JAPAN INTELLECTUAL PROPERTY ASSOCIATION

Asahi-Seimei Otemachi Bldg. 18F.
6-1, Otemachi 2-Chome
Chiyoda-ku, Tokyo 100-0004 JAPAN

Tel: 81 3 5205 3433
Fax:81 3 5205 3391

July 12, 2012

The Honorable Susan C. Wolski,
Office of Patent Cooperation Treaty Legal Administration,
Office of the Associate Commissioner for Patent Examination Policy
United States Patent and Trademark Office
Alexandria, Virginia

Re: JIPA Comments on the "Request for Comments on the Recommendation for the Disclosure of Sequence Listing Using XML (Proposed ST.26)"

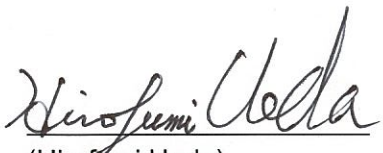
Dear Ms. Susan C. Wolski, Esq.:

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 "Request for Comments on the Recommendation for the Disclosure of Sequence Listing Using XML (Proposed ST.26)", requested by the United States Patent and Trademark Office (USPTO) in the Federal Register, Vol.77, No.94, on May 15, 2012. We would like to offer our comments as follows. Your consideration on our comments would be greatly appreciated.

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

Sincerely, yours,



(Hirofumi Ueda)
Chairperson of Medicinal and Biotechnology Committee
Japan Intellectual Property Association
Asahi Seimei Otemachi Bldg.18F
6-1 Otemachi 2-chome Chiyoda-ku Tokyo, 100-0004,
JAPAN

JIPA Comments on the "Request for Comments on the Recommendation for the Disclosure of Sequence Listing Using XML (Proposed ST.26)"

1. With respect to aspect of the proposed standard or Annexes, transition issues or expected implementation in the United States

- Given the lack of a fully-evaluated stable software program to prepare XML-format sequence listings in compliance with ST.26, applicants are hoping to continue using the currently adopted sequence listing authoring tool. Applicants are afraid that the lack of such a software program will result in imposing burdens on applicants, causing problems in inputting and outputting sequence information and increasing the risk of submitting incorrect sequence information as a result of human errors.

- For the aforementioned reasons, applicants are hoping to continue using the currently adopted software program (PatentIn) to prepare ST.25-compliant sequence listings and submit them to a receiving Office. Applicants think that the sequence listings should be converted at each country's patent office by use of an ST.25/ST.26 conversion software program (the WIPO unified standard could be adopted) under the responsibility of the Office.

- Since ST.26 requires the use of a large number of DTD tags in a complicated manner, the risk of human errors in inputting data is expected to increase. Therefore, applicants are requesting the development of a sequence listing authoring tool that can minimize the occurrence of human errors and ensure stability. Also, applicants are requesting the preparation and provision of an easy-to-understand manual explaining, among other things, the difference between the newly developed tool and PatentIn.

2. With respect to the issues which were specifically requested by the USPTO:
(1) Is the main body of the standard sufficiently clear and comprehensive?

While understanding the explanation about ST.26 (XML format using DTD), applicants find ST.26-compliant sequence listings much more difficult to read due to a large number of tags in comparison with ST.25-compliant sequence listings (test format). Applicants find it necessary to use an effective tool to prepare accurate, error-free ST.26-compliant sequence listings.

(2) Does the standard include any unnecessary procedural requirements, or exclude any procedural requirements that should be retained?

Although ST.26 is capable of describing short sequences, D-amino acid sequences, and modified sequences, which cannot be described by ST.25, this cannot be considered as a merit of ST.26 because such incapability of ST.25 has never been an issue. The sequence listings are prepared to be attached to the specification of a patent application and to be submitted to a patent office in order to support the description of the invention claimed in the patent application. Sequence listings are important in stabilizing the rights to the invention. Since the compatibility with other databases is not of primary importance, the

consistency with INSDC and UniProt may be a merit for patent offices, but not necessarily a merit for applicants.

(3) Are there any feature keys or qualifiers that are not clear, or that are optional and should be mandatory (or vice versa)?
[Input of information on the inventor] It is not certain whether such information item is independent from the application or the specification (claim). In the case of a lawsuit concerning inventorship identification or a usurped application, it is uncertain whether inventorship may be corrected if there is inconsistency with the application and the specification (claim) or if the inventorship is changed as a result of the filing of a divisional application. For this reason, this information item should be deleted.

[Title of an invention]
The title of an invention will be changed if an examiner corrects it in the course of examination or if a divisional application is field. Since it is uncertain whether the title of an invention may be corrected, the provision of this information should not be mandatory.

[Tag] In the case of a PCR primer, it is necessary to describe all of the primer sequences disclosed in a specification in one line. Consequently, some patent applications would contain a very large number of tags, making it difficult to read them. Since such patent applications are likely to cause human error in checking the input and output data, applicants are requesting a change in the method of describing a PCR primer, proposing that a new paragraph should be created to describe each primer sequence. Since an applicant is not necessarily able to state accurate "Feature Keys," when filing an application, each applicant should be permitted to make an amendment (a correction) to "Feature Keys" excluding "nucleic acid sequences or amino acid sequences" at the time of registration.

(4) Are the major change made in ST.26 desirable and what difficulties, if any, are likely to be faced in complying with the XML standard?
- From the viewpoint of applicants, there is no merit in adopting the XML format as a standard. As described above, applicants have received neither explanation about the merits and convenience in submitting XML-format sequence listings nor assistance such as the provision of a tool, guidance on how to prepare sequence listings accurately and efficiently, or information on its reliability. Therefore, applicants find no reasons to voluntarily adopt the XML format.

- Inputting one letter to describe each amino acid could be regarded as a merit because of its simplicity, but could be regarded as a demerit as well because it would increase the risk of input error. It would also increase the risk of human error because input errors are more likely to be overlooked at the time of checking output data.

- The compatibility with UniProt and other databases may be regarded as a merit. However, the risk of human error will increase because the number of input items is large. The inability to output data in the form of sequence listings, which can be done by ST.25, would

make the input checking process more difficult.

- Applicants are afraid that the adoption of the XML-format will increase the number of pages of a specification.

(5) ST.26 does not provide for the inclusion of prior publications of references in the sequence listing. Is there any perceived detriment to this?

Comment: There is no necessary this.

However, we are expected to describe any nucleic acid sequences or amino acid sequences related with any invention in such specification for supporting any description requirement or avoiding any defectiveness.

(6) How much time is likely to be needed for applicants to transition to the XML standard, and what difficulties should an applicant anticipate if some national or regional offices required compliance with ST.25 while others required compliance with ST.26?

- It would be desirable if specific information is provided about a new sequence listing authoring tool (software programs) and the time schedule for the provision of the tool. In particular, since the U.S. and Japan have been promoting the use of PatentIn in preparing sequence listings, applicants are requesting a 6- to 12-month transition period after the stability check of the new tool so that applicants can switch to a new program and master how to use it.

If the format is changed from the text format to the XML format, confusion is expected to follow for some time because of the frequent occurrence of checking errors and the misunderstanding concerning the description method. Therefore, the establishment of a trial period or a transition period will be necessary so that correction of an error on a sequence listing is permitted during such a period following the transition to the XML format.

- If countries are divided over whether to adopt ST.26, applicants will have to prepare sequence listings in two formats. This will impose heavy burdens on applicants in terms of workload, time, and costs and is likely to cause procedural confusion.

Therefore, if possible, all countries should make the transition simultaneously. The challenge would be whether it is possible for each country to make progress in tandem with other countries in terms of the establishment of necessary systems and infrastructures. If the time schedule for the adoption and implementation of ST.26 differs from one country to another, it would be desirable to set a transition period that will last until such difference disappears. During the transition period, applicants should be permitted to submit ST.25-compliant sequence listings even to the countries that have implemented ST.26.

- If the transition from ST.25 to ST.26 occurs in the middle of the application examination procedure, it could be problematic. For example, in some cases, a PCT application is filed based on a basic application, and then the PCT application enters the national phase in each country. In particular, in the case of an application filed in the U.S., many divisional applications such as a CIP application could be filed. If an applicant who has filed an

ST.25-compliant sequence listing is required to submit an ST.26-compliant sequence listing within a short period of time, it will cause excessive burdens and confusion to the applicant. Therefore, ST.26 should be implemented in such a way that, if the initially-filed application is in the ST.25 format, the applicant will be at least permitted to submit ST.25-compliant sequence listings for a series of applications filed based on the initial application.

- As long as an applicant has stated nucleotide sequences and amino acid sequences and described their characteristics and natures in a specification, in the event that sequence listings are incorrect due to a human error, the applicant is currently permitted to amend incorrect sequences based on the specification. This practice should be maintained.

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