From:
Sent: Thursday, August 19, 2010 4:03 AM
To: 3-tracks comments
Subject: Comments on "Enhanced Examination Timing Control Initiative"

Dear Commissioner,

We, the Japan Pharmaceutical Manufacturers Association (JPMA) appreciates the opportunity to present our views on the proposed "Enhanced Examination Timing Control Initiative", published in the Federal Register on June 4, 2010.

Please see the attached file.
If you have any questions, please contact to international@jpma.or.jp

Yours faithfully

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August 19, 2010

Commissioner for Patents
U.S. Patent and Trademark Office
United States Department of Commerce
P.O. Box 1450
Alexandria, VA 22313-1450
U.S.A.
Attention: Robert A. Clarke 3trackscomments@uspto.gov

Re: Comments on Proposed “Enhanced Examination Timing Control Initiative”, Federal Register, Vol.75, No.107 (June 4, 2010) [Docket No. PTO-P-2010-0035]

Dear Commissioner:

The Japan Pharmaceutical Manufacturers Association (JPMA) appreciates the opportunity to present its views on the proposed “Enhanced Examination Timing Control Initiative (EETC Initiative)”, published in the Federal Register on June 4, 2010.

1. Patent applications that are based on a prior foreign-filed application should not be treated differently from those that are not based on a prior foreign-filed application due to the following reasons:

(1) The requirement to the applicants of applications filed in the USPTO that are based on a prior foreign-filed application is unduly burdensome.

(2) The above requirement would lead to the delay of the issuance of patent rights for applications filed in the USPTO that are based on a prior foreign-filed application, which also would mean the prolongation of the instability of the patent right.

(3) When applicants who usually file the first application in their own country other than US desire early issuance of the patents, the cases wherein it would be necessary for them to file the first application in US would increase, which would lead to early burden on the applicants.

(4) Arguments regarding why the claims in the USPTO-filed application were allowable over the evidence relied upon in the foreign office action could

increase the risk of unnecessary estoppels in the future, since the examination procedures vary depending upon patent offices of each country.

(5) The preparation and submission of the documents of an appropriate reply to the foreign office action and arguments regarding why the claims in the USPTO-filed application were allowable over the evidence relied upon in the foreign office action would cause the burden for the translation on applicants and also could lead to the mistranslation problem.

2. Although JPMA appreciates the purpose of introducing proposed Track I to III, JPMA would strongly request that more simple system should be considered. The following are possible alternatives.

(1) To introduce a deferred examination system:

Deferred examination should be introduced more broadly than the current proposal, which could make the proposed Track II and Track III into one procedure. The due date for request for examination could be set, for example, 30 months after the filing date of the application. The fee for the request for examination should be set so that it almost equals to the current fee for filing an application for patent when combined with the amended fee for filing an application for patent. Further, when introducing a deferred examination system, the following provisions should also be introduced: (a) 18-month publication of all applications, and (b) request for examination by third parties, which enables them to confirm the established patent right.

Broad introduction of the deferred examination system would also contribute to international harmonization.

(2) To introduce an accelerated examination system:

In addition to the deferred examination, which is expected to reduce the number of pending application, accelerated examination system would contribute to the decrease of the pendency of the patent applications.

However, introducing an accelerated examination system should not lead to the delay of normal examinations.

JPMA would appreciate it if you would take a close look at its views on the proposal and make an appropriate system to enhance the examination.

Very truly yours,

Yuji Watanabe
Head of Intellectual Property Committee
The Japan Pharmaceutical Manufacturers Association
e-mail: international@jpma.or.jp

About Us:

The Japan Pharmaceutical Manufacturers Association (JPMA) is a voluntary association comprising 68 research-oriented pharmaceutical companies (as of June 1, 2010).

As a member of the IFPMA (International Federation of Pharmaceutical Manufacturers & Associations), JPMA is engaged with various global issues in the pharmaceutical and healthcare sector, including countermeasures against emerging diseases across the globe and infectious diseases in developing countries, drug access problems, intellectual property rights and the threat of counterfeit drugs.

Working collaboratively with PhRMA (Pharmaceutical Research and Manufacturers of America) and EFPIA (European Federation of Pharmaceutical Industries and Associations), JPMA takes active roles at ICH (International Conference on Harmonization), which aims at international harmonization of pharmaceutical regulations.

Through mutual information sharing and close collaboration with each member organization, JPMA continues to act globally for the advancement of medical treatments for patients worldwide.