

JAPAN INTELLECTUAL PROPERTY ASSOCIATION

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25th March, 2013

To: Chaitanya Prasad, IAS
Controller General of Patents, Designs & Trade Marks
Bhoudhik Sampada Bhavan,
Antop Hill, S.M. Road,
Mumbai-400037,
India

Dear Chaitanya Prasad, IAS,

Re: Guidelines for Examination of Patent Applications in the Field of
Pharmaceuticals

The Japan Intellectual Property Association (JIPA) is a non-governmental organization that was established in 1938, which represents users of intellectual property systems. As an association having about 900 Japanese leading companies, JIPA submits recommendations and proposals to the relevant authorities and organizations with regard to the establishment of intellectual property systems overseas and improvements in the implementation thereof.

JIPA appreciates the latest draft of the Guidelines for Examination of Patent Applications in the Field of Pharmaceuticals. However, with regard to some points on the attached document, JIPA finds that the draft is still unclear or inappropriate in certain respects and would therefore request its revision.

Your deeply consideration on these matters will be appreciated.

Yours faithfully,

(Hiroshi ISHIKAWA)

Vice President of Japan Intellectual Property Association
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Opinions on the Draft Guidelines for Examination of Patent Applications
in the Field of Pharmaceuticals

Japan Intellectual Property Association

We fully appreciate that the draft guidelines have become very easy to understand with an abundance of illustrative examples. However, we consider that the following matters are still unclear and insufficient, and thus would request modifications as described below.

- We request that the term "all" in "(i) it discloses all the possible embodiments covered ..." in line 7 from the bottom in the description of the "Markush claims" on page 7 be changed to "at least one" as "(i) it discloses at least one the possible embodiments covered"
- The phrase ", but the question of lacking in novelty was maintained" in 6.2, which makes the connection between 6.1 and 6.2 unclear, should be deleted.
- We request that cases where novelty is determined for a compound, a combination, and a composition be added to 7.6.
- Ex.1 and Ex.2 in 10.11 both are cases which are rejected by 3 (d). What improving effect is a therapeutic efficacy which is not a mere discovery? We request that cases where an improving effect is recognized be added.
- The term "best" should be deleted from the clause "it must be ensured that the best method for performing the invention is ..." in line 3 of 11.5 because this requirement is too strict with a patent applicant in countries including India.
- We request that the term "all" in "supported with examples for all the compounds claimed or at least all the genus of the compound claimed. Method for preparation and experimental data relating to properties of each compound claimed shall be incorporated in the description, ..." in line 3 from the bottom of 11.6 be changed to "at least one" as "supported with examples for at least one the compounds claimed or at least one the genus of the compound claimed. Method for preparation and experimental data relating to properties of at least one compound claimed shall be incorporated in the description,"
- As for Example 3 (on page 40) of 11.17, we propose that the term "insecticidal" in the Claim be deleted because this term is meaningless.

End of Document

