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Office of the Controller General
of Patents, Designs and Trade Marks
S M Road,
Antop Hills
Mumbai - 400037

Basle, April 1, 2008



Draft Manual of Patent Practice and Procedure

Dear Sirs,

thank you very much for the possibility to comment on the
„Draft Manual of Patent Practice and Procedure“.

Please find enclosed our comments.

We hope that our statements can be considered and remain

with kind regards,

Thomas B. Cueni
- Secretary General -

Bruno Henggi
- Board Member -

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

Introduction

These comments are provided on behalf of companies 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 companies.

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 non-obviousness 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.

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

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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.

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 no comment implies agreement with what is stated in the MPPP.

21 Mar 08

att. table of detailed comments

INTERPAT review of Indian Manual of Patent Practice and Procedure – draft third edition: Feb 2008

Chap. Contents	Pages	Comments
2	16	The sub-headings are confusing since they do not relate properly to the sub-headings in the individual chapters 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 (3): 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, trial 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.
	58	4.5.2 It would be helpful to give an indication with examples of what is envisaged by the term "other derivatives of known substances". 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", but 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(3) 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.

nd are not relevant to of novelty and lian patent law. e any polymorph per se
valuations and so are not it context, whilst it may be not be the case that this by conventional means. the raised against process
ant for Section 3(d). vision as such remains to tion to Internationally
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Chap.	Pages	Comments
	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 3(6) and 8(1) instead of to section 301.
	134	5.10.9 (i) – y/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 11A should be referred to instead of Section 11
	141	Rule 24 A should be referred to instead of Rule 24
	144	6.2 Section 11B 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 list 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?

licant details and does not match the experience of applicants who have filed, the time frames for filing an opposition are described (a person has six months from the date of publication) with no indication of the time to file an opposition. In practice, pre-grant oppositions seem to be permitted at any time so long as the applicant notifies the applicant after the opposition has been received. There is a suggestion that the Controller's decision should come later. There should be reconsideration of the decision since this is possible in practice. Also, the decision should be mentioned. the Controller is to substantively decide the numerous grounds of opposition of the prior art and a description of a second case involving opposition. It would also be helpful to have examples of oppositions which were successful on the nature of the evidence to be provided to substantiate or rebut opposition. 25(1) of the act and how proceedings should be conducted, etc. Many examples to prove or rebut (e.g. incorrect mention of source/geographical origin, etc.) alone the 3(d) concerns which are so prevalent in opposition proceedings of a how an opposition can be successfully rebutted and a patent granted. the third party (opponent) files a "Statement and Evidence" and the Controller reprints of the rules about how post grant proceedings are to be conducted. It would be helpful if similar rules were available for pre and post grant oppositions are basically the same. The Controller is helpful since they seem to provide examples of some of the grounds considered as broadly applicable to either pre or post grant oppositions, but summaries lack the details critical to understanding the cases. "Recliff" no specific comments in relation to 8.1.2	ance requests will "ordinarily" be dealt with within 21 days. In practice with virtually all other patent offices and a procedure should be provided for accelerated clearance on payment of a fee in 21 days. 21 days should be the maximum, but in practice the grant process under Sections 22-24 is expedited as to the time which might reasonably be expected before the patent is granted.
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at any time on or after the of patent application could be very helpful. In particular it tion for a patent of addition. As the reference in 11.1.1 vance of section 11.1.8 to
in filing an application for a
) to clarify that first ent relating thereto, while plete specification.
y provision [Section 57(1)] for infringement in any
than making amendments
g amendments to
59(1) to change second tual fact:
within 18 months of the date 18-month period plus ch can occur – has a
restoration of the patent, the patent ceased to have
ation
the statutorily defined term additional condition.

and (iv) into one section since both revocation options can be undertaken by the ents in the [] brackets
flow the statutory requirements more closely to make clear that the Controller of ity of revocation for non-working under Section 85 following grant of a compulsory conditional findings
action to read: Section 6 of the Patents Act specifies the categories of persons cluding the true and first inventor. Section 2(1)(y) excludes certain persons from der the Patents Act and therefore not entitled to apply for patent.
vention" [Section 2(1)(j)] specifically eliminates requirement for invention to be with the requirement for "industrial applicability". To the extent the revocation ful", such term should be understood as meaning having "industrial applicability" which is an issue properly addressed under the enablement requirements. See
ted to as 1-4.2.3(h)
based", first sentence, should be amended to provide that the determination is own in the specification in view of current amendment rules, see Section 59.
der Section 64(f) are limited to secret use in India before the priority date. The title text should be clear on this point.
ating to failure to disclose information as to foreign applications included a passage just have been known to him as false. Further, the prior guidelines stated that, in s ground for revocation may not apply. What is rationale and basis for not including ent guidelines?
read as ".....as evidence".
nd to read "....document registered under section 62 should be an agreement pecify at least one patent."
nd to read "....is not an agreement between the parties and therefore cannot be
1 of ".....inter...."
".....cannot be registered"
e precedent provides any guidance on working an invention
ally be rewritten to provide guidance to examiners and practitioners in the form of working rather than what may not. It has to be recognized that simply because a cture a patented article such as a drug product in India does not mean that the ed by the patentee through importation given the nature of the invention.

both parties have the right to be heard. The Rules acknowledge this principle
ent: "The Controller, after giving the applicant an opportunity of being
sent for the patentee is missing. The patentee must instead scrutinize the
has launched proceeding according to Sec. 87(1) since the publication in the
notice of opposition can be filed, see MPPP 13.2.a. It is true that the
ave copies of the patentee" (see Sec. 87). However, if the applicant delays
if his right to be heard. The Indian Patent law envisages this problem and
a prescribed in Rule 93(1), see Sec. 87(2). The MPPP should mention this
travel arrangements which may be required if the minimum notice period to
rather than the impractical 10 days specified in 18.2.9e.