

JAPAN INTELLECTUAL PROPERTY ASSOCIATION

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September 2, 2014

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

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

Dear Chaitanya Prasad, IAS,

We, the Japan Intellectual Property Association, are a private user organization established in Japan in 1938 for the purpose of promoting intellectual property protection, with about 900 major Japanese companies as members. When appropriate opportunities arise, we offer our opinions on the intellectual property systems of other countries and make recommendations for more effective implementation of the systems. (<http://www.jipa.or.jp/english/index.html>)

Having learned that the "Revised Draft Guidelines for Examination of Patent Applications in the Field of Pharmaceuticals", published by Intellectual Property India on August 12, 2014, we would like to offer our opinions as follows. Your consideration on our opinions would be greatly appreciated.

JIPA again thanks the Intellectual Property India for this opportunity to provide these comments and welcomes any questions on them.

Sincerely, yours,

Hiroshi MORITA

Standing Director

Japan Intellectual Property Association

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JAPAN

Opinions on the “Revised 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 phrase "(i) it discloses best representatives, as known to the applicant, of the possible embodiments ..." in lines 9-10 from the bottom in the description of the "Markush claims" on page 8 be changed to "(i) it discloses one or more representatives of the possible embodiments" to harmonize with description of 11.6 on pages 35-36.
- We request that illustrative examples where novelty is recognized for compound, combination and composition claims be added to 7.6 and 7.8.
- 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.
In addition, the term of "a derivative" should NOT be interpreted as an unfairly broad meaning. We also request that "a derivative" be illustrated by examples.
- 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.
- As for Example 3 (on page 40) of 11.17, we propose that the term "insecticidal" in the claim be deleted because the claim directs to a compound product, not to an use of compound.

(EOD)