



COMMENTS ON MPPP:

Paragraph 4.5.1: 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.

FICCI's Comments: (a) This section provides that the new form of the substance shall not be considered as patentable unless it shows enhancement in efficacy. The proviso covers examples namely, crystalline to amorphous; hygroscopic to dried or one isomer to other isomer. This section does not cover guidelines about those inventions in which one crystalline form is converted into another crystalline form. To quote an example, the drugs namely, atorvastatin (cholesterol lowering), perindopril (anti-hypertensive) and fluvastatin (cholesterol lowering) exist in more than one crystalline form.

It is further not clear whether enhanced efficacy can be proved by factors such as better stability, lesser side effects, wider spectrum of activity, reduction in treatment time etc. If new form of the known substance is more stable then it means that it does not decompose into by-products as a result of which the said form will have more bioavailability than the other form of the drug which is less stable. For example, Eletriptan (useful for the treatment of migraine) exists in two crystalline forms alpha and beta. The drug sold in market contains active ingredient (Eletriptan) in alpha form due its greater stability as compared to beta form.

(b) There might also be chances that the applicant claims the new form of the known substance in the form of a composition (for example, a composition comprising a carrier or an excipient and the new form of a known substance) in order to escape obligation of section 3d.

Recommendations: (a) The patent office may consider revising the text by including the term, “crystalline form to another crystalline having different crystalline structure” in the proviso;

(b) clarification should be provided on whether enhanced efficacy can be proved by showing better stability, lesser side effects, wider spectrum of activity, reduction in treatment time etc

(c) guidelines regarding patentability of claims directed to new form of the existing substance in the form of composition should be included.

Paragraph 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.

FICCI's Comments: This section provides that in case one form of the known substance is converted into another form then the comparison will be made between the existing form and the new form and not between new form and the base compound. There might be occasions where the existing form of the known substance is less efficacious than the base compound thus in such cases it will become very easy for the applicant to prove enhanced efficacy of the new form vis-à-vis existing form.

This further provides that the comparison will be made with regard to “improved pharmacological property” and/or “unexpected advantage” of the new form. It appears that the applicant can prove patentability of the new form either by showing its improved pharmacological properties or by showing its unexpected advantage (i.e. enhanced

efficacy). This is contrary to section 4.5.1 which states that comparison will only be made with regard to increased efficacy.

Recommendations: The patent office may consider inserting the text “the comparison will be made between base compound or the known form having higher efficacy and another new form.”

The patent office may consider providing clarification as to whether the comparison has to be made with regard to “enhanced efficacy” or “improved pharmacological effects” (This refers to the characteristics or properties of a drug, especially those that make it medically effective.) and/or both. It is also recommended that clear cut definition should be provided detailing difference between the two terms i.e. “enhanced efficacy” or “improved pharmacological effects”.

Paragraph 4.5.7(viii): Purification Compounds: - Mere purification of known material is not patentable as they are considered the purified compound. However, the purification process or the purified compound which never existed before due to inherent long standing problem can be considered patentable. Some of the examples of new forms are given below without limiting the scope of the application of the provisions of the Act.

FICCI's Comments: The term “purification compounds” is misleading. Purification compounds refer to the compounds which are used for purification.

Recommendations: (a) The term purification compound should be replaced with “purified compounds” or “purified forms of the known substances” and it should be further explained.

(b) Reference to Boards of Appeal of the European Patent Office decision in case of T0278/98 can be made here wherein it was remarked that “it is common practice for a person skilled in the art of preparative organic chemistry to further purify a compound obtained in a particular chemical manufacturing process according to the prevailing needs and requirements. Since, as a rule, conventional methods for the purification of organic compounds are within his common general knowledge, a document disclosing a

particular compound and its manufacture makes normally available this compound to the public in all desired grades of purity”. In deciding the same case the Board has also remarked that “if there exist an exceptional situation where it was proved on the basis of the balance of all probabilities that to achieve a particular level of purity by conventional purification methods have failed”. However, in such case method of purification of a substance may be considered patentable.

Paragraph 4.5.8: Mere discovery of new property of a known substance

A mere discovery of a new property of known substance is not considered patentable. For instance, the paracetamol has antipyretic property. Further discovery of new property of paracetamol as analgesic can not be patented. Similarly, ethyl alcohol is used as solvent but further discovery of its new property as anti knocking, thereby making it usable as fuel, can not be considered patentable.

Paragraph 4.5.9: Mere discovery of any new use of known substance

A mere discovery of new property of known substance is not considered patentable. For instance, new use of Aspirin for treatment of the cardio-vascular disease, which was earlier used for analgesic purpose, is not patentable. However, a new and alternative process for preparing Aspirin is patentable. Similarly, the new use of methyl alcohol as antifreeze in automobiles. The use of methanol as a solvent is known in the prior art. A new use has been claimed in this claim as antifreeze which is not allowable. Further, a new use of Chloroquine for Sarcoidosis (a fungal disease) and for Infectious mononucleosis (a viral disease) and for Diabetic neuritis (inflammation of nerves) is not patentable.

Recommendations: The new property and new use of the known substances have been covered under different headings which creates confusion. It is therefore recommended that paragraph 4.5.8 and 4.5.9 should be combined and be re-worded as “Mere discovery of new property or new use of the known substance”. Alternatively, for clarity the examples of paracetamol, aspirin and chloroquine may be covered under paragraph 4.5.8

and the examples of methyl alcohol and ethyl alcohol may be covered under paragraph 4.5.9.

Paragraph 4.6.2: A mixture of sugar and some colorants 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

FICCI's Comments: It appears that the combination of two or more therapeutically active substances will be considered as non-patentable in itself without giving any consideration to its technical advancement and is being treated as analogous to mixture of sugar and some colourants in water to produce a soft drink. It is emphasized here that preparation of pharmaceutical compositions involves complicated scientific experimentation and is not merely admixture or aggregation of properties of the known substances. Diverse set of experiments have to be carried out to rule out the occurrence of toxic effects as a result of combination of two or more active ingredients. Further, the pharmaceutical composition should be such that it is stable and produce intended therapeutic effect. To quote an example, which combination will produce desired stability besides having improved patient compliance requires innovative processing. Also, not every pharmaceutical excipient can be formulated with every active ingredient. Another example of complex composition is extended release pharmaceutical composition. It requires controlled release of active ingredient in such a manner that it produces optimum therapeutic effect, better and more uniform clinical effects, possible enhanced bioavailability, reduced side effects or reduced frequency of dosing.

Recommendations: It is recommended that proper guidelines should be given as to the standard that may be applied with regard patentability of pharmaceutical compositions.

Paragraph 4.6.3: However, an admixture resulting into synergistic properties of a mixture is not considered as mere admixture, e.g., soap, detergent, lubricants and polymer composition etc.

Recommendations: The term synergy has not been defined. The patent office may consider including following general definition. “Synergy refers to the phenomenon in which two or more agents acting together (a) produce an effect greater than the normal sum of the effects produced by individual agent or (b) produce therapeutic effect when therapeutically ineffective amounts are combined. For example, consider a drug A and drug B which does not produce therapeutic effect when administered individually at a dosage amount of 0.5 mg. If the two drugs are combined containing therapeutically ineffective amount (i.e. 0.5mg) and if such combination produce therapeutic effect then it will be considered as synergistic combination”.

Paragraph 4.11.4: In order to distinguish the invention from the prior art, relevant prior art is also required to be given in the specification. It is always essential to analyze the invention in the light of what is described and the prior art, in order to identify the contribution to the art and hence determine whether this advancement resides in, or necessarily includes technological features and technical application or is solely intellectual in its content. A hardware implementation performing a novel function is not patentable if that particular hardware system is known or is obvious irrespective of the function performed.

FICCI’s Comments: This implies that the hardware implementation performing a novel function is not patentable if that particular hardware system is known or is obvious. It is emphasized here that a hardware implementation that performs novel and non-obvious functions defines the essence of most inventions. For example, a computer programmed to provide a novel and non-obvious function should be accorded a patent protection as a result of which it distinguishes it over other computers which do not perform that function.

Recommendations: The patent office should therefore consider deleting the sentence “A hardware implementation performing a novel function is not patentable if that particular hardware system is known or is obvious irrespective of the function performed”. This sentence also appears to be inconsistent with the last sentence of paragraph 4.11.8 “An

invention consisting of hardware along with software or computer program in order to perform the function of the hardware may be considered patentable *e.g.* embedded systems.

Paragraph 4.11.8: The claims relating to software programme product are nothing but computer programme *per se* simply expressed on a computer readable storage medium and as such are not allowable. For example, if the new feature comprises a set of instructions (programme) designed to control a known computer to cause it to perform desired operations, without special adoption or modification of its hardware or organization, then no matter whether claimed as “a computer arranged to operate etc” or as “a method of operating a computer”, etc., is not patentable and hence excluded from patentability. The claim might stipulate that the instructions were encoded in a particular way on a particular known medium but this would not affect the issue. *e.g.*, A program to evaluate the value of pi or to find the square root of a number are held not allowable. An invention consisting of hardware along with software or computer program in order to perform the function of the hardware may be considered patentable. *e.g.*, embedded systems.

FICCI comments: The term “computer programme *per se*” has not been defined. It is to bring to your notice that EPO construes the term “computer programme” “as such” or “*per se*” to mean a programme that is merely abstract creation, lacking in technical character. In view of this interpretation, it takes a position that “a computer programme claimed by itself is not excluded from patentability if the programme, when running on computer or loaded onto a computer, brings about, or is capable of bringing about, a technical effect which goes beyond the “normal” physical interactions between the programme (software) and the computer (hardware) on which it is running.

Recommendation: Patent office may consider furnishing the definition of term “computer *per se*”.

Paragraph 5.6.1: Complete Specification is required to have the following components:

- (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'

FICCI's Comment and Recommendation: The listed items should also include disclosure of “source and geographical origin of biological material in accordance with section 10(4) proviso (ii)(D).

(c) Disclosure in the complete specification about the “agreement related to access and benefit sharing with Competent Authority” should also be made mandatory.

Paragraph 6.1.5(c): Publication of patent application includes information on the following parameters as may be applicable to a particular case

- (a) Number of application
- (b) Date of filing of application
- (c) Title of invention
- (d) Publication date
- (e) International Patent Classification
- (f) Name and address of the applicant

- (g) Name of the inventor(s)
- (h) Priority details like document number, date, country, PCT Application number and date, etc
- (i) Patent of Addition to / Divisional Application to: along with filing date of the parent application
- (j) Abstract of the Invention including drawing (if any)

FICCI's Comments: The particulars of publication do not include publishing information about number of pages. No. of pages of the patent if included in the publication details would facilitate in calculating the correct amount of fees required to be paid for procuring the specifications from patent office.

Recommendations: Particulars of publication should also include publication of information related to total no. of pages.

Paragraph 6.2.7(b)(x): Substantive /Technical Examination - Steps involved in Substantive Examination - Permission from National Bio diversity Authority.

FICCI's Comments: It provides that for substantive examination of the application the patent applicant is required to intimate to the patent office in writing that he has taken permission from National Biodiversity Authority (NBD) to use the biological material. To the contrary, as per Form I, the permission from competent authority can be submitted anytime before the grant of patent. It is emphasized here that in order to seek permission from NBD the applicant has to sign an agreement according to which he agrees to pay royalty if his invention commercialized. The amount of royalty that can be paid cannot be decided unless an applicant is aware about the claims which will be finally allowable.

Recommendations: It is therefore suggested that changes should be made in guidelines to make it compliant with the requirements of Form I i.e. the applicant should not be forced to submit permission from NBD anytime before the grant of patent.

Paragraph 7.1.1 (b): Grounds for Pre-grant Opposition by way of Representation u/s 25(1) are summarized as follows:

b) Prior publication / prior claiming

FICCI's Comments: (a) Mode of publication: There is no mention about the mode in which prior art will be considered as published i.e. printed on paper or electronic form. With the increasing use of internet and online databases in today's knowledge economy, the electronic publication should also be considered as a prior art. These prior arts available electronically would be instrumental in granting only valid patents.

(b) Meaning of term "published" and the extent to which prior art document should be accessible: The term "published" has not been defined in the act and there are no guidelines which provides details about the extent to which the publication should be accessible to public so that it could be considered as a prior art. The scope of expression 'published' under section 25(1)(b) is much broader and appears to include any document published anywhere in the world which is capable of being admitted as evidence. The information available to public in any form should be considered as a prior art immaterial of its nature, manner, time, place or language in which it is available

When the matter in question is distributed with the object of spreading the knowledge among the interested parties, it would constitute publication [(1927)44 RPC 294].

Where documents relating to the invention were sent by the patentee to a commercial partner, it could be assumed that they had a duty of confidence to each other [(1959) RPC 141 at 147].

Recommendations: Patent Office could consider providing (a) definition of the term "published"; (b) mode of publication; (c) guidelines about the extent to which documents should be available to public so as to render it as a prior art.

Paragraph 21.3.4: The orders passed by Central Government in relation to inventions relevant to defense purpose and orders of Controller giving direction of secrecy in respect

of such inventions under Section 35 and revocation of Patents by the Controller under Section 65, or by the Central Govt. under Section 66, are not appealable.

FICCI's Comments: This implies that the orders by the Central Government under section 66 are not appealable. This is contrary to section 117A(2) according to which the decisions of Central Government under section 66 are appealable.

Recommendations: Term “by the Central Govt. under Section 66” should be deleted.

Paragraph 20.4: Parallel Import

Parallel import provisions are provided in S. 107A(b), which says that importation of patented products by any person authorized by the Patentee will not be considered as an infringement. Therefore it is possible to import the patented products from the licensee of the patentee in any country with out the permission of the Patentee. The purpose of Parallel import is to check the abuse of patent rights and meant to control the price of patented product.

FICCI's Comments: The term “authorized by patentee” has been wrongly mentioned..

Recommendations: The term “authorized by the patentee” should be replaced with “any person authorized under the law” which is in compliance with 107A(b). The manual should further define “who is the person authorized under the law”.

Chapter XIX: This chapter does no provide any guidelines about where the decision of the Appellate Board can be appealed whether before the division bench for High Court or Supreme Court.