JAPAN INTELLECTUAL PROPERTY ASSOCIATION

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

Dear Shri Chaitanya Prasad, IAS,

Re: Invitation of Views on GUIDELINES FOR PROCESSING OF PATENT APPLICATIONS RELATING TO TRADITIONAL KNOWLEDGE AND BIOLOGICAL MATERIAL

We, the Japan Intellectual Property Association, are a private user organization established in Japan in 1938 for the purpose of promoting intellectual property right 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.

Now with regard to the 'GUIDELINES FOR PROCESSING OF PATENT APPLICATIONS RELATING TO TRADITIONAL KNOWLEDGE AND BIOLOGICAL MATERIAL' on your website, we would like to submit important issues for IP stakeholders.
Your consideration would be greatly appreciated.

Sincerely yours,

(Kenichi Osonoe)
Vice chief director
Japan Intellectual Property Association
18F 6-1 Otemachi 2-chome,
Chiyoda-ku Tokyo, 100-0004,
JAPAN

Views on the GUIDELINES FOR PROCESSING OF PATENT APPLICATIONS RELATING TO TRADITIONAL KNOWLEDGE AND BIOLOGICAL MATERIAL

Japan Intellectual Property Association

This draft of the examination for patent applications relating to traditional knowledge (hereinafter abbreviated to "TK") and biological material, illustrates inventions relating to a pharmaceutical composition and presents a plurality of judgment cases with regard to novelty or an inventive step. Therefore, this might be useful as a reference for an applicant who files a patent application for an invention in this field. We expect you to incorporate this into the examination manual and to carry out rigid examination.

Our views will be expressed by item number as follows.

(1) Guidelines for processing of patent application relating to traditional knowledge

・ With regard to item number 2

This guideline said that "Further, India has been able to conclude TKDL Access (Non-Disclosure) Agreements with several international patent offices including USPTO, EPO, JPO etc.," If TK is adopted as a reason for rejection, it would be better to open TKDL also to the public in some way. All of applicants, including Indian domestic applicants, would be puzzled by the fact that only the examiners may access TKDL unavailable for themselves.

TKDL is partially open as a sample to the public at present. We think that data structure of TKDL is not suitable for easy search in view of the sample. Carrying out data maintenance which makes the search easier enables the public to search with TKDL and further also leads to reduction of the burden of prior art search using TKDL also to the examiners in the Indian Patent Office.

・ With regard to item numbers 7 to 13

With regard to screening process (item numbers 7 to 10), allotment process (item numbers 11 to 12), and examination process (item number 13) of patent applications for inventions relating to TK, we expect you to put these processes into the patent examination manual and to conduct rigid examination proceedings according to the guidelines.

・ With regard to item number 14.1

We think that the decision "active ingredients extracted from plants cannot be

considered novel if the plants and the use thereof are known." in Guiding Principle 1 is extravagant. Moreover, we expect you to investigate the corresponding criteria in other countries and to make criteria which harmonize with the criteria in other countries.

・ With regard to item number 14.2

With regard to combinations of specific medicinal plants or active ingredients (Guiding Principles 2, 3), specific ratio ranges of a composition (Guiding Principle 4), difficulty in an extraction technique (Guiding Principle 5), and effects achieved by isolation (Guiding Principle 5), in some cases an inventive step based on unexpected or unpredictable effects is confirmed according to the conditions. Therefore, we expect you to add the cases also for the above-mentioned guiding principles.

(2) Disclosure of source and geographical origin of the biological material

・ With regard to item numbers 16 and 17

With regard to the content of the specification in Article 10 (4)(ii)(D) of the Patent Law, the Article recites "disclose the source and geographical origin of the biological material in the specification, when used in an invention," and the subject of the disclosure is not limited to the source and geographical origin of the biological material in India.

As described in item number 5 of this draft, with regard to "Non-disclosure or wrong mention of the source or geographical origin of biological material used for an invention in the complete specification," it will be a reason for a pre-grant opposition in Article 25(1)(j) of the Patent Law or a post-grant opposition in Article (25)(2) (j) of the Patent Law. Moreover, although not described in this draft, it will be a reason for cancelling a patent which is stipulated in Article 64(1)(p) of the Patent Law.

With regard to this "Non-disclosure or wrong mention of the source or geographical origin of biological material used for an invention in the complete specification," that "wrong mention" will be a reason for a pre-grant opposition or a post-grant opposition or a reason for cancelling a patent forces the applicant to bear an excessive burden and causes destabilization of rights because in some cases the patent applicant or the patentee cannot obtain information about an accurate source or geographical origin of biological material at the time of filing the patent application in India or by the time of acquisition of the right to a patent. Therefore, we expect you to eliminate this Article or to change this from obligation to being subject to a reasonable effort.

・ **With regard to item number 20**

As is the case with the above item numbers 16 and 17 discussions, although it recites "and should clearly specify the country of source and geographical origin of the same," we expect you to change this from obligation to being subject into a reasonable effort, if biological material is not from India.

Moreover, although it recites "the specification should be amended by way of incorporation of a separate heading/paragraph at the beginning of the description that the biological material used in the invention is not from India," we expect that such amendment will not affect the patent right of the amended Indian patent application

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