Mr. Chaitanya Prasad
Office of The Controller General
Patents, Designs & Trade Marks
Boudhik Sampada Bhavan,
S.M. Road, Antop Hill
Mumbai-400 037 India

September 2, 2014

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

Dear Mr. Prasad,

The Japanese Group of AIPPI (AIPPI Japan) appreciates the opportunity to offer comments regarding the “Revised Draft Guidelines for Examination of Patent Applications in the Field of Pharmaceuticals" published in August 2014.

AIPPI Japan is the local group in Japan of AIPPI, The International Association for the Protection of Intellectual Property, which has more than 9,000 members worldwide. The Japanese group was founded in 1956 and currently has about 1,100 members (approximately 900 individuals and 200 corporate members). It is the largest national/regional group of AIPPI. Its members include patent attorneys, lawyers and other patent practitioners in private and corporate practice, and scholars in the academic community. AIPPI Japan represents a wide and diverse spectrum of individuals, companies, and institutions involved directly or indirectly in the practice of patent, trademark, copyright, and unfair competition law, as well as other fields of law affecting intellectual property.

Our comments are as follows:

1) As to section 6.1 bridging pages 9 and 10:

It is advisable to reconsider the logic appearing in this section. First, the "use of compounds in the treatment of" claim is considered not to be a process. We strongly believe that "use of compounds" claim is a PROCESS claim, because "use" is a process step like "use of edible salt in preparing a food" or "using edible salt in preparing a food." Also, the example claim directed to "a product of known substance for the treatment of new disease" is clearly a PRODUCT claim, simply because the claims starts with "a product". We can envisage that these claims are rejected on the basis of Section 3(d) or other provisions, but it is, respectfully submitted, illogical and wrong to say that these claims are not directed to a process or a product.

2) As to section 6.2 on page 10:

This section deals with second uses of known compounds. We find a statement that: "Necessary care may be exercised to examine these cases in the light of Section 2(1)(j)." In the cases discussed in this section, Section 3(d) of your patent law should be applicable. We respectfully suggest to amend this statement to read: "Necessary care may be exercised to examine in the light of Section 3(d)." This is for the sake of furthering international harmonization with other countries. In many developed countries, a second use of a known compound is a patentable matter. It is possible to argue that technological and economic development is reflected in what may be patented in each country. We believe, however, that to say that such use is not an invention under Section 2(1)(j) is against the spirit of international harmonization since we should use and think in terms of common concepts among different jurisdictions, while such common concepts may result in different patentable inventions.

3) As to section 7.2 with the heading of "Documents":

This section deals with novelty. We find a statement that: "it is generally not permitted to combine separate items of prior art together." Only for clarification purposes, we suggest this statement be revised as "a single reference may be relied upon, and it is generally not permitted to rely on two or more references of prior art and combine them together." This suggestion is a simple clarification for what the original statement meant to say in the revised draft.

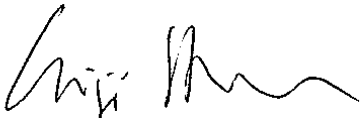
4) As to section 7.6, example 3, bridging pages 13 and 14:

In this example 3, the compounds of Formula I is noted to lack novelty. We suggest, however, such case is evaluated also in terms of inventive step rather than summarily finding lack of novelty. We suggest that example 3 should be examined in terms of novelty AND inventive step.

Since the compounds of Formula I are much narrower than those of Formula II, the inventiveness of Formula I should be considered as well. If the compounds of Formula I have exhibited unknown and remarkable results in treating a specific type of cancer, and the compounds have not been disclosed in the prior art document as one or more of specific examples of Formula II compounds, these compounds should be patentable as an invention of selection depending on how remarkable results are. In view of the prior art reference which discloses a broad range of compounds with, possibly sketchy data on obesity, AIDS and cancer, there should be some room for a researcher to carry out more refined research and have the fruits of the research patented. This proposition should be very good for stimulating research in India as well against Western big pharmaceutical companies. We may also say that the prior art reference is not enabling with respect to the compounds of Formula I. Therefore, a more careful analysis should be given to example 3.

If you have any questions or need more information, please let us know.

Very truly yours,



Eiji Katayama
President
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