Piramal Life Sciences
knowledge action care

April 15, 2008

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

Subject: Draft Manual of Patent Practice & Procedure, The Patent Office, India
Suggestions to improve Manual

Dear Sir,

The manual has been on the whole improvised in the following ways:

1) Details of changes in each amendment to Patents Act.
2) Explanation of inventive step and person skilled in the art.
3) Introduction of case studies.
4) Explanation of formal and substantive examination.
5) Explanation of the process of pre-grant and post-grant opposition.
6) Combining each section of the Act with the corresponding rules for a better understanding of the Act.

However, the Manual still needs a lot of improvement to ensure that the contents of the manual are technically and grammatically correct, and unambiguous. This will simplify examination procedure for the examiners and reduce the incidence of opposition and litigation.

Within the limited time available, we have put together some suggestions. If the date is further extended or more time is available, we would definitely be able to provide many more suggestions for further improvement of the Manual, which is still required.

A few points are highlighted below. More details are given in the enclosed Table.

Many definitions in Section 2 need further explanation, e.g. definition of "pharmaceutical substance" and "inventive step".

The definition of inventive step (pg 18 of the Manual, 2.35 (ja)) seems to indicate that the inventive step requirement is satisfied if the invention has an economic significance even in the absence of technological advance. This stems from wording in the Act and the Manual should provide an explanation.

A main focus of improvement is needed towards Section 3 – Inventions not patentable
In Section 3(d), many definitions e.g. homologues, polymorphs, isomers, etc. need to be more accurate.

mumbai-patent@nic.in
sumeetakulkarni@yahoo.com

Piramal Life Sciences Limited
1 Nirlon Complex Off Western Express Highway Goregaon East Mumbai 400 063
T +91 22 3031 3000 F +91 22 3031 3036

A clear explanation for "differ significantly in the properties with regard to efficacy" needs to be given for Section 3(d).

Section 3(d) 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, must differ significantly in the properties ***with regard to efficacy.***

At some places in the Manual, an impression is given that that "properties of the new form" and "enhancement in efficacy" are independent criteria while making comparison between the known substance and the new form of known substance.

Examples need to be given for the measures which may be used to prove significant difference in efficacy. Would the only indicators be efficacy/potency determination in animals/humans or would *in vitro* tests suffice? Could factors like better stability, more specificity, less side effects, easier formulation, wider spectrum of activity, reduction in treatment period, etc. also qualify?

Pre-grant opposition: A time limit (within six months after publication) should be set for filing a pre-grant opposition. At present, one pre-grant opposition can be followed by another, leading to a significant delay in grant. The opposition statement should be accompanied by complete details regarding grounds of opposition to prevent frivolous oppositions aimed at delaying the grant.

In 6.2.7 of the Manual, b) Steps involved in substantive examination (Page 152-153)
Step x. requires permission from National Biodiversity Authority as a requirement during substantive examination
On the other hand, in Form 1, the declaration from the applicant requires that permission from competent authority for use of biological material will be submitted **before the grant of the patent**. This needs clarification.
Permission from the National Biodiversity Authority (NBD) requires the applicant to sign an Agreement agreeing to pay royalty (which may change on a case by case basis) in the event the patent is licensed or in the event of commercial production.
It is difficult to arrive at a royalty rate before substantive examination without knowing which claims will be finally allowed.
The permission from the NBD should not be required before substantive examination. Once the patent is ready for grant, the permission from the NBD should be obtained and submitted by the Applicant.

We respectfully request you to consider our suggestions and give us a chance to submit further suggestions if more time is permitted.

With best regards

Swati Bal-Tembe

Dr. Swati Bal-Tembe
Vice President & Head, Patents Dpartment

SUGGESTIONS FOR IMPROVEMENT OF MANUAL OF PATENT PRACTICE AND PROCEDURE

CHAPTER IV – INVENTIONS NOT PATENTABLE

No.	Relevant Portion From The Draft Manual Of Patent Practice & Procedure	Corrections /suggestions	Remarks
	CHAPTER II – PREAMBLES AND DEFINITIONS		
1	**Page 19** **2.3.12:** "pharmaceutical substance" means any new entity involving one or more inventive steps	The definition for 'Pharmaceutical substance' lacks clarity. An explanation should be provided in the manual as to 'what constitutes a pharmaceutical substance' so that the scope of patentability of pharmaceutical substance is better understood. The word 'entity' needs to be elaborated and defined appropriately in the practice manual to evaluate the scope of patentability of pharmaceutical inventions.	
	CHAPTER IV – INVENTIONS NOT PATENTABLE		
2	**Page 54:** *(d) 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;* *(e) the mere arrangement or re-arrangement or duplication of known devices each functioning independently of one another in a known way;* *(f) Omitted.*	~~*(d)*~~ *(e) a substance obtained by a mere admixture resulting only.....;* ~~*(e)*~~*(f) the mere arrangement or re-arrangement or duplication of.....;* ~~*(f)*~~ *(g) Omitted.*	**<u>On page 54</u>** all the clauses following the clause "d" of Section 3 are wrongly denoted. For example, clause "e" is wrongly designated as "d". Likewise, clause "g" and not "f" is omitted.

	(g) a method of agriculture or horticulture; *(h) any process for the medicinal, surgical, curative, prophylactic, diagnostic, therapeutic or other treatment of human beings or any process for a similar treatment of animals to render them free of disease or to increase their economic value or that of their products.*	~~(g)~~ *(h) a method of agriculture or horticulture;* ~~(h)~~ *(i) any process for the medicinal, surgical, curative, prophylactic, diagnostic.....;*	
3	**Page 57:** **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.	The term "sub-section" should be replaced with the term "**clause**". This statement should be properly structured, particularly the phrases "amorphous to crystalline" or "crystalline to amorphous" or "hygroscopic to dried" or "one isomer to another isomer" appear to be out of place. The statement may be re-written as follows : "According to the proviso to this clause, a new form of a known substance may be the one wherein an amorphous form of a substance is converted to its crystalline form or crystalline form is converted to amorphous or a hygroscopic form is converted to an anhydrous form, or one isomer is converted to other isomer; further examples of new forms include metabolites, complexes, combination of plurality of forms, salts, hydrates, polymorphs, esters, ethers, or substances having new particle size; and all such new forms shall be considered to be the same substance unless they significantly differ in the properties with regard to efficacy."	In respect of deletion of Section 3(g), the footnote on page 7 of the bare act refers to "(g)" as "clause (g)" and not as sub-section.
4	**Pages 57-58:** **4.5.2.** In order to be patentable, any salts, esters, ethers, polymorphs, metabolites, pure form,	This point should be deleted as it is does not provide any additional explanation to point no. 4.5.1. Albeit this is a	----------

	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.	repetition of the point no. 4.5.1 .	
5	**Page 58:** **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.	Point no. 4.5.3 may be re-written as follows. The reasons for this revised statement are provided in the adjacent column. "In determining patentability of the new form of a known substance the examiner may seek comparative data which demonstrates improved pharmacological properties and/or an unexpected advantage of the new form over the known substance. In case, the subject matter of the claimed invention is a new form which is obtained by conversion of another new form of the known substance (the parent compound), the comparative data should demonstrate improved pharmacological properties and/or an unexpected advantage of the claimed new form with that form of the known substance from which it is obtained and not the known substance ("the parent compound")." Example: An earlier patent application claimed a particular polymorph of a salt of a pharmacologically active compound. The alleged invention which claims a second polymorphic form must compare its advantages or efficacy with the first polymorphic form and not with the amorphous salt or the free base	This point in its present form is vague. It says that the examiner makes comparison with regard to "**properties or enhancement of efficacy**". It may be interpreted that the examiner may consider either "**properties of the new form**" or "**enhancement in efficacy**" as two independent criteria during the comparison. In earlier points it is specifically mentioned that the new form should differ in properties with regard to efficacy. In other words there should be a co-relation between properties and enhancement in efficacy.
6	**Page 58:** **4.5.4.** The comparison with regard to properties	Point no. 4.5.4 may be re-written as follows. The reasons	This statement may be

	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.	for this revised statement are provided in the adjacent column. "The comparison with regard to properties in terms of enhancement in efficacy of the new form 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."	interpreted that the examiner may consider either "**properties of the new form**" or "**enhancement in efficacy**" as two independent criteria during the comparison.
7	**Pages 58-59:** **4.5.7. (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. 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.	The explanation provided for isomers should be revised as follows: "(i) **Isomers**: Isomer is the term used to describe two or more chemical compounds which can be represented by the same molecular formula. There are two main types of isomers: (a) **structural or positional isomers;** (b) **stereoisomers.** (a) **Structural or positional isomers** Structural isomers are molecules that have the same chemical formula, meaning they have the same atoms in each molecule, but differ in the order in which the atoms are connected. The different order of the atoms produces two completely different molecular structures. The simplest examples are butane and isobutane as one set of structural isomers and ethanol and dimethyl ether as the other set. In the first set, the compounds are having structural and functional similarity whereas in the second set although they have the same molecular formula they are structurally and functionally different. Such isomers even though having close similarity may be considered to be novel over the prior art. Isomers having the same empirical formula but different structures may be considered novel but may still lack inventive step unless a clear advantage is shown.	The statements are re-phrased for clarity and precision.
8	**Pages 59:** **4.5.7. (ii) Stereo Isomers:** - Stereo isomers are prima facie obvious.	It is required to include definition of stereoisomer and the types of stereoisomers, namely diastereomers and	More explanation is required.

	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.	enantiomers (optical isomers) should be provided. Also, the following explanation may be included under the heading. "Where a compound having a chiral centre is known to have a particular property (therapeutic use), and the problem is to find a compound having the same property in an enhanced level, the question inevitably arises whether one of the isomers in isolation is an obvious solution. It is reasonable to presume that it is common general knowledge that one isomer is often more active than the other, although this is not invariably the case. The single isomer will be the obvious solution if it would have been a matter of routine experimentation to prepare the single isomer and test its activity." Example: 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. In such a case, claim to (S)-enantiomer of a compound is not allowable when the racemate (mixture of (R)-enantiomer and (S)-enantiomer of the compound) possessing anti-diabetic property is known from the prior art.	required.
9	**Page 59** **(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. **e.g.** Polymerization process using a sterically hindered amine was held non-obvious over a similar prior art process because the prior art disclosed a large number of unhindered amines.	Proper definition of homologue should be provided. The following definition may be considered. "Homologue" is the term used to describe a compound belonging to a series of compounds differing from each other by a repeating unit, e.g. a methylene group, a peptide residue. The illustration is out of place as it does not refer to a claim wherein a homologue per se is claimed but it refers to a claim wherein "polymerization process" is claimed. An illustration relevant to the subject matter (homologues) should be provided.	The definition or explanation to the term "homologues" is ambiguous. The illustration referring to polymerization process is not relevant.
10	**Page 60**		

	4.5.7. (iv) Polymorphs Some compounds are present in polymorphic forms , i.e., they crystallize in diverse forms.	Explanation to polymorphism should be included under the heading "Polymorphs". Polymorphism is defined as the ability of a substance to crystallize in several crystal structures. Each modification or polymorphic form has thus the same chemical structure but differs in the stacking of atoms, ions or molecules within the crystal lattice	----------
11	**Page 60** **4.5.7. (iv) 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.	The proviso to section 3 clause (d) does not expressly refer to the term "prodrugs" but it may be deemed to have been implied. Proper definition and explanation of the term is required The following explanation may be considered: The term "prodrug" is used in the pharmaceutical field to characterize reversible derivatives of drugs which are not active on their own. Prodrug may also be defined as a compound formed by chemical modification of a therapeutically active compound that will liberate the active compound *in vivo* by enzymatic or hydrolytic cleavage. Prodrug may provide a solution e.g in improving bioavailablity or in minimizing the undesired properties of the parent compound. In such case the prodrugs may be deemed novel and non-obvious as such a solution in the form of prodrug of an active compound may not have been disclosed in the product patent of the compound.	The explanation to the term "prodrugs" should be revised to make it more clear and understandable.
12	**Pages 60-61** **(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	For clarity and precision the term "other derivatives" should defined or proper explanation to the term should be provided since not all derivatives would necessarily mean a new form of a known substance and many derivatives could be totally new substances by themselves. Factually, the term "other derivatives" meaning "other derivatives of	

	be considered.	known substance" appearing in the proviso to clause (d) of section 3 is too broad in its scope. Without corresponding guidelines elucidating the scope of "other derivatives of known substances", it is inappropriate to state that "derivatives of known substances" are routinely prepared and that they prima facie lack inventive step. It would be difficult to make a judgement in the absence of illustrations as to what kind of derivatives of known substance would be treated as the same substance and for which enhanced efficacy need be demonstrated.	
13	**Page 61** **(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.	The title of point no. (viii) "**Purification compounds**" should be replaced with "**Compounds of higher purity**" or "***Purified compounds" or "pure form of known substances".*** The explanation to the term "Purification of known substances should be revised as the wordings currently used implies that a reference to a purification process of known compounds is provided. I suggest that reference to a case (T0278/98) decided by the Boards of Appeal of the European Patent office. During the review of the manual I have observed that cases decided by the Boards of Appeal of EPO have been cited in the manual for better understanding of a particular point. "In T0278/98 decided by the Boards of Appeal of EPO the Board 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 chemical compound and its manufacture makes normally available this compound to the public in all desired grades of purity." In decoding the same case the Board had also remarked that: " if there exist an exceptional situation where it was proven on the basis of the balance of	An appropriate explanation should be provided.

		all probabilities that attempts to achieve a particular level of purity by conventional purification methods have failed." However, in such a case method of purification of the substance may be considered patentable.	
14	**Page 61** **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 cannot 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. **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 cardiovascular 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.	The heading of point nos. 4.5.8 and 4.5.9 respectively should be combined. The heading may be rewritten as : "**Mere discovery of new property or new use of known substance** " For the sake of simplicity the illustrations to new property of solvents and new use of known therapeutically active substances should be covered under separate points. Examples of paracetamol, aspirin and chloroquine may be covered under point no. 4.5.8. Examples of methyl alcohol and ethyl alcohol may be covered under a separate point 4.5.9. Also, the statement that "a new and alternative process for preparing aspirin is patentable" may be deleted, as it is not relevant to the subject matter discussed under the specified heading.	The suggested revision would make the subject matter discussed under the specified points clear.
15	**Page 61:**		----------

	4.5.10 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.	As in other cases the heading "**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**" should be indicated in **bold.**	
16	**Page 62:** **4.5.13** In a patent application No. 782/Cal/1981; dated 13th July, 1981, an invention related to pharmaceutical composition exhibiting anti-phlogistic, antipyretic and analgesic activity and high gastroenteric tolerance in unit doses form which contained imidazol salicylate as the active ingredient in the amount of 100-600 mg and an inert carrier was claimed which was later amended to a process for the preparation of novel composition containing imidazole salicylate having formula 1, as the active principle . The invention was characterized in a product that was previously obtained by reacting, mole by mole, acetylsalicylic acid with imidazole in an inert organic solvent and that, using the solid product obtained in the reaction after purification by recrystalization , homogenous composition were produced with pharmaceutically acceptable vehicles suitable for oral, parental or **topic** administration. It was held by the Controller that the active compound such as imidazole salicylate was known in the art and applicant could not develop any special property or even improve upon the property of the compound to be mixed up with the usual carrier	It is understandable from the description under **point no. 4.5.13** that the patent application no. 782/Cal/1981 was rejected by the Controller as the amended claim directed to process for preparation for novel composition as it was a known process as well as no new reactant was employed in the claimed process. However, the manner in which last statement: "Furthermore, the description contained no indication of using any special type of solvent for its purification by re-crystallization and, **therefore, the invention was not patentable under section 3(d) of the Act."** , is recited is erroneous. From the statement it appears that the patent application no. 782/Cal/1981 which was filed on July 13, 1981 was found not patentable under Section 3(d) at the time the Controller rejected the application. The Patent Act, 1970 which was in force prior to 2005 (or even 1995) didn't have the section 3(d). Therefore, the aforementioned statement should be revised to indicate that " like wise inventions directed to process for obtaining compositions may be considered not patentable under section 3(d) by applying the same standards as applied in the above case. Additionally the term "topic" should be replaced with the term "topical".	----------

	to form the composition. Furthermore, the description contained no indication of using any special type of solvent for its purification by re-crystallization and, **therefore, the invention was not patentable under section 3(d) of the Act.** (*Decisions on Patent and Designs* vol. (4) published by Patent Office Technical Society, page 21).		
17	**Page 63:** **4.5.15** 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...".	It is not clear from the explanation to the cited case as to which criteria of section 3(d) is applied. Whether it falls under the category of new form of known substance or mere new property or new use of known substance or mere use of a known process. Proper modification is required.	----------
18	**Page 63:** **4.5.16** Patent application No. 1577/Del/1996 was refused, *inter alia*, under the provisions of section 3(d) of the Patents Act, 1970. The Controller in his decision dated 12th June, 2007 held that "the present invention provides a new form of known substance either in anhydrous or hydrated form III of Atorvastatine having same therapeutic activity and in the same	Since this citation pertains to new form of known substance, it should form part of the illustrations where patentability of new forms of known substances is discussed. In other words it should be shifted to page 60.	

	field. It only claims some improvement in physical property, which does not make any change in therapeutic efficacy of the compound as compared to the prior art compound. Therefore this new form does not qualify the requirement under section 3(d)."		
19	**Section 3(e)** **Page 63** **4.6.2.** 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.**	In this point two examples are provided to explain a mere admixture, the first example refers to a mixture obtained by mixing sugar and colourants to water to produce a soft drink and the other relates to mixture of different types of medicaments or medicine. Firstly, it is inappropriate to draw an analogy between a mixture to be used as a soft drink and a mixture of known therapeutically active substances (referred to as medicines or medicaments in the point) to be used to cure multiple diseases (as stated). Secondly, in the absence of any explanation, the statement : **"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"** , imply that **any combination of two or more therapeutically active substances** would be regarded **as a not patentable invention** by itself and that the inventive step with regard to technical advancement would not be assessed. It is highly recommended that either this point be deleted or a proviso (proper explanation) as to the standard that may be applied to regard a composition (containing mixture of known substances) as a mere admixture should be included in the statement. Additionally, the case cited in point no. 4.6.1. should be preferably provided after the explanation so that one can correlate the guidance provided in the form of an	

		explanation with the case.	
20	**Page 63** **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.	This statement is vague. It is not clear as to how soap or detergent or lubricants or polymer composition would be regarded as mixtures having synergistic properties and not mere admixtures. Proper explanation as to what criteria or standard is applied to regard the specified examples, as having synergistic properties should be provided.	
21	**Page 63:** **4.6.5.** 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. **Page 64** **4.6.6.** A mere aggregation of features must be distinguished from a combination invention. The existence of a combination invention requires that the relationship between the features or groups of features be one of functional reciprocity or that they show a combinative effect beyond the sum of their individual effects. The features should be functionally linked together which was the actual characteristic of a combination invention. **4.6.8.** In general all the substances which are produced by mere admixing, or a process of producing such substances should satisfy the requirements of synergistic effect in order to be patentable. The synergistic effect should be clearly brought	The statements made in point nos. 4.6.5 and 4.6.6 are complex is nature and also ambiguous. In fact, point no. 4.6.8 is good enough to explain the criteria to assess patentability of an invention which falls under the scope of section 3(e). It is clear from point no. 4.6.8 that to establish patentability of an invention directed to a composition containing two or more known substances, it is essential to demonstrate synergism between the known substances contained in the composition. This may be well understood with the case law or examples that follow the explanation. In view of the above, it is suggested to delete point nos. 4.6.5 and 4.6.6.	

	out in the description and examples by way of comparison at the time of filing of the application and should be stressed in the principal claim.		
22	**Section 3(i)** **Page 68** 3(i) Any process for the medicinal, surgical, curative, prophylactic, diagnostic therapeutic or other treatment of human beings or any process for a similar treatment of animals to render them free of disease or to increase their economic value or that of their products.	It would more appropriate to provide an explanation and provide standards / criteria to assess patentability of an invention which falls under the scope of section 3(i) before providing any illustrations/ case etc. This suggestion may be considered for other clauses as well. In this case it is essential to explain as **to why any process for the medicinal, surgical, curative, ... or other treatment of human beings or animals would not be considered patentable.** In this case, it is pertinent to draw one's attention to the definition of "invention" provided under section 2(j) of the Act. As per section 2(j) , "an invention means new product or process involving an inventive step and **capable of industrial application**". The criteria of "capable of industrial application" is relevant to the section 3(i) as medicinal, surgical, curative, diagnostic methods etc. are practiced on the human body and therefore, they are not considered to be industrially applicable. Ultimately such methods are not inventions under the definition of the term "invention" under the act. However, it should be strictly evaluated whether the method under consideration is **practiced directly** on a human or an animal body, **if not**, then the patentability of such a method should be considered as an invention assessed by applying the other criteria of novelty and inventive step.	
	CHAPTER VI: PUBLICATION AND EXAMINATION OF APPLICATIONS		
23	**Page 152-153** **6.2.7 b) Steps involved in substantive examination**	In Form 1, the declaration from the applicant requires that permission from competent authority for use of biological material will be submitted **before the grant of the patent**.	

	Step x. requires permission from National Biodiversity Authority as a requirement during substantive examination	This needs clarification. Permission from the National Biodiversity Authority (NBD) requires the applicant to sign an Agreement agreeing to pay royalty (which may change on a case by case basis) in the event the patent is licensed or in the event of commercial production,. It is difficult to arrive at a royalty rate before substantive examination without knowing which claims will be finally allowable. The permission from the NBD should not be required before substantive examination. Once the patent is ready for grant, the permission from the NBD should be obtained and submitted by the Applicant.	
24	**Page 174** **6.6.2 Flow chart of examination procedure and Page 180**	The flow chart "Procedure for the grant of patent" showing pre-grant opposition needs to be modified indicating (perhaps with an asterisk) that the hearing, etc should follow request for examination and not before request for examination. The Controller will consider pre-grant opposition only if a request for examination has been filed in respect of the patent application.	
	CHAPTER VII: OPPOSITION PROCEEDINGS TO GRANT OF PATENT	A time limit (within six months after publication) should be set for filing a pre-grant opposition.	

Patents Department

Piramal Life Sciences Limited