

Patent Cooperation Treaty (PCT) Working Group

**Eleventh Session
Geneva, June 18 to 22, 2018**

SEQUENCE LISTINGS

Document prepared by the International Bureau

SUMMARY

1. The Working Group is invited to review preliminary draft amendments to the PCT Regulations and modifications to the PCT Administrative Instructions required in order to permit the filing and processing of international applications with sequence listings in compliance with new WIPO Standard ST.26, with a view to providing guidance to the International Bureau and the sequence listings task force of the Committee on WIPO Standards (CWS) in developing procedures and a formal proposal for changes to the PCT legal framework.

BACKGROUND

2. The CWS has adopted new WIPO Standard ST.26 for the presentation of sequence listings in XML format. The sequence listings task force has recommended working towards implementation of this Standard for national and international applications filed on or after January 1, 2022, subject to the satisfactory development of various software tools to support the preparation, filing and processing of listings.

3. The key differences between ST.25 and ST.26 for the purposes of the PCT procedure are as follows:

- (a) ST.26 defines a format for the submission of sequence listings which can only be submitted in electronic form (XML) – unlike ST.25, ST.26 does not cater for the submission of a sequence listing on paper or in electronic formats other than XML, such as PDF. Consequently, it will become strongly preferable for sequence listings to be filed

as part of an international application in electronic form. Where this is not possible, international applications filed on paper would need to be accompanied by a sequence listing in electronic form submitted on physical media.

(b) ST.26 more strictly defines which sequences must and must not be included in a sequence listing – in summary, all sequences of 10 or more nucleotides or unbranched sequences of 4 or more amino acids must be included and shorter sequences must not.

4. Most of the detailed differences in the Standards otherwise will be handled by the software tool which is being developed by the International Bureau to support the service.

ISSUE

5. Transition from WIPO Standard ST.25 to ST.26 for PCT purposes will require amendments to the PCT Regulations and modifications to the Administrative Instructions, in addition to development of procedures and support tools. The annexes to this document contain preliminary drafts of proposed changes to the PCT legal framework as follows:

(a) Annex I contains proposed draft amendments to the PCT Regulations (it further contains, for ease of reference, certain provisions relating to sequence listings which at this stage are not proposed to be amended);

(b) Annex II contains proposed draft modifications to the main body of the PCT Administrative Instructions; and

(c) Annex III contains a proposed draft replacement for Annex C of the PCT Administrative Instructions, including a number of explanatory comments. Proposed new Annex C is intended to take the form of a complete, consolidated explanation of the overall PCT procedures involved in filing and processing sequence listings. To that end, it contains a number of duplications with certain provisions set out in the PCT Regulations (Annex I) and in the main body of the Administrative Instructions (Annex II), as well as with WIPO Standard ST.26. Furthermore, it contains certain provisions which, from a strictly legal point of view, might not be required but which provide background information to clarify the purpose of certain provisions. It has been drafted in a way that, in the case of duplications, it is made clear whether any particular requirement is based on a particular Rule in the PCT Regulations, a particular section of the main body of the Administrative Instructions, or is a new instruction being set out specifically within that Annex.

6. These draft proposals are aimed at highlighting the issues which will require detailed consideration over the coming year by the International Bureau and the CWS sequence listings task force with a view to developing a formal proposal at a later date. Particular consideration still needs to be given to issues concerning free text (see, in particular, the comments following paragraph 9 in Annex III) and ensuring that procedures allow international applications to proceed effectively even when they have been filed on paper or else in an electronic format which is not fully compliant with the Standard.

7. The Working Group is invited to note the provisional changes to the PCT legal framework set out in the Annexes to this document and to offer guidance to the International Bureau and inform the CWS of issues which should be further explored.

[Annexes follow]

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Rule 5

The Description

5.1 [No Change]

5.2 Nucleotide and/or Amino Acid Sequence Disclosure

(a) Where the international application contains disclosure of one or more nucleotide and/or amino acid sequences for which inclusion in a sequence listing is required in accordance with the Administrative Instructions, the description shall include a separate part of the description (“sequence listing part of the description”) ~~contain~~ containing a sequence listing complying with ~~the standard provided for in the Administrative~~ those Instructions and presented ~~as a separate part of the description in accordance with that standard~~ in the form of a single electronic file in accordance with those Instructions (“compliant sequence listing”).

[COMMENT: The substance of the new standard is mostly defined by reference to WIPO Standard ST.26 (as distinct from the present arrangement where the standard is contained entirely within Annex C of the Administrative Instructions). It is nevertheless proposed to refer to the Administrative Instructions rather than to ST.26 directly in order to allow fine details of version control and specific procedures and implementation for the PCT to be specified more clearly. The term “compliant sequence listing” is proposed for use in later provisions, noting that only very limited checks, if any, would be applied to sequence listings by some receiving Offices, but compliance may be tested and required by International Authorities or designated and elected Offices.]

(a-bis) Any file contained in the international application as filed, purporting or appearing to be a sequence listing, shall be considered to form part of the description whether or not that listing is referred to in the main part of the description or in the request.

[COMMENT: This proposal is not directly related to the transition from WIPO Standard ST.25 to ST.26 as such, but seeks to minimize the risk of listings failing to be considered part of the application as filed due to their being mis-labeled, a risk which may increase if filings are made with the application body on paper and an electronic sequence listing on a physical medium.]

(b) [No change] Where the sequence listing part of the description contains any language-dependent free text as defined in the ~~standard provided for in the~~ Administrative Instructions, that language-dependent free text shall also appear in the main part of the description in the language thereof.

[COMMENT: See further explanation under paragraphs 6 to 9 in Annex III.]

Rule 12

Language of the International Application and Translations for the Purposes of International Search and International Publication

12.1 *Languages Accepted for the Filing of International Applications*

(a) An international application shall be filed in any language which the receiving Office accepts for that purpose.

(b) Each receiving Office shall, for the filing of international applications, accept at least one language which is both:

(i) a language accepted by the International Searching Authority, or, if applicable, by at least one of the International Searching Authorities, competent for the international searching of international applications filed with that receiving Office, and

(ii) a language of publication.

(c) Notwithstanding paragraph (a), the request shall be filed in any language of publication which the receiving Office accepts for the purposes of this paragraph.

(d) Notwithstanding paragraph (a), any text matter contained in the sequence listing part of the description ~~referred to in Rule 5.2(a)~~ shall be presented in accordance with the standard provided for in the Administrative Instructions.

12.1bis to 12.2 *[No Change]*

12.3 *Translation for the Purposes of International Search*

(a) [No change] Where the language in which the international application is filed is not accepted by the International Searching Authority that is to carry out the international search, the applicant shall, within one month from the date of receipt of the international application by the receiving Office, furnish to that Office a translation of the international application into a language which is all of the following:

(i) a language accepted by that Authority, and

(ii) a language of publication, and

(iii) a language accepted by the receiving Office under Rule 12.1(a), unless the international application is filed in a language of publication.

(b) [No change] Paragraph (a) shall not apply to the request nor to any sequence listing part of the description.

[COMMENT: There does not appear to be any need to change the above provision.]

(c) to (e) [No change]

12.4 *Translation for the Purposes of International Publication*

(a) [No change] Where the language in which the international application is filed is not a language of publication and no translation is required under Rule 12.3(a), the applicant shall, within 14 months from the priority date, furnish to the receiving Office a translation of the international application into any language of publication which the receiving Office accepts for the purposes of this paragraph.

(b) [No change] Paragraph (a) shall not apply to the request nor to any sequence listing part of the description.

[COMMENT: There does not appear to be any need to change the above provision.]

(c) to (e) [No change]

Rule 13ter

Nucleotide and/or Amino Acid Sequence Listings

13ter.1 Procedure before the International Searching Authority

(a) Where the international application contains disclosure of one or more nucleotide and/or amino acid sequences for which inclusion in a sequence listing is required in accordance with the Administrative Instructions but the international application as filed does not contain a compliant sequence listing, the International Searching Authority may invite the applicant to furnish to it, for the purposes of the international search, a compliant sequence listing ~~in electronic form complying with the standard provided for in the Administrative Instructions~~, unless such listing ~~in electronic form~~ is already available to it in a form and manner acceptable to it, and to pay to it, where applicable, the late furnishing fee referred to in paragraph (c), within a time limit fixed in the invitation.

[COMMENT: Modified because the new standard more closely defines which sequences must and must not appear in a sequence listing and because a listing is required to be in electronic form by definition.]

~~(b) Where at least part of the international application is filed on paper and the International Searching Authority finds that the description does not comply with Rule 5.2(a), it may invite the applicant to furnish, for the purposes of the international search, a sequence listing in paper form complying with the standard provided for in the Administrative Instructions, unless such listing in paper form is already available to it in a form and manner acceptable to it, whether or not the furnishing of a sequence listing in electronic form is invited under paragraph (a), and to pay, where applicable, the late furnishing fee referred to in paragraph (c), within a time limit fixed in the invitation.~~

[COMMENT: The above paragraph would appear to be redundant since it is not possible to file a compliant sequence listing in paper form.]

(c) The furnishing of a sequence listing in response to an invitation under paragraph (a) ~~or (b)~~ may be subjected by the International Searching Authority to the payment to it, for its own benefit, of a late furnishing fee whose amount shall be determined by the International Searching Authority but shall not exceed 25% of the international filing fee referred to in item 1 of the Schedule of Fees, not taking into account any fee for each sheet of the international application in excess of 30 sheets, ~~provided that a late furnishing fee may be required under either paragraph (a) or (b) but not both.~~

(d) If the applicant does not, within the time limit fixed in the invitation under paragraph (a) ~~or (b)~~, furnish the required compliant sequence listing and pay any required late furnishing fee, the International Searching Authority shall only be required to search the international application to the extent that a meaningful search can be carried out without the compliant sequence listing.

(e) Any sequence listing not contained in the international application as filed, whether furnished in response to an invitation under paragraph (a) ~~or (b)~~ or otherwise, shall not form part of the international application; ~~but~~ however, pursuant to Article 34(2)(b), this paragraph shall not prevent the applicant from amending the description in relation to the disclosure of any nucleotide and/or amino acid sequences contained in the international application as filed, whether or not those sequences were included in a compliant sequence listing pursuant to Article 34(2)(b).

[COMMENT: Amendment may be appropriate to better reflect the fact that “sequence listing” would have a narrower definition than before and that it should be possible to make amendments which put disclosures of sequences into the format of a proper sequence listing, as long as this does not result in added subject matter.]

(f) [No change] Where the International Searching Authority finds that the description does not comply with Rule 5.2(b), it shall invite the applicant to submit the required correction. Rule 26.4 shall apply *mutatis mutandis* to any correction offered by the applicant. The International Searching Authority shall transmit the correction to the receiving Office and to the International Bureau.

13ter.2 [No Change] Procedure before the International Preliminary Examining Authority

Rule 13ter.1 shall apply *mutatis mutandis* to the procedure before the International Preliminary Examining Authority.

13ter.3 [No Change] Sequence Listing for Designated Office

No designated Office shall require the applicant to furnish to it a sequence listing other than a sequence listing complying with the standard provided for in the Administrative Instructions.

Rule 49

Copy, Translation and Fee under Article 22

49.1 to 49.4 [No Change]

49.5 *Contents of and Physical Requirements for the Translation*

(a) [No change] For the purposes of Article 22, the translation of the international application shall contain the description (subject to paragraph (a-bis)), the claims, any text matter of the drawings and the abstract. If required by the designated Office, the translation shall also, subject to paragraphs (b), (c-bis) and (e),

(i) contain the request,

(ii) if the claims have been amended under Article 19, contain both the claims as filed and the claims as amended (the claims as amended shall be furnished in the form of a translation of the complete set of claims furnished under Rule 46.5(a) in replacement of all the claims originally filed), and

(iii) be accompanied by a copy of the drawings.

(a-bis) [No change] No designated Office shall require the applicant to furnish to it a translation of any text matter contained in the sequence listing part of the description if such sequence listing part complies with Rule 12.1(d) and if the description complies with Rule 5.2(b).

[COMMENT: This is an important principle, which should remain unchanged, though the issues around what is considered free text may change slightly. See the comment following paragraph 9 in Annex III.]

(b) to (l) [No change]

49.6 [No Change]

[Annex II follows]

PRELIMINARY DRAFT MODIFICATIONS
TO THE PCT ADMINISTRATIVE INSTRUCTIONS

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Section 101

Abbreviated Expressions and Interpretation

(a) In these Administrative Instructions:

(i) to (xi) [No change]

(xii) the expressions “sequence listing”, “sequence listing forming part of the international application” and “sequence listing not forming part of the international application” have the same meaning as in Annex C.

[COMMENT: The exact group of expressions which should be defined at this point will be considered following further consideration of the substantive changes which may be required.]

(b) [No change]

Section 204

Headings of the Parts of the Description

(a) The headings of the parts of the description shall preferably be as follows:

(i) to (vi) [No change]

(vii) [Deleted] ~~for matter referred to in Rule 5.2(a), “Sequence Listing”;~~

[COMMENT: It would only be possible to submit sequence listings as separate electronic files. Consequently, there will be no purpose for a section with a heading “Sequence Listing”. Any description of or reference to the sequence listing could be placed elsewhere in the main part of the description.]

(viii) for matter referred to in Rule 5.2(b), “Sequence Listing Free Text.”

(b) [No change]

Section 207

Arrangement of Elements and Numbering of Sheets of the International Application

(a) In effecting the sequential numbering of the sheets of the international application in accordance with Rule 11.7, the elements of the international application shall be placed in the following order:

(i) the request;

(ii) the description (if applicable, including the sequence listing free text referred to in Rule 5.2(b) but excluding the sequence listing part of the description referred to in [Rule 5\(2\)\(a\)](#) ~~item (vi) of this paragraph~~);

(iii) the claims;

(iv) the abstract;

(v) if applicable, the drawings;

(vi) [Deleted] ~~if applicable, the sequence listing part of the description.~~

(b) The sequential numbering of the sheets shall be effected by using the following separate series of numbering:

(i) the first series applying to the request only and commencing with the first sheet of the request;

(ii) the second series commencing with the first sheet of the description (as referred to in paragraph (a)(ii)) and continuing through the claims until the last sheet of the abstract;

(iii) if applicable, a further series applying to the sheets of the drawings only and commencing with the first sheet of the drawings; the number of each sheet of the drawings shall consist of two Arabic numerals separated by a slant, the first being the sheet number and the second being the total number of sheets of drawings (for example, 1/3, 2/3, 3/3);

~~(iv) if applicable, a further series applying to the sequence listing part of the description, commencing with the first sheet of that part.~~

(c) Any sequence listing shall be presented as a compliant sequence listing in the form of an electronic file in XML format, which is not a page-based format and thus does not require page numbering.

[COMMENT: The above paragraph is not strictly necessary as it is of a merely explanatory nature. However, it may be worth considering in order to avoid concern that a section of the international application might have been omitted accidentally.]

Section 208
Sequence Listings

Any sequence listing, ~~whether on paper or in electronic form,~~ whether forming part of the international application or not forming part of the international application, shall comply with Annex C.

Section 313

Documents Filed with the International Application; Manner of Marking the Necessary Annotations in the Check List

(a) Any power of attorney, any priority document, any fee calculation sheet and any separate sheet referred to in Section 209(a) containing indications as to deposited biological material, filed with the international application shall accompany the record copy; any other document referred to in Rule 3.3(a)(ii) shall be sent only at the specific request of the International Bureau. If any document which is indicated in the check list as accompanying the international application is not, in fact, filed at the latest by the time the record copy leaves the receiving Office, that Office shall so note on the check list and the said indication shall be considered as if it had not been made.

(b) Where, under Rule 3.3(b), the receiving Office itself completes the check list, that Office shall enter, in the margin, the words "COMPLETED BY RO" or their equivalent in the language of publication of the international application. Where only some of the indications are completed by the receiving Office, the said words and each indication completed by that Office shall be identified by an asterisk.

~~(c) [Deleted] Any sequence listing not forming part of the international application, whether on paper or in electronic form, that is furnished for the purposes of the international search to the receiving Office together with the international application or subsequent to the filing of the international application, shall be transmitted to the International Searching Authority together with the search copy. Where such a sequence listing is received by the receiving Office after the transmittal of the search copy, that sequence listing shall be promptly transmitted to the International Searching Authority.~~

[COMMENT: According to proposed Rule 5.2(a-bis), all sequence listings filed together with the international application would be considered part of the description – there would be no need or possibility to file a second sequence listing, not forming part of the description, for the purposes of international search.]

(c) Where an international application is filed on paper, ~~or where the international application is filed in electronic form but it is either not possible or not practical to include the sequence listing within the package containing the remainder of the international application,~~ any sequence listing shall be filed on a physical medium in accordance with the procedures set out in Annex C. Each receiving Office shall notify the International Bureau of the forms of physical media accepted for this purpose. The International Bureau shall promptly publish details of the notification in the Gazette.

(d) Paragraph (c) shall apply *mutatis mutandis* to international applications filed in electronic form where any sequence listings in the application were not included within the package containing the remainder of the international application.

Section 513
Sequence Listings

(a) Where the International Searching Authority receives a correction of a defect under Rule 13^{ter}.1(f), it shall:

(i) indelibly mark, in the upper right-hand corner of each replacement sheet, the international application number and the date on which that sheet was received;

(ii) indelibly mark, in the middle of the bottom margin of each replacement sheet, the words "SUBSTITUTE SHEET (Rule 13^{ter}.1(f))" or their equivalent in the language of publication of the international application;

(iii) indelibly mark on the letter containing the correction, or accompanying any replacement sheet, the date on which that letter was received;

(iv) keep in its files a copy of the letter containing the correction or, when the correction is contained in a replacement sheet, the replaced sheet, a copy of the letter accompanying the replacement sheet, and a copy of the replacement sheet;

(v) promptly transmit any letter and any replacement sheet to the International Bureau, and a copy thereof to the receiving Office.

[COMMENT: The procedures concerning the sequence listing free text in the main part of the description would remain unchanged.]

(b) Where the international search report and the written opinion of the International Searching Authority are based on a [compliant](#) sequence listing not forming part of the international application but furnished for the purposes of the international search, the international search report and the written opinion of the International Searching Authority shall so indicate.

(c) Where a meaningful international search cannot be carried out and a meaningful written opinion, as to whether the claimed invention appears to be novel, to involve an inventive step (to be non-obvious) and to be industrially applicable, cannot be established because a [compliant](#) sequence listing is not available to the International Searching Authority ~~in the required form~~, that Authority shall so state in the international search report or declaration referred to in Article 17(2)(a), and in the written opinion.

(d) ~~The International Searching Authority shall indelibly mark, on the first sheet of any sequence listing on paper which does not form part of the international application but was furnished for the purposes of the international search, the words “SEQUENCE LISTING NOT FORMING PART OF THE INTERNATIONAL APPLICATION” or their equivalent in the language of publication of the international application.~~ Where ~~such~~ [a](#) sequence listing [for the purposes of the international search](#) is furnished ~~in electronic form~~ on a physical medium, that Authority shall physically label that medium [in accordance with the procedures in Annex C](#) ~~accordingly~~.

[COMMENT: It is not necessary to regulate the metadata used internally by International Searching Authorities to identify the different types of sequence listing which have been transmitted electronically, rather than submitted on physical media; the means of identifying the files for the purpose of exchange with the International Bureau or other Offices are set out in Annex F and/or the “minspec” document exchange specification.]

(e) The International Searching Authority shall:

(i) keep in its files one copy of any sequence listing, ~~whether on paper or in electronic form,~~ which does not form part of the international application but was furnished for the purposes of the international search; and

(ii) ~~where the sequence listing which does not form part of the international application but was furnished for the purposes of the international search is in electronic form,~~ transmit one copy thereof to the International Bureau together with the copy of the international search report. If that listing ~~in electronic form~~ is filed on a physical medium in less than the number of copies required by the International Searching Authority, that Authority shall be responsible for the preparation of the additional copy and shall have the right to fix a fee for performing that task and to collect such fee from the applicant.

(f) ~~Any~~ Each International Searching Authority ~~which requires, for the purposes of the international search, the furnishing of a sequence listing in electronic form~~ shall notify the International Bureau ~~accordingly. In that notification, the Authority shall specify~~ of the means of transmittal of the sequence listing ~~in electronic form~~ accepted by it in accordance with Annex F. The International Bureau shall promptly publish details of the notification in the Gazette.

[COMMENT: It would be mandatory for all International Searching Authorities to accept sequence listings in electronic form, though this could be limited to physical media.]

Section 610
Sequence Listings

(a) Where the written opinion of the International Preliminary Examining Authority or the international preliminary examination report is based on a [compliant](#) sequence listing not forming part of the international application but furnished for the purposes of the international preliminary examination, the written opinion and the international preliminary examination report of the International Preliminary Examining Authority shall so indicate.

(b) Where a meaningful written opinion of the International Preliminary Examining Authority cannot be established, or a meaningful international preliminary examination cannot be carried out, as to whether the claimed invention appears to be novel, to involve an inventive step (to be non-obvious) and to be industrially applicable, because a [compliant](#) sequence listing is not available to the International Preliminary Examining Authority ~~in the required form~~, that Authority shall so state in the written opinion and in the international preliminary examination report.

(c) ~~The International Preliminary Examining Authority shall indelibly mark, on the first sheet of any sequence listing on paper which does not form part of the international application but was furnished for the purposes of the international preliminary examination, the words “SEQUENCE LISTING NOT FORMING PART OF THE INTERNATIONAL APPLICATION” or their equivalent in the language of publication of the international application.~~ Where ~~such a~~ [sequence listing for the purposes of the international preliminary examination](#) is furnished in ~~electronic form~~ on a physical medium, that Authority shall physically label that medium [in accordance with the procedures in Annex C](#) ~~accordingly~~.

[COMMENT: As for Section 513(d).]

(d) The International Preliminary Examining Authority shall keep in its files one copy of any sequence listing, ~~whether on paper or in electronic form,~~ which does not form part of the international application but was furnished for the purposes of the international preliminary examination.

(e) ~~Any~~ Each- International Preliminary Examining Authority ~~which requires, for the purposes of the international preliminary examination, the furnishing of a sequence listing in electronic form~~ shall notify the International Bureau ~~accordingly. In that notification, the Authority shall specify~~ of the means of transmittal of the sequence listing ~~in electronic form~~ accepted by it in accordance with Annex F. The International Bureau shall promptly publish details of the notification in the Gazette.

[COMMENT: As for Section 513(f).]

(f) Where the national Office or intergovernmental organization that acted as the International Searching Authority also acts as the International Preliminary Examining Authority, any compliant sequence listing not forming part of the international application but furnished to that Office or organization for the purposes of the international search shall be considered to have been furnished to it also for the purposes of the international preliminary examination.

Section 703

Filing Requirements; Basic Common Standard

(a) An international application may, subject to this Part, be filed in electronic form if the receiving Office has notified the International Bureau in accordance with Rule 89*bis*.1(d) that it is prepared to receive international applications in such form.

(a-bis) All receiving Offices shall be required, in the circumstances referred to in Section 313(c), to accept the filing of sequence listings in electronic form on physical media and shall specify at least one form of physical medium in accordance with Annex F which it accepts for the filing of such sequence listings. Preferably, such media shall include at least one form of medium accepted by each International Searching Authority which is competent for searching international applications filed with it.

[COMMENT: Given the difficulties of obtaining notifications from all receiving Offices, most of which would never actually receive such a physical medium, it may be appropriate to indicate a default, where in the absence of a notification the receiving Office must accept a sequence listing on a physical medium of a type accepted by the relevant International Searching Authority. Consideration might be given to an amendment to Rule 19.4, allowing receiving Offices which do not wish to deal with physical media to forward the international application to the International Bureau to act as receiving Office.]

(b) to (f) [No change]

Section 707

Calculation of International Filing Fee and Fee Reduction

(a) Where an international application is filed in electronic form, the international filing fee shall, subject to paragraph (a-bis), be calculated on the basis of the number of sheets that the application would contain if presented as a print-out complying with the physical requirements prescribed in Rule 11.¹

(a-bis) Where ~~a sequence listing is contained in an~~ the international application as filed contains a sequence listing in electronic form, the calculation of the international filing fee shall, in the calculation of the number of sheets, not take into account any ~~sheet of the sequence listing if that listing is presented as a separate part of the description in accordance with Rule 5-2(a) and is in the electronic document format specified in paragraph 40 of Annex C~~ material contained in an electronic file which appears to the receiving Office to be a sequence listing.

[COMMENT: The receiving Office would not be required to perform any checks on the format of the sequence listings – notably, receiving Offices which have no electronic filing systems and simply accept the listing on a physical medium may assume that any appropriately labeled disk is a compliant listing. This is intended simply to allow page fees to be collected in cases where a file is provided which is clearly not intended to be a sequence listing, for example if a PDF file of further description or drawings had been attached, mislabeled as sequence listings.]

(b) Item 4(b), (c) and (d) of the Schedule of Fees annexed to the Regulations shall apply to reduce the fees payable in respect of an international application filed in electronic form with a receiving Office which has notified the International Bureau under Section 710(a) that it is prepared to receive international applications in electronic form or which has decided to receive such an application in accordance with Section 703(d).

¹ *Editor's Note:* Noting that Rule 11 leaves some flexibility as to the margins of the sheets (see Rule 11.6) and the size of the characters (see Rule 11.9(d)), the international filing fee should be calculated on the basis of the number of sheets that the application would contain if presented as a print-out complying with the minimum margin and character size requirements. In practice, however, the receiving Office should not print out the international application but rather rely on the number of pages of the international application as calculated by the electronic filing software and indicated in the request.

Section 710

Notification and Publication of Receiving Offices'

Requirements and Practices

(a) A notification by a receiving Office to the International Bureau under Rule 89*bis*.1(d) and Section 703(a) that it is prepared to receive international applications in electronic form shall indicate, where applicable:

(i) the electronic document formats (including, where applicable, the versions of such electronic document formats), means of transmittal, types of electronic packages, electronic filing software and types of electronic signature specified by it under Section 703([a-bis](#)), (b)(i) to (iv) and (c), and any options specified by it under the basic common standard;

(ii) the conditions, rules and procedures relating to electronic receipt, including hours of operation, choices for processes to verify or acknowledge receipt, choices for electronic communication of invitations and notifications, any methods of online payment, details concerning any help desks, electronic and software requirements and other administrative matters related to the filing in electronic form of international applications and related documents;

(iii) the kinds of documents which may be transmitted to or by the Office in electronic form;

(iv) whether and under what conditions the Office accepts the filing under Section 706(a) and (f), of documents in pre-conversion formats and the electronic document format(s) (including, where applicable, the versions of such electronic document format(s)) accepted by it under that Section;

(v) procedures for notification of applicants and procedures which applicants may follow as alternatives when the electronic systems of the Office are not available;

(vi) the certification authorities that are accepted by the Office, and the electronic addresses of the certificate policies under which certificates are issued;

(vii) the procedures relating to access to the files of international applications filed or stored in electronic form.

(b) The receiving Office shall notify the International Bureau of any change in the matters previously indicated by it in a notification under Section 705*bis*(a) or paragraph (a) of this Section.

(c) The International Bureau shall promptly publish in the Gazette any notification received by it under Section 705*bis*(a) or paragraph (a) or (b) of this Section.

(d) The effective date of any change notified under paragraph (b) shall be as specified by the receiving Office in the notification, provided that any change which restricts filing options shall not be effective earlier than two months after the date of publication of the notification of the change in the Gazette.

[Annex III follows]

PRELIMINARY DRAFT REPLACEMENT FOR
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ANNEX C
INSTRUCTIONS RELATING TO THE PRESENTATION
OF NUCLEOTIDE AND AMINO ACID SEQUENCE LISTINGS
IN INTERNATIONAL PATENT APPLICATIONS UNDER THE PCT

INTRODUCTION

1. This Annex provides Instructions for the procedures involved in the filing and processing of sequence listings in international applications. The requirements for the presentation of the listings are set out in WIPO Standard ST.26, subject to the specific requirements set out below.

DEFINITIONS

2. For the purposes of these Instructions:

(i) the expression “sequence listing” has the same meaning as defined in WIPO Standard ST.26, having regard to paragraph 3, below;

(ii) “sequences”, “nucleotides” and “amino acids” have the same meanings as in WIPO Standard ST.26.

(iii) the expression “sequence listing forming part of the international application” means a sequence listing contained in the international application as filed, including any sequence listing or part thereof which is included in the international application under Rule 20.5(b) or (c), which is considered to have been contained in the international application under Rule 20.6(b), or which has been corrected under Rule 26, rectified under Rule 91 or amended under Article 34(2); or a sequence listing included in the international application by way of an amendment under Article 34(2)(b) of the description in relation to sequences contained in the international application as filed;

(iv) the expression “sequence listing not forming part of the international application” means a sequence listing which does not form part of the international application but is furnished for the purposes of the international search or international preliminary examination.

RELATIONSHIP WITH WIPO STANDARD ST.26

3. Following any revision of WIPO Standard ST.26, the Director General shall decide a date from which the revised version of the Standard shall apply to international applications and publish that information in the Gazette. Sequence listings shall be presented in accordance with the version of WIPO Standard ST.26 so applicable to international applications on the international filing date.

SEQUENCES WHICH MUST BE PRESENTED IN A LISTING

4. In accordance with WIPO Standard ST.26, a sequence for which inclusion in a sequence listing is required for the purposes of Rule 5.2 is one that is disclosed anywhere in an international application by enumeration of its residues and can be represented as:

(a) an unbranched sequence or a linear region of a branched sequence containing ten or more specifically defined nucleotides, wherein adjacent nucleotides are joined by:

(i) a 3' to 5' (or 5' to 3') phosphodiester linkage; or

(ii) any chemical bond that results in an arrangement of adjacent nucleobases that mimics the arrangement of nucleobases in naturally occurring nucleic acids; or

(b) an unbranched sequence or a linear region of a branched sequence containing four or more specifically defined amino acids, wherein adjacent amino acids are joined by peptide bonds.

5. In accordance with WIPO Standard ST.26, a sequence listing must not include, as a sequence assigned its own sequence identification number, any sequences having fewer than ten specifically defined nucleotides, or fewer than four specifically defined amino acids.

[COMMENT: This is a fundamental aspect of what must and must not be included in a sequence listing and is very unlikely to change between versions of ST.26. It is also fundamentally different from most of the formatting issues in that it needs to be actively understood by the applicant, rather than being a matter which will be handled transparently by the software used for preparing the listing. As such, it seems useful to expressly include these

provisions within this Annex, rather than expecting applicants to find the reference within WIPO Standard ST.26.]

PRESENTATION OF SEQUENCE LISTINGS AND FREE TEXT

6. A sequence listing compliant with WIPO Standard ST.26 takes the form of an electronic file in XML format. In accordance with Rule 5.2, the sequence listing part of the description shall be presented as separate from the main part of the description. It is unnecessary and usually undesirable to set out the sequences themselves elsewhere in the description.

7. According to WIPO Standard ST.26, qualifiers are used to supply information about features in addition to that conveyed by the feature key and feature location. There are three types of value formats to accommodate different types of information conveyed by qualifiers: (i) free text; (ii) controlled vocabulary or enumerated values (for example, a number or date); and (iii) sequences. Free text is a type of value format for certain qualifiers (as indicated in Annex I to WIPO Standard ST.26) that is presented in the form of a descriptive text phrase that should preferably be in the English language. In any case, such text phrases shall only use characters from the Unicode Basic Latin code table (excluding certain reserved characters defined in WIPO Standard ST.26), which precludes including free text in several of the PCT languages of publication.

8. The qualifiers indicated in Annex I of WIPO Standard ST.26 as being “free text” fall into several categories. Some are entirely language independent since, while being described as free text and not controlled by the schema, the expected format is specified as a number or code which does not vary between languages. Some may be effectively language-independent because the expected values are personal names or internationally used terms for an organism (for example “homo sapiens”). Some are always language dependent, taking the form of genuinely free text comments. Where the sequence listing part of the description contains any language-dependent free text, that free text shall also appear in the main part of the description in the language thereof. It is recommended that the free text in the language of the main part of

the description be put in a specific section of the description called “Sequence Listing Free Text”.

9. For the purposes of Rule 49.5(a-bis), a sequence listing filed as part of the international application shall be considered to comply with Rule 12.1(d) only if the language-dependent free text is in English. However, the International Searching Authority and International Preliminary Examining Authority shall not require the applicant to furnish a sequence listing for the purposes of international search or preliminary examination solely because the listing forming part of the international application contains free text in a language other than English, provided that the free text is included in the “sequence listing free text” part of the description in the language of the international application or the translation provided for publication, international search or international preliminary examination, as the case may be.

[COMMENT: One of the key objectives of WIPO Standard ST.26 was to permit the sequences to be imported efficiently by database suppliers, who expect any language-dependent annotations to be in English, even where that is not the main language of the country in which they are based. It is not practical to strictly require this in the international phase because amendment is only possible using Chapter II and most receiving Offices would not be capable of making the checks which would be necessary.

The above provisions are intended to allow the application to proceed efficiently within the international phase, but for English language listings to be required in the national phase where it appears appropriate in order to provide high quality information to database providers.

A final version of this section of the Annex may need to include guidance on how best to set out the free text within the sequence listing free text part of the description, based on the experience gained in extracting and presenting the information as part of development of the relevant IT tool.

Examples of the different types of free text qualifier from WIPO Standard ST.26 include the following. It will be noted that all qualifiers defined as free text within WIPO Standard ST.26 currently include the note “this value may require translation for National/Regional purposes” irrespective of the type of free text involved:

(i) “Free text” is actually a number in a specific format – not language-dependent, nor free text in the normal sense

6.16.	Qualifier	EC_number
	Definition	Enzyme Commission number for enzyme product of sequence
	Value format	free text

(NOTE: this value may require translation for National/Regional procedures)

Example	<pre><INSDQualifier_value>1.1.2.4</INSDQualifier_value> <INSDQualifier_value>1.1.2.-</INSDQualifier_value> <INSDQualifier_value>1.1.2.n</INSDQualifier_value></pre>
Comment	valid values for EC numbers are defined in the list prepared by the Nomenclature Committee of the International Union of Biochemistry and Molecular Biology (NCIUBMB) (published in Enzyme Nomenclature 1992, Academic Press, San Diego, or a more recent revision thereof). The format represents a string of four numbers separated by full stops; up to three numbers starting from the end of the string may be replaced by dash "-" to indicate uncertain assignment. Symbol "n" may be used in the last position instead of a number where the EC number is awaiting assignment. Please note that such incomplete EC numbers are not approved by NC-IUBMB.

(ii) "Free text" is usually a personal or internationally used form of name (but may be a local species name, which would be language dependent)

6.10.	Qualifier	collected_by
	Definition	name of persons or institute who collected the specimen
	Value format	free text
		(NOTE: this value may require translation for National/Regional procedures)
	Example	<pre><INSDQualifier_value>Dan Janzen</INSDQualifier_value></pre>
6.44.	Qualifier	organism
	Definition	scientific name of the organism that provided the sequenced genetic material, if known, or the available taxonomic information if the organism is unclassified; or an indication that the sequence is a synthetic construct
	Value format	free text
		(NOTE: this value may require translation for National/Regional procedures)
	Example	<pre><INSDQualifier_value>Homo sapiens</INSDQualifier_value></pre>

(iii) "Free text" is truly free text and will always be language dependent

6.40.	Qualifier	note
	Definition	any comment or additional information
	Value format	free text
		(NOTE: this value may require translation for National/Regional procedures)
	Example	<pre><INSDQualifier_value>A comment about the feature</INSDQualifier_value></pre>

Further consideration of these issues will be needed as part of the development of the IT tools, possible further modification of WIPO Standard ST.26, what is appropriate to ask of PCT applicants in terms of extracting and translating text and what "free text" within the main body of the application may be useful and what may be active barriers to effective reading by patent information users. Issues include:

- (i) the extent to which non-latin characters may be accepted by the validation tool despite being forbidden by the standard;

- (ii) the way in which terms requiring translation can be extracted by the software tool for inclusion into the sequence listing free text part of the description and whether this should always include all qualifiers designated as free text within ST.26;
- (iii) whether the software tools should provide features to assist the replacement of free text originally in a language not in English with an English language translation, either to create a new sequence listing file or by creating a translation file to accompany the original sequence listing which can map the translated texts to the correct points within the original XML;
- (iv) whether the frequency of use of qualifiers which are described as free text but are in fact highly regulated would justify the sub-division of free text into “language-dependent” and “language-independent” categories; and
- (v) if it is desirable to separate the free text into different categories, whether the software tool can offer a sufficiently simple interface to deal with the qualifiers which are sometimes, but not always, language-dependent.]

SEQUENCE LISTINGS AND SEQUENCES FORMING PART OF THE INTERNATIONAL APPLICATION AS FILED

10. In accordance with Rule 5.2(a-bis), any file contained in the international application as filed, purporting or appearing to be a sequence listing shall be considered to be part of the description, whether or not a listing is referred to in the main part of the request and whether or not the file is in fact compliant with WIPO Standard ST.26.

International Applications Filed in Electronic Form

11. International applications containing a sequence listing shall preferably be filed in fully electronic form. Preferably, the sequence listing shall form part of a package filed in accordance with Annex F with the listing indexed in accordance with the standards in that Annex.

[COMMENT: The relationship between Annexes C and F will need to be given further consideration once the required principles are clear.]

12. Nevertheless, any receiving Office may accept a sequence listing as a file provided separately from the main package on the date of filing and shall accept such a separate listing in any case where it is not practical for the applicant to include the listing as part of the main

package, for example because the file size is too large to be handled by the software used for preparing or receiving the main part of the international application.

International Applications Filed on Paper

13. Where the international application is filed on paper, the receiving Office shall accept a sequence listing filed on a separate physical medium of a type accepted by that Office.

Sequence Listings Filed on Physical Media

14. Any physical media on which a sequence listing is filed together with an international application filed on paper or separately from the main part of an international application filed in electronic form shall be clearly labeled “Sequence Listing”, or its equivalent in the language of publication, and the receiving Office shall add the international application number. Preferably, the physical media used for a sequence listing forming part of the international application as filed shall be of a type accepted by both the receiving Office and the International Searching Authority.

[COMMENT: It does not appear necessary to have special provisions for dealing with the case where a sequence listing and the main part of the application are received by the receiving Office on different days. These would be handled in exactly the same way as cases where other parts of an international application are received on different ways in accordance with Article 11 and Rule 20.5(c) – that is, the application would be accorded an international filing date according to the date of the later received part.]

Purported Sequence Listings Not Compliant with the Standard

15. The receiving Office shall not be required to validate whether a sequence listing is compliant with WIPO Standard ST.26. However, where the Office becomes aware of a defect, for example because its online filing processes or other Office procedures check the sequence listing file using the validation tool provided for the purpose by the International Bureau, the Office shall notify the applicant accordingly.

16. For the purposes of section 707(a-bis), any file which appears to be a sequence listing shall not be taken into account for the purpose of calculating the number of pages for the filing fee. Page fees should, however, be charged if it is seen that a file in fact contains material which is clearly not a sequence listing, such as PDF pages of description or drawings mislabeled as a sequence listing.

[COMMENT: This is basically intended to say that anything which is properly trying to be a sequence listing should not be treated as pages for the purpose of the filing fee even if there are minor defects, but that proposed Rule 5.2(a-bis) cannot be used to add normal description (for example, as a PDF file) into the application while avoiding the associated page fees.]

ACCEPTED TYPES OF PHYSICAL MEDIA

17. Each receiving Office and International Authority shall notify the International Bureau of at least one of the physical media types referred to in Appendix IV of Annex F which it accepts for the purpose of the receipt of sequence listings. The International Bureau shall promptly publish any such notification in the Gazette. In the absence of such a notification, the Office or Authority shall accept physical media of any type which has been the subject of a notification in accordance with Section 710(a) or (b), or else any of the media referred to in Appendix IV of Annex F.

EXTREMELY LARGE FILES

18. Where a sequence listing is too large to include on a single physical medium, it may be split such that the files can be rejoined to form one single contiguous file without any missing or repeating contents in accordance with the procedures set out in paragraphs 2(c) and (c-bis) of Appendix IV to Annex F of these Administrative Instructions. In addition to the physical labeling appropriate to the type of sequence listing, the physical media shall each be numbered, for example "DISK 1/3", "DISK 2/3", "DISK 3/3".

[COMMENT: This requirement may be modified in the course of development of the IT tools if it emerges that a different method of splitting the file would be more effective for either creating or processing very large listings.]

SEQUENCE LISTINGS FURNISHED FOR THE PURPOSES OF INTERNATIONAL SEARCH OR PRELIMINARY EXAMINATION

19. Any sequence listing furnished under Rule 13*ter*, 45*bis*.5(c) or 76.5 to an International Authority for the purposes of international search or preliminary examination shall, where possible, in compliance with WIPO Standard ST.26, maintain the original numbering of the sequences in the application as filed, using “intentionally skipped sequence” identifiers where necessary. Otherwise, the sequences shall be numbered in compliance with that Standard in the order in which they appear in the international application.

[COMMENT: WIPO Standard ST.26 requires sequences to have consecutive numbering. Usually, the sequences in the application as filed will either have no numbering (in which case they should be numbered in the order in which they appear) or else they will have sequential numbering which can be reused in the sequence listing for the purposes of international search or preliminary examination. However, in exceptional cases (typing errors or incorporation by reference), there may be repeated numbers or other situations which would require an alternative approach to be used.]

20. In accordance with Rule 5.2, any sequence listing referred to in paragraph 14, above, shall contain all the sequences in the international application as filed which meet the criteria referred to in paragraph 4 above and shall not go beyond the disclosure as filed. The listing shall be accompanied by a statement to that effect.

21. Where such a listing is furnished on physical media, the media shall be labeled “Sequence Listing Not Forming Part of the International Application”, or its equivalent in the language of publication, together with the international application number.

CORRECTION, RECTIFICATION AND AMENDMENT OF SEQUENCE LISTINGS

22. Any correction under Rule 26, rectification under Rule 91 or amendment under Article 34(2)(b) of the description submitted in relation to a sequence listing contained in the international application as filed and any sequence listing included in the international application by way of an amendment under Article 34(2)(b) of the description in relation to sequences contained in the international application as filed shall be made using a complete

sequence listing compliant with WIPO Standard ST.26 including the relevant correction, rectification or amendment. The nature of the correction, rectification or amendment shall be clearly explained in an accompanying letter.

23. The sequences in any sequence listing referred to in paragraph 17 shall, where possible, in compliance with WIPO Standard ST.26, maintain the original numbering of the sequences in the application as filed, using “intentionally skipped sequence” identifiers where necessary.

Otherwise, the sequences shall be numbered in compliance with that Standard in the order in which they appear in the international application.

24. Where the sequence listing as proposed to be corrected, rectified or amended is presented on physical media, the media shall be labeled “Sequence Listing – Correction”, “Sequence Listing – Rectification” or “Sequence Listing – Amendment”, as the case may be, or the equivalents in the language of publication, together with the international application number.

PROCEDURE BEFORE DESIGNATED AND ELECTED OFFICES

25. For the purposes of the procedure before a designated or elected Office before which the processing of an international application which contains the disclosure of one or more nucleotide and/or amino acid sequences has started (see Rule 13*ter*.3):

(i) any reference to the receiving Office or the competent authority shall be construed as a reference to the designated or elected Office concerned;

(ii) any reference to a sequence listing which is included in the international application by way of a rectification under Rule 91 or an amendment under Article 34(2)(b) of the description in relation to sequences contained in the application as filed shall be construed to also include any sequence listing included in the application, under the national law applied by the designated or elected Office concerned, by way of a rectification (of an obvious mistake) or amendment of the description in relation to sequences contained in the application as filed;

(iii) any reference to a sequence listing furnished for the purposes of international search or international preliminary examination shall be construed to also include any such listing furnished to the designated or elected Office concerned for the purposes of national search or examination by that Office;

(iv) the designated or elected Office concerned may invite the applicant to furnish to it, within a time limit which shall be reasonable under the circumstances, for the purposes of national search and/or examination, a sequence listing in electronic form complying with this Standard, unless such listing in electronic form is already available to that Office in a form and manner acceptable to it.

[COMMENT: This paragraph is a direct copy of paragraph 42 of existing Annex C. It is not intended to change the principles involved regarding the processing of sequence listings at designated and elected Offices, except for the fact that the Offices should be required to accept sequence listings according to WIPO Standard ST.26 rather than ST.25 for international applications filed on or after the date on which the new provisions come into force. However, the paragraph does not read well onto the other proposed modifications to the Administrative Instructions and further consideration will be required on drafting once the substance of the remainder is agreed.]

[End of Annex III and of document]