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14 Apr 2008

Dear Sir

Manual of Patent Practice and Procedure: 3rd edition

I am writing on behalf of INTERPAT to offer comments on the recently issued draft Manual. As you may know INTERPAT is a Swiss registered association of the major global research based pharmaceutical companies committed to the establishment and maintenance of effective intellectual property protection for pharmaceuticals. As such its member companies are very interested in, and very much welcome, the recent extension of patent protection to pharmaceutical products in India.

The issuance of a revised Manual is most helpful for both applicants and the Patent Office in giving guidance on how the revised law should be complied with. The enclosed comments have resulted from a detailed study of the draft revised Manual carried out by experienced patent attorneys in several INTERPAT member companies and are offered in good faith to assist the Patent Office in finalising the revised edition of the Manual. If there are any questions, please let me know (preferably by email to ipat@nupharms.com) and I will try to assist with further information.

Yours faithfully

Dr Stephen C Smith
Director of Secretariat

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Draft Manual of Patent Practice and Procedure (3rd Edition)

Introduction

These comments are provided on behalf of companies in INTERPAT[1] involved in the discovery and introduction of new research based medicines and who are committed to a balanced and fair patent system. The comments follow from a detailed review of the draft Manual by individual patent practitioners in thirteen different member companies of INTERPAT.

General comments

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. Unfortunately the current draft does not yet achieve this as is pointed out in the detailed comments below.

The new edition is almost double the size of the previous edition. However much of the bulk is taken up by the reprinting of the applicable amended sections from the patent law and rules. It is certainly helpful to see this material in the MPPP but it would be much better consolidated in one place as a separate appendix so that is clear what is guidance on practice and procedure and what is law and regulation.

The exclusion from patentability of certain chemical inventions following the introduction of Section 3(d) into the patent law has produced considerable uncertainty and litigation, for example, the Glivec case. Unfortunately the current draft MPPP as yet provides little clarification and seems to confuse the established patentability criteria of novelty and unobviousness with the regulatory preconditions for obtaining marketing authorization.

It is understood that Section 3 was intended to set out limited exceptions to patentability rather than eliminating whole classes of invention by an over-broad interpretation of "derivative" and an over-narrow interpretation of "efficacy" as this would have been discriminatory against chemical/pharmaceutical inventions and contrary to TRIPs.

Chapter 4 of the MPPP lists some "examples" of new forms which are excluded from patentability under Section 3 (pages 57-61). Most are what we understand the Section was drafted to cover e.g., isomers, stereo-isomers, polymorphs, purified substances, and perhaps even metabolites of known compounds. However, the other two "examples" listed, homologues and pro-drugs, should not be included since they are not mentioned anywhere in exhaustive list of exclusions specified in Section 3. It may be pertinent to discuss inventive step requirements of homologues and pro-drugs elsewhere in the MPPP but not in the context of the exclusions under Section 3.

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[1] INTERPAT is a Swiss registered association of major European, Japanese and US research-based pharmaceutical companies committed to the establishment and maintenance of effective intellectual property protection for pharmaceuticals.

We believe that the sections dealing with "efficacy" (4.5.4 – 4.5.6) need significant amendment. Efficacy is a concept which relates to the regulatory process governing the marketing authorization of drug products. For this regulatory purpose, efficacy is normally established in clinical studies in human patients. A drug product which obtains marketing authorization is acknowledged to be safe and efficacious. By contrast, patents are granted in patent offices in most countries for pharmacologically active substances based on data showing an effect in models that are thought to be predictive for disorders rather than on the basis of clinical studies.

Equally the apparent requirement in section 4.5.4 that the comparison with regard to efficacy must be made at the date of filing or priority is completely impractical. If it were to be the case then it would require "black box" applicants to have anticipated the 3(d) amendment in the 2005 Act and to have carried out appropriate comparative efficacy studies even before they filed the original priority establishing applications.

In all patent systems around the world, a distinction is made between data that must be provided in the patent filing and data that can be delivered later during the examination process. Data that must be included on filing in most countries is such data that enables the person skilled in the art to put the invention into practice. For instance, if a new chemical compound is involved, the applicant has to describe how to obtain this new chemical compound. The other type of data pertinent to patent examination is data showing that the claimed invention is inventive compared to the closest prior art. Such data can always be provided by the applicant during examination. However the Examiner normally has first to decide what kind of data is required to show an inventive step. Only after this decision is taken, is the applicant required to deliver the data.

Sections 25 (1) and 25 (2)(j) of the 2005 Act have introduced a new basis for pre-grant and post-grant oppositions that "the complete specification does not disclose or wrongly mentions the source or geographical origin of biological material used for the invention." In view of the critical nature of non-compliance, it would have been helpful if the manual had provided some guidance on what is meant by "biological material" and just what relationship is required to the subject-matter of the invention for the requirement to supply source/origin data to apply. Thus many different materials having a biological origin may be referred to in a patent specification (for example egg albumin, starch gels etc.) but which have no critical connection with a claimed invention. Specifying source/origin information for all such incidental "biological materials" surely cannot be what is required. Also, in spite of good faith efforts it may in practice be impossible to specify the source/origin precisely for a whole range of materials obtained commercially or from indirect collections. Some guidance in the manual on what should reasonably be expected would be helpful to applicants and the Patent Office.

Detailed Comments

These are provided in good faith in the attached table to assist the IPO in improving the value of the MPPP. However, it should not be assumed that the research based pharmaceutical industry necessarily supports the interpretation of the law and regulations in any of the commentary in the MPPP or that the absence of any comment implies agreement with what is stated in the MPPP.

13 April 08
att. table of detailed comments

Detailed review of Indian Manual of Patent Practice and Procedure – draft third edition (Feb 2008)

Chap.	Pages	Comments
Contents		The sub-headings are confusing since they do not relate properly to the sub-headings in the individual chapters
2	**16**	2.3.2: It should be made clear that in relation to an invention "capable of industrial application", made or used in an industry includes agriculture (see for example Art. 57 EPC). The same clarification should be made in section 3.25 on page 51.
	18, 21	2.3.8 (ja): It should be made clear that "inventive step" does not necessarily imply "technical advance" or "economic significance" even if these two features can be indicia of inventive step.
	19	2.3.12: It is not explained why the criterion of inventive step was included in the "definition" of "pharmaceutical substance"
	19	2.3.13: Why does this decision refer specifically to a communication "from abroad". Wouldn't the decision have been the same if the invention had been derived from an Indian "true and first inventor".
3	**21**	3.2.1 provides that knowledge, oral or otherwise, available within any local indigenous community in India or elsewhere is part of the prior art. This knowledge may be difficult to prove, so examples should be provided. Prior use is limited to India for the purposes of being novelty destroying, however local knowledge is everywhere - difficult to distinguish in practice without guidance in the MPPP.
	23	3.3.9 is unclear - it should read "prior art dates" not –priority dates.
	28	3.5.2 has a grammatical error in the 2d sentence from the end. Change "infringe" to "infringement," and delete – when--.
	36	In 3.11(b), add "a" before "mosaic."
4	**54**	The number of the subsections needs correction: subsection (d) exists twice and subsection (f) is presented as "omitted" which is inconsistent with the following text (see p. 64 regarding subsection (f) Correct the spelling of "esters" in the Explanation to 3(d)
	55	4.1 The quote from Section 3(a) of the Patent Act is incomplete. 4.2c, d It should be further explained why the decimal time measurement was held as a "frivolous" invention; which criteria are applied to examine what would constitute a "frivolous invention"?; it appears that example d is a question of inventive step rather than a question of exclusion from patentability
	56	4.3 Being contrary to the law currently in force should not be sufficient to exclude an invention from patentability per se since some inventions with potential value would not be protectable, e.g. because they are against current environmental legislation, but in a few years that legislation may be changed; "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 (e.g. a knife can be used to kill people or used in surgery to save lives); the wording should be changed to indicate that only those inventions may be excluded from patentability if their exclusive use is to harm human beings; also questionable whether it is necessary to include animals and plants here – for example it is surely not intended to exclude herbicides from patentability; the term "terminator gene technology" needs to be more fully elaborated?

Chap.	Pages	Comments
4	57	4.4.3 It is not clear whether the use of a known pharmaceutical for a new indication would be regarded as a "new product or process" but, in view of the later sections, it seems probably not; this discriminates against a whole class of inventions which can be of similar value to patients and society as a newly discovered compound with no previous medical use - a good example of such a new indication/use of a known compound is alendronate.
	57	4.4.4 It should be further clarified that a compound or microorganism could well be patentable if it is isolated/separated from its natural environment, even if it is structurally identical to the compound/microorganism occurring in nature
	57	4.5.1 Section 3d 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. 4.5.2 It would be helpful to give an indication with examples of what is envisaged by the term "other derivatives of known substance". Without any specific qualification, "derivative" in organic chemical terminology has a very broad meaning since almost any compound may be said to be theoretically derivable from another. Thus it surely cannot be the intention to exclude under Section 3d chemical inventions involving otherwise new chemical substances merely because they may have been referred to loosely in the patent specification as "derivatives" of another substance.
	58	4.5.2 Efficacy should be given a broad interpretation, for example including better stability, advantages in handling of a chemical compound etc. and not just clinical superiority. It would be useful to provide examples of what parameters might be used to demonstrate efficacy.
	58	4.5.3 This passage is very confusing. In the explanation reference is made to the "base compound", bu this is a term which is not used before
	58	4.5.4 - this states that the comparison with regard to efficacy is required to be made at the date of filing or priority; this cannot be correct and must be rewritten since, as stated, it would require "black box" applicants to have anticipated the 3(d) amendment in the 2005 Act and made their comparative efficacy studies before filing their priority applications. This would be contrary to TRIPs Art 70(8) and is also discriminates against chemical/pharmaceutical inventions.
4	58	4.5.6 This section needs significant amendment if proper guidance is to be given to both examiners and applicants. Efficacy is a concept which relates to the regulatory process governing the marketing authorization of drug products. For this regulatory purpose, efficacy is normally established in clinical studies in human patients. A drug product which obtains marketing authorization is acknowledged to be safe and efficacious. However patents are granted worldwide for pharmacologically active substances on the basis of data showing an effect in models that are thought to be predictive for disorders rather than on the basis of clinical studies.

Chap.	Pages	Comments
	58-61	4.5.7 The remarks about enantiomers and homologues concern inventive step evaluations and are not relevant to Section 3(d). Exclusion from patentability based on section 3(d) of the Act and assessment of novelty and obviousness are distinct concepts governed by different and independent Sections of the Indian patent law. Only the last sentence makes sense regarding polymorphs; it would be unjustified to exclude any polymorph per se from patentability – instead it is a question of novelty and inventive step. The remarks about metabolites, pro-drugs and hydrates concern novelty and obviousness evaluations and so are not relevant to Section 3(d) and should be moved elsewhere in the MPPP e.g. chapter 3. In that context, whilst it may be the case that derivatives which are routinely prepared start off as prima facie obvious, it cannot be the case that this applies to all derivatives since they may be chemically unusual salts and/or difficult to make by conventional means.
	62	4.5.13 This needs amendment since it appears to indicate that Section 3(d) objections can be raised against process claims although Section 3(d) does not make any reference to processes
	62	4.5.14 The considerations reported all relate to inventive step evaluations and are not relevant for Section 3(d).
	63	4.5.16 Although this last example may correctly apply the principles of Section 3(d), the provision as such remains to discriminate between different technologies and therefore be against TRIPS and in contradiction to internationally recognized and well-established principles of patent law and practice.
	63	4.6.1 It is not clear from the example whether new pharmaceutical carriers improving the pharmacokinetics of a substance and pharmaceutical compositions containing them would themselves be excluded from patentability; if this is intended by section 3e then this subsection seems also be contrary to TRIPs
	63	4.6.2 The evaluation of whether the properties of the mixture are more than an "aggregation of the properties of the components" that is the enquiry of whether there is synergistic interaction, should be done when assessing inventive step rather than when deciding on exclusion from patentability.
	63	4.6.3 This passage might be better worded: "However, where the admixture possesses synergistic properties in comparison with those of its components, it not considered as a "mere admixture" and so is not excluded by Section 3(e). Examples may include special soaps, detergents, lubricants, polymer compositions etc."
	63	4.6.5 This passage refers to "assessing inventive step" which is not the focus of consideration under Section 3 examination; thus, this text should be shifted to the guidance on inventive step.
	64	4.6.8 Suggest amending this passage to read: "In general all those substances which are produced by mere admixing individual components, or processes for producing such substances, should satisfy the requirements of synergistic effect in order to be patentable. The key question to be answered under Section 3(e) is "are the properties of the mixture greater than those of the constituent components". The degree of synergy and its unpredicted nature are questions when considering assessing inventive step. Normally the synergistic effect should be specified clearly in the description and examples with supporting data in the specification as filed and should be stressed in the principal claim. However where this is not possible such supporting data may be filed later during examination of the application in question." It should be 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.
	65	4.7.5 Add at the end of the sentence: "...unless some unexpected surprising effects of the combination of features can be shown".

Chap.	Pages	Comments
	65	4.7.6 This concerns novelty and inventive step and may be better placed elsewhere.
	66	4.7.8 Some text appears to be missing in this example
	68	Section 3(I): this section is written in a similar way to the EPO guidelines for examination of patents about methods of medical treatment. However, in practice the IPO is not granting claims in the so-called Swiss form even for 1st uses of new compounds which are not objectionable under section 3(d)
	68	4.9.2 Not sure how "industrial applicability" is relevant to exclusion from patentability
	69	4.9.7 The relevance of the Australian decision to the situation in India should be explained
	72	4.10.2 Improved wording would clarify the outcome of the cited case
	76	4.16.1 Should explain what the provision adds beyond examination of novelty
5	**83-96**	Most of this is repetition of the relevant sections and rules applicable to this chapter – however it is interspersed with comments –see page 83- section 5.1 however some sections e.g. types of patents follow much later – this is a bit confusing
	88	5.3.1 – not sure what the last sentence is supposed to mean.
	90	Rule 121(A) ^six months] – error in the typesetting. Rule 12 refers to section 8 which is not recited in this manual.
	92	Section 10(D) uses the words "in the invention", rather than "for the invention" seen in Sections 25 (1) and 25 (2) (j) of the Patents Act. Without clarification in the manual, this could rise to serious practical difficulties for applicants.
	97	Section 5.4 types of applications – the list does not include provisional applications but these are discussed in detail.
5	**98**	5.4.5, 5.4.6: clarification is needed about when an English translation of the priority document must be submitted in the case of the PCT route. Under Rule 21(2) and (3) of the Patents Rule 2003 it is necessary to supply an English translation of the priority document. However, in accordance with PCT Rule 51 bis 1(e), such a translation of the priority document is only required where the validity of the priority claim is relevant to the determination of whether the invention concerned is patentable. On the other hand, Rule 23 of the Indian Patents Rule 2003 states that in case of conflict, the PCT regulation shall apply. So it seems that the English translation of the priority document for a national phase application under the PCT should only be required under the circumstances specified in the PCT Rule 51 bis 1(e). This should be stated clearly to help both applicants and examiners.
	103	5.5.13- details of corresponding applications. Guidance is needed on the detailed particulars required by the Controller under Rule 12, e.g. incorporate the details from Form 3 into this section. This is a particularly onerous requirement on the applicant and seems of little value to the IPO given that details of patentability objections raised by other offices are dealt with under Section 8. As the provision of information of corresponding foreign applications and prosecution occurs during examination this section would be better placed in that chapter.
	103	5.3.14 –filing of patentability objections raised by other offices. Section 8 says the Controller may require the applicant to furnish details relating to the processing of the application in other countries. Rule 12 says that when so required by the Controller the applicant shall furnish information relating to objections raised in respect of novelty etc... Specific guidance would be helpful as to the processing of which foreign applications is requested.

Chap.	Pages	Comments
	106	5.6.1 j) vii) The requirement in the manual that "the source and geographical origin of the biological material specified in the specification also should be disclosed therein" is not clear. It could be read to require an origin of anything mentioned in the specification, whether it was ever used or is critical to the invention. Because of the practical difficulties which can occur, it should be made clear that it is acceptable for an applicant to state that the source and/or geographical origin of biological material used "in the invention" is not known.
	115	Clarity of claims. Given that pharmaceutical products are now patentable in India it would be helpful to include guidance on the wording of acceptable claims including pharmaceutical compositions, for example a claim such as "a pharmaceutical composition comprising compound A and a pharmaceutical carrier" which would be allowed in Europe and most other countries.
	121	Section 5.9.3- extra comma in first line
	121	Section 5.9.7 – Typo in first line
	126	Rule 21 (4) – second line, typo - replace "snail" with "shall"
	130	The section on sequence listings refers incorrectly to section 8(6) and 8(1) instead of to section 801.
	134	5.10.9 (i) – u/s presumably stands for "under section"
	136	5.10.2 (ii) (b) insert Transmittal between International and Fee
6	**140-143**	6.1 It would be helpful to have guidance on the following: - What happens if the priority right is lost or withdrawn? Is the publication deferred? - What is the formal procedure to prevent publication? - Is the application published in electronic form? - What happens if timely printed or electronic publication cannot occur – is the specification in the file made available to the public?
	140	Section 11**A** should be referred to instead of Section 11
	141	Rule 24 **A** should be referred to instead of Rule 24
	144	6.2 Section 11**B** should be referred to instead of Section 11
	151	Item 6.2.4 (a): By making an application for patent, an applicant/inventor obtains the **filing date** (not: date of patent).
	155	6.2.9 (1): it is not clear what is meant by a gist of objections
	156	Item 6.29 viii: Some guidance would be helpful for applicants about any possible legal remedies (such as extensions) if this date cannot be met as a result of the often very short period in practice to reply to examination reports.
	144-165	Further guidance could usefully be given on the following: - is there a legal remedy if time limit for filing request for examination has expired? - can the examination fee be refunded if the application is withdrawn? - the level of detail in examination reports (as per 6.2.9(i)) supporting any opinion that the invention is not patentable and/or anticipated by or obvious over the prior art. Simply listing prior art documents is inadequate and unhelpful to applicants. - what happens at the end of the 12 month period if a proper response has been filed to the objections in the examiner's report – if no further action is issued, is the application allowed?

Chap.	Pages	Comments
7	177-178	7.1.2 The process discussion contains insufficient details and does not match the experience of applicants who have had several pre-grant oppositions. For example, the time frames for filing an opposition are described (a person "should try to file such representation within six months from the date of publication") with no indication of the consequences if the deadlines are not met. In practice, pre-grant oppositions seem to be permitted at any time so long as the patent has not been granted. The time for notifying the applicant after the opposition has been received whether the Controller intends to favourably consider the opposition is not set, though the patent applicant has a three month time frame to reply including evidence. The procedure for requesting a hearing is not described, though these are commonly held in pre-grant oppositions. There is a suggestion that the Controller's decision should come "ordinarily" within one month of the completion of the proceedings, but in practice it is often much later. There should be a description of the procedure to request for reconsideration of the decision since this is possible in practice. Also there should the form of appeal possible from the decision should be mentioned.
7	178	It would be helpful to have a description of how the Controller is to substantively decide the numerous grounds of opposition set forth. Instead, there is only a description of the Glivec case and a description of a second case involving selection of ingredients not being inventive. It would also be helpful to have examples of oppositions which were unsuccessful. Guidance would be appreciated on the nature of the evidence to be provided to substantiate or rebut the grounds of opposition (taken from Section 25(1) of the act) and how proceedings should be conducted, etc. Many of the grounds of opposition are difficult ones to prove or rebut (e.g. incorrect mention of source/geographical origin, anticipated by traditional knowledge, etc), let alone the 3(d) concerns which are so prevalent in opposition proceedings. Also there should be some discussion of a how an opposition can be successfully rebutted and a patent granted.
7	180ff	The chart at the top of the page contains errors: the third party (opponent) files a "Statement and Evidence" and the applicant files the Reply Statement. Post grant opposition proceedings: Extensive reprinting of the rules about how post grant proceedings are to be conducted are set forth, and a number of older decisions are cited. It would be helpful if similar rules were available governing pre-grant oppositions. The grounds for pre and post grant oppositions are basically the same. The reprinting of summaries of relevant decisions is helpful since they seem to provide examples of some of the grounds for oppositions. However, if they are to be considered as broadly applicable to either pre or post grant oppositions, that should be indicated especially since the summaries lack the details critical to understanding the cases.
7	191	7.2.11 Case reference: correct the spelling of "Reckitt"
8	204-210	Text is mainly existing Sections and Rules – no specific comments in relation to 8.1.2
9	211-216	Page 214, Rule71(2) states that security clearance requests will "ordinarily" be dealt with within 21 days. In practice this period is much too long by comparison with virtually all other patent offices and a procedure should be provided for ordinary security clearance in 7 days with accelerated clearance on payment of a fee in 2 days. 21 days should be an absolute maximum.
10	217-226	The commentary on pages 223-223 seems straightforward, but in practice the grant process under Sections 22-24 is not quick. Guidance could usefully be provided as to the time which might reasonably be expected before the patent is finally sealed.

Chap.	Pages	Comments
11	227-229	Pages 228-229, it would appear from Sections 54-56 that a patent of addition can be filed at any time on or after the filing date of the "main" application and up to the date of expiry of such patent, indeed any patent application could be converted on request into a patent of addition. However the commentary in 11.1 is not very helpful. In particular it seems to confuse the inventive step as required for the "main" application with the application for a patent of addition. A patent of addition does not require an inventive step vis-à-vis the "main" application. Thus the reference in 11.1.1 that "the invention does not involve a substantial inventive step" is confusing as is the relevance of section 11.1.8 to patents of addition. There is no mention in Chapter XI of any particular forms or procedures to be followed when filing an application for a patent of addition
12	232	12.1.3 This paragraph should be written more closely to statutory provision [Section 59(1)] to clarify that first sentence refers to amendments of an application or a complete specification or any document relating thereto, while the reference to an amendment in the third sentence is limited to amendments to the complete specification.
	233	12.1.6 The introductory clause should be written to confrom more closely with the statutory provision [Section 57(1)] to clarify that the Controller shall not pass any order as to an amendment if there is a suit for infringement in any court or a revocation proceeding pending before the High Court.
	234	12.1.11 (b) – replace "en" by "an"
	234-35	12.1.12 this decision is misplaced – it appears to refer to application of Section 3(d) rather than making amendments to specification or any other part relating thereto.
	235-36	12.1.14 this decision is misplaced – it appears to refer to inventive step rather than making amendments to specification or any other part relating thereto.
	236-37	12.1.15 this decision is also misplaced – it refers to inventive step
	237	12.1.17 Is this decision still applicable in view of post-decision statutory change to Section 59(1) to change second clause relating to incorporation from "correcting an obvious mistake" to incorporation of actual fact?
13	240	13.1.1 An application for restoration of patent due to failure of renewal fees must be filed within 18 months of the date the patent ceased to have effect. The corresponding guidelines from 2005 provided for an 18-month period plus consideration of any extensions for payment of renewal fees. This is a typical situation which can occur – has a change in practice occurred?
	240	13.1.1 In relation to Section 62, it should be made clear whether a suit can be filed after restoration of the patent, against persons that have availed themselves of the patented invention between the date the patent ceased to have effect and the date of publication of the application for restoration.
14	247	14.2 Statute section should include Section 85 because it is an additional ground for revocation
	247	14.2.1a. refers to "interested person", while statutes/definitions use "person interested"
	247	14.2.1b. delete because it is redundant in view of the more complete summary in 14.2.1 c.
	247	14.2.1d. The applicability of the court decision in this sub-section is unclear as it relates to the statutorily defined term "person interested", Section 2(1)(t). Thus it is unclear if it is an alternative definition or an additional condition.

Chap.	Pages	Comments
	248	14.2.2 Recommend combining (I) and (iv) into one section since both revocation options can be undertaken by the High Court and deleting the comments in the [ ] brackets
	248	14.2.2 Subparagraph (v) should follow the statutory requirements more closely to make clear that the Controller of Patent can only exercise his authority of revocation for non-working under Section 85 following grant of a compulsory license and subject to certain other conditional findings
	248-49	14.2.3(b) Recommend clarifying section to read: Section 6 of the Patents Act specifies the categories of persons entitled to apply for Patents as including the true and first inventor. Section 2(1)(y) excludes certain persons from being a "true and first inventor" under the Patents Act and therefore not entitled to apply for patent.
	250	14.2.3(g) Current definition for "invention" [Section 2(1)(j)] specifically eliminates requirement for invention to be "useful" and replaces that concept with the requirement for "industrial applicability". To the extent the revocation provisions continue to refer to "useful", such term should be understood as meaning having "industrial applicability" and no longer refer to operability, which is an issue properly addressed under the enablement requirements. See Section 64(1)(h) in particular.
	250	14.2.3(c) should be correctly referred to as 14.2.3(h)
	250	14.2.3(I)The description of "Fairly Based", first sentence, should be amended to provide that the determination is based on the matter disclosed or shown in the specification in view of current amendment rules, see Section 59.
	251	14.2.3(I)Grounds for revocation under Section 64(I) are limited to secret use in India before the priority date. The title for this section and accompanying text should be clear on this point.
	251	14.2.3(m) The 2005 Guidelines relating to failure to disclose information as to foreign applications included a passage stating that the false information must have been known to him as false. Further, the prior guidelines stated that, in the absence of such knowledge, this ground for revocation may not apply. What is rationale and basis for not including this knowledge requirement in present guidelines?
15	260	Section 67, para (1)(c)(5): should read as ".....as evidence".
	261	Section 68, 15.1.1: for clarity, amend to read "....document registered under section 68 should be an agreement executive 'Inter Vivos' and should specify at least one patent."
		Section 68, 15.1.1: for clarity, amend to read "....is not an agreement between the parties and therefore cannot be registered under section 68."
		Section 68, 15.1.2: correct spelling of ".....inter....."
		Section 68, 15.1.1: amend to read ".....cannot be registered"
16-17		No specific comments
18	291	18.1.7 - it is not clear how this case precedent provides any guidance on working an invention
	293	18.2.6(4) - this section could usefully be rewritten to provide guidance to examiners and practitioners in the form of illustrations of what does constitute working rather than what may not. It has to be recognized that simply because a third party has the wish to manufacture a patented article such as a drug product in India does not mean that the patent is not being adequately worked by the patentee through importation given the nature of the invention.

Chap.	Pages	Comments
18	294-5	18.2.9 It is a normal principle of law that both parties have the right to be heard. The Rules acknowledge this principle explicitly for the applicant, see Rule 100(3): "The Controller, after giving the applicant an opportunity of being heard...". However, such an explicit statement for the patentee is missing. The patentee must instead scrutinize the Journal to find out whether the Controller has launched proceeding according to Sec. 87(1) since the publication in the Journal triggers the time frame in which a notice of opposition can be filed, see MPPP 18.2.a. It is true that the Comptroller "Shall direct the applicant to serve copies of the patentee" (see Sec. 87). However, if the applicant delays the service, the patentee will be deprived of his right to be heard. The Indian Patent law envisages this problem and allows the Controller to extend the deadline prescribed in Rule 98(1), see Sec. 87(2). The MPPP should mention this opportunity in 18.2.9. It would be helpful to all parties given the travel arrangements which may be required if the minimum notice period to attend the hearing could be set at 60 days rather than the impractical 10 days specified in 18.2.9e.
19		No specific comments
20-21		No specific comments
22-25		No specific comments