

Manual:

"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:- Mere use of a known process is not patentable unless such known process results in a new product or employs at least one new reactant. Similarly mere use of known apparatus or machine for another purpose is also not considered patentable."

Suggestions:

A known process may be considered patentable when a sequence of steps or parameters are changed resulting into a substance having different properties with regard to efficacy.

Para 4.5.15 at Page 63 w.r.t. Section 3(d)

Manual:

"In the case of M/s. Astra Aktiebolag [Patent Application No. 1354/del/1998], the Controller in his decision dated 12th June, 2007, held that the claimed invention is not patentable under section 3(d) of the Patent Act 1970, as "present pharmaceutical formulation is a selection from the prior art formulation due to the specific selection of HPMC of cloud point above 45.6° C having similar medicinal use and with the same therapeutic efficacy... the benefit claimed by the applicant in the present application is not accruable to the user in terms of therapeutic quality of the product but to the manufacturer only in terms of consistency in the production of formulation...".

Suggestions:

Provisions of Section 2(1)(ja) requires that the invention should have technical advancement or economic significance or both and does not demand benefits accruable to the consumer. In view of this the invention like this may be considered for the grant of patents.

Para 4.6.1 at Page 63 w.r.t. Section 3(e)

Manual:

"In the patent application No. 782/Cal/1981, dated 13th July, 1981 referred to in para 4.5.13, it was held by the Controller that the pharmaceutical vehicle having the primary intended function of acting as vehicle or carrier or diluent performed the very function when incorporated in the composition. There was no explicit disclosure or experimental data to indicate that the presence of the carrier in any way influenced the antiphlogistic, antipyretic and analgesic activity of the active ingredients. Therefore, the invention was held not allowable under Section 3(e) of the Act as well as and merely an admixture."

Suggestions:

It is apparent from the above case study that the invention would have been considered favorably provided adequate data with regard to synergism would have been disclosed in the body of specification. However, we suggest that submission of such data during prosecution may kindly be taken on record and accepted for grant of patent.

Para 4.6.2 at Page 63 w.r.t. Section 3(e)

Manual:

"A mixture of sugar and some colourants in water to produce a soft drink is a mere admixture resulting into aggregation of the properties. Similarly, a mixture of different types of medicament or medicine to cure multiple diseases is also a mere admixture of substances and is not a patentable invention."

Suggestions:

It may be noted that in any formulation including medicament and/or medicine, the vehicle or carriers or diluents, which normally are conventional, always work interdependently and in synergism with the active ingredient thereby facilitating enhanced pharmacokinetics of the active ingredient/key substance and directing the delivery of the therapeutically or other active ingredient in desired quantity, in a desired manner, and at a desired place. Neither the vehicle or carriers or diluents nor the active ingredient in isolation can be effectively used. Without appropriate coordination of these various components the desired effect can not be achieved. This is particularly true for a composition having the novel title compound as main ingredient and acceptable carrier.

Para 4.6.5 at Page 63 w.r.t. Section 3(e)

Manual:

"In assessing the inventive step involved in an invention based on a combination of features, consideration must be given to whether or not the state of the art was such as to suggest to a skilled person precisely the combination of features claimed. The fact that an individual feature or a number of features were known does not conclusively show the obviousness of a combination."

Suggestions:

This para refers to "assessing inventive step" which is not the focus of consideration under Section 3 (e); thus, this text may be appropriately shifted to the guidance on inventive step.

It should be further added that a combination invention should be permitted where a technical prejudice existed against combining the individual components e.g. because of assumed incompatibilities of the two components.

Paras 4.9.1 to 4.9.19 Pages 68 to 72 w.r.t. Section 3(i)

Suggestions:

Since the prophylactic, diagnostic methods being preventive in nature can not render the subject, free of disease, which is human being or animals according to Section 3(i). It can only prevent or arrest if the ailment has already in progress. Under no circumstances it can render the subject free of disease, which is the requirement of the Act. Further, the entire analysis of the Section leaves far too much scope for discretion as to what could constitute disease and therapy.

Paras 4.10.1 to 4.10.3 at Page 72 w.r.t. Section 3(j)

Suggestions:

We suggest the incorporating some guidelines with regard to biologicals, phyto-chemicals, genetic material when removed from its natural habitat (plant or seed or animal or any other biological material) for possible grant of Patent is desirable. Also some illustrations in respect of essentially biological processes for production or propagation of plants or animals will be helpful.

III. PRE-GRANT OPPOSITION (CHAPTER VII)

Paras 7.1.1 to 7.1.4, Pages 177 to 179 w.r.t. Section 25(1)

Suggestions:

The issues discussed under Pre-grant Opposition seem to be irrelevant which the subject. Discussions on substantive law on patentability by citing Glivec Opposition case is not relevant to be put in under Pre-grant Opposition head.

The real issue with Pre-grant opposition in India is that they are open ended and cyclic in nature and thus eat away considerable effective patent life of an invention.

The Manual does not provide any guideline to the Patent Office to streamline the procedure for dealing with Pre-grant Oppositions so that the applicants are not deprived of the valuable patent protection period that is lost due to delay in grant of patent in the wake of multiple pre-grant oppositions.

IV. WORKING OF A PATENT AND COMPULSORY LICENSING (CHAPTER XVIII)

Para 18.2.6 at Page 293 w.r.t. Section 84

Manual:

" *Grounds for Compulsory Licence:-*

.....

(4) Failure to work the patented invention within the territory of India will be considered with respect to the facility available in India for the working of the invention. Provision of importation of patented article is allowed. But the mere importation of patented articles when there is a possibility of manufacturing within India will be a factor that will receive consideration....."

Suggestions:

This interpretation goes beyond or even against the legislative intent of the Patents Act. The intent of the legislature is clear from the fact that the phrase "*....manufactured in India*" was deleted during the amendment to the Act, thus negating the requirement of local manufacture. As the present Manual cannot go beyond the legislative intent of the parent Act, the term "working' should have been made to include manufacture, sale, offering for sale or otherwise distribution in India.

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ORGANISATION OF PHARMACEUTICAL PRODUCERS OF INDIA

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Tapan Ray
Director General

Ref.IPP-2008/178 April 14, 2008

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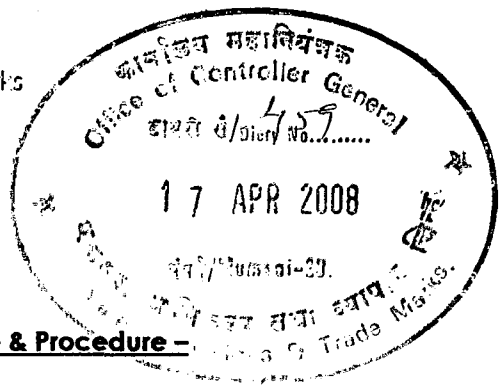

Dear Shri Ravi,

OPPI Comments on Draft Manual of Patent Practice & Procedure – ADDENDUM

This has reference to our letter Ref.IPP-2008/169 dated April 10, 2008, giving our comments on the Draft Manual of Patent Practice and Procedure.

In addition to what has been stated in the above mentioned letter, we would like to bring to your attention that it is possible that the Office of the Drugs Controller General (India) may grant marketing permission to a generic manufacturer for a product for which the patent already exists in India. Such instances can put the patent holder in hardship and avoidable litigation involving huge resources in terms of time and money. This can be avoided if the the DCGI ascertains the patent status before granting marketing permission to the generic manufacturer.

To cite another possibility, a Company may apply for a compulsory licence from a neighbouring country for a patented drug in India. This ultimately can lead to potential abuse of the provision of compulsory licensing with a large percentage of exported product being sold back in India. Such a possibility will increase if the product is exported to a neighbouring country with relatively porus border.

The possible scenarios cited above, if get translated into reality, may tarnish the image of the IPP regime in India.

To prevent the above adverse scenario from taking place in India, **it is very necessary that there should be an Administrative arrangement for the Patent Office to invariably send the details of Patent granted on Pharmaceutical Products / New Chemical Entities (NCEs) to the Drugs Controller General (India) so that the latter Authority can prevent issuing Marketing / Manufacturing Licences to 3rd parties during the life of the Patents.**

We hope the above suggestion is considered favourably while finalising the Draft Manual of Patent Practice & Procedure.

Thanking you and with regards,

TAPAN RAY
DIRECTOR GENERAL

cc:: Mr. N.N. Prasad / Mr. T.C. James / Mr. N.J. Thomas