AIPLA
AMERICAN INTELLECTUAL PROPERTY LAW ASSOCIATION

May 20, 2013

The Honorable Teresa Stanek Rea
Acting Under Secretary of Commerce for Intellectual Property and
Acting Director of the United States Patent and Trademark Office
United States Patent and Trademark Office
600 Dulany Street
Alexandria, VA 22314 via email: teresa.rea@uspto.gov

RE: AIPLA Recommendations for Reducing Paperwork, Time, and Cost for the Office and Applicants With Respect to Sequence Listings

Dear Acting Under Secretary Rea:

The American Intellectual Property Law Association (AIPLA) is pleased to take this opportunity to provide the United States Patent and Trademark Office (Office) with recommendations that would reduce burdens on the Office and on Applicants with respect to Sequence Listings. This letter was drafted originally as a response to a Federal Register request for comments and recommendations pertaining to the Paperwork Reduction Act.[1] However, AIPLA decided instead to provide its recommendations directly to you via this letter.

AIPLA is a national bar association with approximately 15,000 members who are primarily lawyers in private and corporate practice, in government service, and in the academic community. AIPLA 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 members represent both owners and users of intellectual property.

For the most part, AIPLA believes that the Sequence Listing Requirements set forth in 37 C.F.R. §§ 1.821-1.825 are not overly burdensome. Nevertheless, the current Sequence Listing Requirements and procedures can be and should be simplified to reduce paperwork, processing, and costs that Applicants and the USPTO bear. AIPLA makes seven specific procedural recommendations to reduce Sequence Listing burden for Applicants and the Office.

AIPLA understands that there may be internal processing considerations and "patent harmonization" factors relating to Sequence Listings that AIPLA may not fully appreciate. AIPLA additionally notes that the Office regularly seeks and has been receptive to input regarding costs and burden to Applicants, such as recently seeking comments to an XML

[1] 78 FR 12744, February 25, 2013, "Requirements for Patent Applications Containing Nucleotide Sequence and/or Amino Acid Sequence Disclosures."

standard for Sequence Listings. AIPLA strongly encourages the Office to continue discussions with stakeholders who regularly prepare and submit Sequence Listings in order to identify solutions to streamline preparation, submission, and processing of applications containing Sequence Listings. Working together, we hope to reduce the backlog of applications, reduce the paperwork, time, and expense required to prepare and process Sequence Listings, and reduce the pendency time for applications that include Sequence Listings. The Office and Applicants will both benefit.

Background

An official Sequence Listing must be submitted as a paper or compact disc copy (37 C.F.R. 1.821(c)). A copy of the Sequence Listing must also be submitted in Computer Readable Form (CRF) as a text file in ASCII format.

Based on these requirements, Sequence Listing submissions can be of four (4) types:

- "Electronic Sequence Listings" are submitted in CRF via EFS-Web;
- "Paper Sequence Listings" are provided in paper or .pdf format;
- "Compact Disc Sequence Listings" are submitted in ASCII text form. When submitted as the official Sequence Listing, compact discs must be provided in duplicate. A further CRF text copy of the Sequence Listing is still required. This is the only type permitted for "Large Sequences" that are larger than 100 MB; and
- "Paper and Electronic Listings" are provided when the official Sequence Listing is provided on paper or as a PDF image via EFS-Web and a further CRF copy in electronic text form is filed on CD-ROM or as a text file by EFS-Web; and

Sequence Listings may be provided:

- At "Initial Filing" (same day as original application papers);
- "After Filing" (submitted after an original application based on the disclosure in the specification to comply with the Sequence Listing rules); and
- As a "Substitute Sequence Listing" (replacement for a previously-submitted Sequence Listing).

Sequence Listings are required for:

- Utility Applications (35 U.S.C. 111(a));
- Continuing Applications (35 U.S.C. 111(b);
- PCT Applications filed in the U.S. Receiving Office; and
- National Phase Applications (35 U.S.C. 371).

Sequence Listings are required for any patent application that contains disclosure of an un-branched sequence of four or more amino acids or an un-branched sequence of ten or more nucleotides (37 C.F.R. 1.821(a)).

Accompanying Tables A-C briefly summarize requirements and considerations for the four types of sequence submissions at the three time points for the four types of applications.[2] As readily seen from these Tables, many requirements and considerations are the same for the various time points and application types.

The manner in which sequences are presented and described must comply with 37 C.F.R. 1.821 to 1.825. If the requirements are not satisfied, as determined by the Office, a notification to comply with the Sequence Listing rules is issued setting forth a deadline to comply with the rules and to submit a Sequence Listing or substitute Sequence Listing.

Burdens and Issues with Existing Procedures

The existing procedures are burdensome and costly to Applicants. First, the procedures and formats for submission of Sequence Listings are complex. The rules for submitting the various formats are not clearly set forth in the MPEP or in any other source. This is especially true given the large number of media options for submitting a Sequence Listing (e.g. on paper, on CD-ROM or as a text file via EFS-Web). While failure to comply with the rules can be rectified by later submission of the Sequence Listing without affecting the filing date, it creates an unnecessary inefficiency, expense and burden to the filing of Sequence Listings. The process and procedures should be simplified.

Second, the procedures and formats for submission of Sequence Listings are redundant. In particular, the requirement to submit an official copy of the Sequence Listing as a paper copy, as an ASC-II text file on compact disc or as a text file by EFS-Web is redundant with the requirement to submit a CRF form of the Sequence Listing. In particular, the additional requirement to submit a CRF form of the Sequence Listing in all cases, except when the Sequence Listing is filed as a text file by EFS-Web, is redundant. For example, when the official

[2] Much of the information in Tables A-C is not in the MPEP and was instead found at http://www.uspto.gov/patents/process/file/efs/guidance/New_legal_framework.jsp, a site with which many practitioners may not be familiar.

copy of the Sequence Listing is provided only on a compact disc under the procedures set forth in 37 C.F.R. 1.52(e), it is required to be provided in duplicate in ASCII text format. Yet, a further CRF of the Sequence Listing on CD-ROM in ASCII format is still required. For example, the MPEP states:

> The compact disc submitted under 37 C.F.R. 1.821(c) may, if it contains no tables, be identical to the computer readable form (CRF) submitted under 37 C.F.R. 1.821(e) and 37 C.F.R. 1.824, if that CRF is submitted on a compact disc. Even if the compact discs submitted under both 37 C.F.R. 1.821(c) and (e) are identical, each compact disc submitted under 37 C.F.R. 1.821(c) must be submitted in duplicate, in addition to the CRF under 37 C.F.R. 1.821(e).

Further, the procedures for submitting Sequence Listings differ depending on the type of application. This can create further confusion for Applicants. For example, mixed mode filing of Sequence Listings are permitted in a U.S. Utility application under 35 U.S.C. 111(a) (e.g. application filed on paper and Sequence Listing filed on CD-ROM in duplicate). In contrast, mixed mode filings have been expressly prohibited for International PCT applications by amendments adopted by the Assembly of the PCT Union and entered into force on July 1, 2009.

Finally, the validation procedures used by the Office for compliance with the Sequence Listing rules lacks full transparency. Although the Office provides a free downloadable program called Checker that Applicants can use to ensure that submitted Sequence Listings comply with the rules, the Office does not use the same version of the program in its validation procedures. AIPLA understands that the Office uses an in-house verification software program, not available to the public, to validate Sequence Listing submissions.[3] The inconsistent application of compliance rules by the Office is evidenced by the routine rejection of Sequence Listings in a continuation application where the identical Sequence Listing was deemed to be compliant in the parent application.

Procedural Recommendations

Unless an Applicant expressly requests otherwise, AIPLA recommends that the Office apply the following as default procedures for processing a Sequence Listing.

1. For a US utility application for which the Applicant submits a Sequence Listing as a text file or a CRF of a Sequence Listing at the same time as the initial filing of application papers:

[3] See Presentation titled, "Current Sequence Listing Process for Nucleic Acids and Polypeptides," http://www.aipla.org/committees/committee_pages/Biotechnology/Committee%20Documents/USPTO%20Partnership%20Meetings%20with%20BiotechChemPharma/June%202011/Current%20Sequence%20Listing%20process_Final_Nguyen.ppt.

a. A text file in CRF should be automatically processed as the sole legally-recognized Electronic Sequence Listing, regardless of the size of the submission;

b. No Incorporation by Reference should be required, or alternatively, the Application Data Sheet (ADS) should provide the option for the Applicant to specify that a Sequence Listing should be incorporated, which if selected would require the Office to automatically amend the specification to provide the requisite Incorporation by Reference, for example, as it does for priority claims; and

c. No other form of the Sequence Listing (e.g. on paper) should be required.

2. In addition to the changes above, for a continuing application in which the parent application contains a compliant Electronic Sequence Listing or CRF:

   a. The Office should transfer a compliant Electronic Sequence Listing or CRF of the parent application to the continuing application without any Request for Transfer (Form SB 93 or its equivalent), or alternatively, the Office should automatically transfer a compliant Electronic Sequence Listing or CRF of the parent application if the Applicant makes the appropriate selection on an ADS; and

   b. If the Sequence Listing from the parent application has been determined to be compliant, no further compliance review of the Sequence Listing should be conducted in the continuing application.

3. For US national phase entries, the Office should permit automatic transfer of an Electronic Sequence Listing or CRF filed in the PCT application to the US national phase application in a manner similar to recommendation #2 above provided that the Electronic Sequence Listing or CRF complied with PCT Sequence Listing requirements and regardless of which patent office served as the receiving office for the application.

4. For a Sequence Listing After Filing or a Substitute Sequence Listing, the Office should require only that Applicants submit the Sequence Listing or Substitute Sequence Listing as a text file in ASCII similar to recommendation #1 above, or submit a Transfer Request similar to recommendation #2 above.

Recommendation #1 above will eliminate the burden on an Applicant to submit a preliminary amendment merely to add a statement of Incorporation by Reference. Additionally, fewer applications will require a Notice to Comply with Sequence Listing Requirements and fewer responses to such Notices will require processing. Finally, where an Applicant submits a paper copy in addition to an Electronic Sequence Listing or a CRF, the Applicant will not be burdened

by a requirement to provide a Sequence Listing Statement indicating that the paper copy and the CRF are the same and the Office will not be burdened with determining whether extra page fees are required and with mailing a Notice of Missing Parts for extra page fees since no extra page fees would apply.

As with recommendation #1, the proposed default procedures in items #2 and #3 above will reduce the need for an Applicant to submit a preliminary amendment to add Incorporation by Reference. The Office would not be burdened with mailing a Notice to Comply with Sequence Listing Requirements and with having to process the subsequent responses from Applicants for most U.S. utility applications that involve sequences. Finally, when an Applicant submits a paper copy in addition to an Electronic Sequence Listing or a CRF, the Applicant would not be burdened to provide a Sequence Listing Statement indicating that the paper copy and the CRF are the same, and the Office would not be burdened with determining whether extra page fees are required and whether a Notice of Missing Parts should be sent with notice for extra page fees since no extra page fees would apply.

With regard to recommendation #3, the Office regularly rejects Sequence Listings in US national phase applications that have been submitted without issue in the PCT application, particularly when the PCT application was submitted in a receiving office other than the US. The Office uses a different standard for review than Sequence Listings submitted under the PCT in other receiving office (even those submitted at the EPO), mainly with respect to the requirements under the "free text" field (i.e. under numeric identifier <223>). Although Standard ST.25 is apparently being used, the Office requires that the "free text" field contain source information in those instances when the organism is unknown or is an artificial sequence (see Federal Register: June 1, 1998 (Volume 63, Number 104), pp. 29620-29643). The Office regularly rejects Sequence Listings based on the content of the "free text" field. This requirement is not found in Standard ST.25 in WIPO's Handbook on Industrial Property Information and Documentation (2009, see items 33-35, pp. 3.25.8-9). The Office should accept the electronic or CRF Sequence Listing submitted and accepted under the PCT in any receiving office without the need for further checking or reevaluation. This would reduce the burden on the Office for checking the Sequence Listing and for issuing Notices to Comply and also would reduce the costs for Applicants to address such notices and to generate and file Sequence Listings under different formats.

Recommendation #4 above will reduce the instances in which Applicants would have to submit Sequence Listing statements. Consequently, the Office will not be burdened with having to process any Sequence Listing statements. The requisite statement of "No new matter" should be inherently provided by the act of the submission itself. The requirement for submission of a paper copy should be removed, regardless of CRF size. If a paper copy of the Sequence Listing is voluntarily submitted, the requisite statement that the paper copy and the CRF are the same is inherently provided by the act of the submission itself.

Additional Recommendations

AIPLA recommends three additional improvements:

5. Eliminate the requirement for providing in a Sequence Listing the sequence of a molecule that is merely disclosed in an application, say as a research tool, is not covered in any way by the claims, and is already in the public domain.

6. Consolidate all information and procedures relating to Sequence Listings in the MPEP.

7. Make the Office's internal Sequence Listing program available to the public. Alternatively, Checker v. 4.4.6 should be updated, adding the capability of analyzing and verifying free text entries in identifier fields.

Implementing recommendation #5 will reduce the instances in which Sequence Listings need to be submitted. Such a change will reduce the burden on both Applicants and the Office because it will reduce the amount of documents and electronic data which needs to be prepared by Applicants and also processed by the Office following submission of a patent application containing nucleotide or amino acid sequences. AIPLA understands that many patent applications with Sequence Listings do not contain nucleotide nor amino acid sequences in the claimed subject matter. Rather, such sequences are only disclosed as a result of their role in experimental procedures disclosed in the specification. In such applications, these Sequence Listings are not used by the examiner in prior art searches because the nucleotide and amino acid sequences in the Sequence Listing are not part of the claimed subject matter and hence, do not need to be searched. Further, these nucleotide and amino acid sequences are, in most instances, already in the public domain and do not supplement any particular sequence database which may be relied upon by the examiner for prior art searching purposes.

Implementing recommendation #6 will save Applicants confusion, time, and expense. AIPLA is aware of situations in which a patent attorney or agent submitted both an Electronic Sequence Listing and a paper copy because the attorney/agent was unaware the Sequence submission for the most part is not in the MPEP.[4] Applying the Sequence Listing rules and resolving such situations are burdensome for both the Office and Applicants. AIPLA believes that some burdensome paperwork and associated expense to ensure compliance with the rules can be avoided or greatly reduced if all information and procedures relating to Sequence Listings are explicitly set forth in the MPEP.

[4] Most of the most pertinent Sequence Listing information is at http://www.uspto.gov/patents/process/file/efs/guidance/New_legal_framework.jsp, not in the MPEP, where most practitioners would normally first look for information relating to practicing before the USPTO.

Finally, implementing recommendation #7 will also save Applicants confusion, time, and expense. The Office uses an internal software program for checking compliance under the rules and for checking the format and content of Sequence Listings. This internal Office software program is not available to Applicants and it is different than the Checker program that is publically available through the Office website. Sequence Listings that are run through the Checker program without error are regularly rejected as non-compliant by the Office based on the internal Office program. Availability to Applicants of the same software program for checking compliance of Sequence Listings as the program used by the Office would greatly reduce the submission of Sequence Listings that are deemed non-compliant. This would also reduce the burden on the Office for issuing Notices to Comply and the costs for Applicants for addressing such notices. Further, the Office should limit "manual verification" of Sequence Listings, or alternatively, adequately train reviewers for consistent implementation of the rules.

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AIPLA appreciates the opportunity to provide the above recommendations and would be happy to work with anyone you designate in the Office to further consider changes that would reduce paperwork and time burdens for the Office and Applicants.

Sincerely,

Jeffrey I.D. Lewis
President
American Intellectual Property Law Association