JAPAN INTELLECTUAL PROPERTY ASSOCIATION

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January 10, 2013

Dear Chaitanya Prasad
The Office of Controller General of Patent,
Designs and Trademarks
Intellectual Property INDIA
Boudhik Sampada Bhavan,
S.M. Road, Antop Hill,
Mumbai-400 037
India

Re: JIPA Comments on the draft "GUIDELINES FOR EXAMINATION OF BIOTECHNOLOGY APPLICATION"

Dear Chaitanya Prasad:

The Japan Intellectual Property Association is a non-governmental organization that was established in Japan in 1938, which represents users of intellectual property systems, 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 draft "GUIDELINES FOR EXAMINATION OF BIOTECHNOLOGY APPLICATION", on your website, we review this draft carefully and would like to submit our comments as follows. Your consideration on our comments would be greatly appreciated.

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

Sincerely yours,

Hirofumi Ueda

(Hirofumi Ueda)
Chairperson of Medicinal and Biotechnology Committee
Japan Intellectual Property Association
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January 10, 2013

【JIPA comments on the draft "GUIDELINES FOR EXAMINATION OF BIOTECHNOLOGY APPLICATION"】

Many of our members in Medicinal and Biotechnology Committee of Japan Intellectual Property Association (JIPA) are pharmaceutical companies on the development of new pharmaceuticals in the biotechnology fields.

Many subsidiaries of Japanese companies related with our members companies are in India, we are highly interest in this draft of "GUIDELINES FOR EXAMINATION OF BIOTECHNOLOGY APPLICATION".

Hence, we provide our comments and suggestions on this draft guideline to the Indian Patent Office.

1. First of all, we request Section 3 (d) and Section 3 (e) of Patent Act should be move or combined with Section 2 (1) (ja) for assessment of inventor step of the invention. Because it is unclear that Section 3 (d) and Section 3 (e) of Patent Act can be assessment of inventor step of the invention.
   Inventor ship analysis should be dealt with same section for unified standard.

2. We request the Patent Office to show any additional claim amendments as preferred example claims to meet subject matter of patentability in any Illustrative Examples. For example, the JPO, the USPTO, and the EPO provide some of "guideline" for examination for the invention including the biotechnology & pharmaceutical invention to public, i.e. the JPO (Chapter 2 for Biological inventions & Chapter 3 for Medical inventions : http://www.jpo.go.jp/cgi/linke.cgi?url=/tetuzuki_e/t_tokkyo_e/1312-002_e.htm,), the USPTO (for Revised Interim Utility Guidelines Training Materials :http: //www.uspto.gov/web/menu/utility.pdf, for Written Description Training Materials : http://www.uspto.gov/web/menu/written.pdf), and the EPO (For Part G: http://documents.epo.org/projects/babylon/eponet.nsf/0/6c9c0ec38c2d48dfc1257a21004930f4/$FILE/guidelines_for_examination_2012_part_g_en.pdf, specifically, on Annex; Part G-Chapter VII-13-17). Said guideline include patentable examples and indicating any claim amendments to meet patentability in any Illustrative Examples.
3. Our comments and/or suggestions for this draft "GUIDELINES FOR EXAMINATION OF BIOTECHNOLOGY APPLICATION" are follows:

【9. INVENTIVE STEP】

【On pages 7-9 of Illustrative Example 1-2】

On page 7 in 2nd paragraph, regarding the sentence of "in order to prove lack of inventive step, it would be sufficient to show "% homology of amino acid sequence in

structure of the claimed polypeptide". It is better to explain "similarities" more concretely, such as "95 % homology of amino acid sequence in structure of the claimed polypeptide".
Regarding to this Illustrative Example:
It should be more exemplified any evidences to show inventive step, i.e. unexpected highly human bone marrow proliferation-inducing activity, stability, and production of IL-3 in Analysis.
No other comments to this Illustrative Example 1.

Regarding to this Illustrative Example 2:
This case seems to be "hindsight" by the examiner after reading this description of the specification.

【On page 9 of Illustrative Example 1-2】
Regarding Illustrative Example 1:
We prefer to substitute term "the claimed subject-matter lacks inventive step in view of the prior art" to "the subject-matter is held to be obvious".
No other comments to this Illustrative Example 2.

【10.INDUSTRIAL APPLICATION】
【On pages 10-11 of Illustrative Example 1-2】
Regarding Illustrative Example 1:
It is also applicable to a broad range in claim 1 is not allowable in view of Section 10 (4) (c), the claim define the scope of the invention properly.
It is unclear, how many evidences which have antigenic peptide fragment are in the description of the specification. It may be also applicable to insufficient disclosure in view of Section 10 (4) (a), the subject matter is not fully and particularly described in the specification.
Polypeptide of an amino acid sequence having at least 40% homology to the 859 amino acid sequence X will encompass many of polypeptide, which has not shown same function as those polypeptide have low homology.
We request an appropriate Illustrative Example for meet the usefulness.

It is also applicable to a broad range in "another claim" that is not allowable in view of Section 10 (4) (c), the claim defines the scope of the invention properly. However, if concrete condition for hybridization will add to the present claim instead of "selectively", it may be sufficiently enable to meet on requirement under Section 2 (1) (ac) of the Act.

Regarding Illustrative Example 2:
It may be also applicable as to un-sufficient disclosure in view of Section 10 (4) (a), the

subject matter is not fully and/ or particularly described in the specification.

【10.1 FRAGMENTS/ESTs】
【On pages 12-13 of 11.Section 3 (c)】
Regarding to Illustrative Example 1;
Please explain that any possible amendments of claim concretely to meet patentable subject. Claims should be added particular term on requirement of Section 2 (1) (j) of the Act, i.e. "however, process of isolation of this isolated Bacillus sp. IN123 can be consider subject to meet the requirement of Section 2 (1) (j) of the Act.".

Regarding to Illustrative Example 2;
Please explain that any possible amendments of claim concretely to meet patentable subject. Claims should be exemplified concretely, i.e. recombinant agent, chemically produced agent, process of purification of the product on the requirement of Section 2 (1)(j) of the Act, "A pharmaceutical composition ・・・", or "A pharmaceutical agent ・・・" on the requirement of Section 2 (1) (ta) of the Act.

Regarding to Illustrative Example 3;
Please explain that any possible amendments of claim concretely to meet patentable subject. Claims should be exemplified i.e. recombinant agent, chemically produced agent on the requirement of Section 2 (1) (j) of the Act, or "A pharmaceutical composition ・・・" or A pharmaceutical agent ・・・" on the requirement of Section 2 (1) (ta) of the Act.

【On pages 13-14 of 12.Section 3 (d) & 3 (e)】
Please review that Section 3 (d) and Section 3 (e) of Patent Act should be move or combined with Section 2 (1) (ja) for assessment of inventor step of the invention.
Inventor ship analysis should be dealt with same section for unified standard.

【On page 13 of 12.Section 3 (d)】
Regarding to Illustrative Example;
This claim should be considered subject for assessment of inventor step on the requirement of Section 2 (1) (ja) and concretely exemplified i.e. the demonstration of any therapeutic efficacy as a result of claimed modification over the prior art for meeting the patentability.

【On page14 of 13.Section 3 (e)】
This claim should be considered subject for assessment of inventor step on the requirement of Section 2 (1) (ja) and concretely exemplified, i.e. the advantages of a combination of these two fungal species over the sum of their individual effects, as a result of claimed combination over the prior arts for meeting the patentability.

【On page14 of 14.Section 3 (h)】
Regarding Illustrative Example 1 & Example 2;
Please explain that any possible changes of claim terms from "A method of agriculture or horticulture" to a product is capable of industrial application, i.e. "A pesticide" is patentable subject claim, when it is fulfill on the requirement of Section 2 (1)(j) of the Act.
No other comments to Illustrative Example 1 & Example 2.

【On pages14-15 of 15.Section 3 (i)】
Regarding Illustrative Example 1 & Example 2;
Please explain that any possible change of claim terms from "A method of diagnostic and /or prophylactic treatment" to a product claim which is capable of industrial application, i.e. "A kit for diagnostic composition, A diagnostic agent which contains ···, or A detection method of gene mutation or gene signature ···" is patentable subject claim, when it is fulfill on requirements of Section 2 (1)(j) of the Act.
No other comments to Illustrative Example 1 & Example 2.

【On pages15-16 of 16.Section 3 (j)】
Regarding Illustrative Example 1:
It seems like unclear claim language as ex vivo functional meaning of the term on requirement of Section 10 (4) (c).
Please show any proposal amendments in claim to fulfill on the requirement of Section 3 (j) and Section 10 (4) (c) , i.e. "an effective ingredient an autologus NK T cells, said autologus NK T cells is capable of modulating Th1/Th2 cell balance toward anti-inflammatory cytokine producing cells educating in ex vivo".

【On pages17-18 of 18.Section 3 (p)】
Regarding Illustrative Example 1:
It should be relied upon concrete evidence from a published article as being directed a Traditional Knowledge in India within the scope of non-patentable invention under Section 3 (p) of the Act.
It seems like that this example claim is "single means claim" and also is applicable on the requirement of Section 3 (i) in view of comment in the present Analysis.
Claim in this Illustrative Example 2 should be amended to "An anti-paralytic agent comprising serum of pigeon possessing the anti-paralysis activity and pharmaceutical carrier."
No other comments to Illustrative Example 1 & Example 2.

【Sufficiency of disclosure, Clarity and Support of the claims & unity of inventions】
【On pages18-20 of 19.Section 10 (4) of the Act】

Regarding Illustrative Example:
Analysis in this Example seems like correct in the present details.
However, a function of polypeptide X is normally known before filing a patent application and compound(s) which contacting with polypeptide X is/ are known on chemical structure of compound, i.e. specific recombinant protein, fragment of specific antibody, RNAs, or DNAs and how to make those.
Such case may be support on the requirement under Section 10 (4) of the Act.
In the case of antibodies which is claimed, if antibodies showed therapeutic effect using animal model related specific disease in the specification, this evidence may be indicative of a role for target protein in such specific disease, then such disclosure in the specification may be support for claiming antibodies on the requirement under Section 10 (4) of the Act.
Please show and add more concreted examples for support on the requirement as supported claim 2 under Section 10 (4) of the Act.