

C. PCT 1642 May 17, 2022

Madam, Sir,

Proposed modifications of the PCT Receiving Office Guidelines ("the RO Guidelines") and the PCT International Search and Preliminary Examination Guidelines ("the ISPE Guidelines")

This Circular is addressed to your Office in its capacity as a Receiving Office (RO), an International Searching Authority (ISA), an International Preliminary Examining Authority (IPEA), an Authority specified for supplementary search, and/or a designated or elected Office under the Patent Cooperation Treaty (PCT) for the purposes of consultation. It is also addressed to certain non-governmental organizations representing users of the PCT System.

The purpose of this Circular is to consult on proposed modifications of the RO Guidelines and the ISPE Guidelines (contained in the Annexes) to take into account the amendments to the Regulations under the PCT ("the Regulations") adopted by the PCT Assembly at its fifty-third session which implement WIPO Standard ST.26 ("ST.26") as the new standard for the presentation of nucleotide and amino acid sequences in international applications (see document PCT/A/53/3, Annex I and document PCT/A/53/4, paragraph 25). As the amendments to the Regulations will enter into force on July 1, 2022, it is proposed that these Guidelines, as modified, also enter into force on the same date. It is recalled that modifications of the Administrative Instructions under the PCT ("the Administrative Instructions") and the relevant Forms for this purpose have been promulgated via Circular C. PCT 1636, dated February 9, 2022. Accordingly, the proposed modifications of the above Guidelines also reflect the modifications of the Administrative Instructions and Forms already promulgated.

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Detailed explanations of the proposed modifications are provided below, noting that explanations may not be provided in every case, especially when the proposed modifications are self-evident or of an editorial nature.

I. Proposed modifications of the RO Guidelines

In paragraph 41, it is proposed to slightly adjust the order of the sentences to better align them with the contents of the international application.

The proposed modifications in paragraph 55 are consequential to the amendment of Rule 12.1(d).

Paragraph 56A is added to specify that the RO is not required to check whether the language-dependent free text in a sequence listing is filed in a language accepted under Rule 12.1(d). If the RO nevertheless notices that the language-dependent free text is not filed in an accepted language, it transmits the international application to the International Bureau of the World Intellectual Property Organization (WIPO) as receiving Office under amended Rule 19.4(a)(ii). A corresponding change is also made in paragraph 274.

Paragraphs 139, 141, 148 and 149 are modified to reflect that under ST.26 a sequence listing may only be filed as an XML file and to remove any reference to sheets. Consequential to the amendments to Rule 5.2(a) and Annex C of the Administrative Instructions ("Annex C"), paragraph 222 is modified to reflect the new standard and any ex officio correction to Form PCT/RO/101 by the RO.

In case a separate electronic file disclosing sequences in a non-ST 26 compliant file format is furnished (e.g., ST.25 TXT or PDF), new paragraphs 222A to 222C provide guidance on how to process such a file.

Paragraph 223 specifies that the RO is not required to examine any sequence listing for compliance with ST.26 and should only confirm the presence of an XML file appearing to be a sequence listing. If the Office notices any discrepancies in the general information part of the description, paragraphs 223A and 223B clarify that the Office may draw the fact to the applicant's attention and provide guidance on the processing of corrections of sequence listings under Rule 26 (see Annex C, paragraphs 33 to 35).

Paragraphs 224 to 226 are deleted as sequence listings must be furnished in XML format under ST.26 and the procedure dealing with any such file furnished in a non-compliant format is dealt with in paragraphs 222A to 222C.

For any sequence listing furnished after the filing of the international application, paragraph 227 is modified to clarify that the RO should check with the applicant in case the Office has a doubt as to whether the sequence listing is furnished to complete or correct the international application under Rules 20.5 and 20.5*bis*, or for search purposes under Rule 13*ter*. The procedure as to the processing of such a sequence listing furnished on a physical medium is dealt with in new paragraph 227A.

Paragraphs 227B and 227C are added to provide guidance in case a sequence listing is furnished to confirm incorporation by reference and specifies that the RO should make the appropriate markings in the file name or metadata of the XML file (see Annex C, paragraphs 37 and 38).

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New paragraphs 227D and 227E provide guidance on the transmission of sequence listings between Offices and clarify that for any sequence listing received on a physical medium, the Office may extract the file and transmit it between Offices online (see Annex C, paragraphs 42 and 43).

Consequential to modified Section 707, paragraph 242 specifies that no fee is charged for any electronic file appearing to be a sequence listing in ST.26 XML file format.

Further changes to paragraph 274 reflect that, under amended Rule 19.4(a), the national Office transmits the international application to the International Bureau as receiving Office if it cannot accept the international application either because of the language of any sequence listing part of the description or because of its electronic filing format.

Paragraph 290 is modified consequential to the deletion of Section 313(c) reflecting the change that there is usually no need to furnish a sequence listing only for the purpose of international search at the time of filing and to include a reference to the accompanying statement in case of any sequence listing furnished under Rule 13*ter* to the RO.

Lastly, paragraph 307 is modified to remove the reference to WIPO Standard ST.25.

The paragraphs of the RO Guidelines which are proposed to be modified or added are set out in Annex I to this Circular. Certain paragraphs that are not proposed to be modified have been included for ease of reference.

II. Proposed modifications of the ISPE Guidelines

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Paragraph 2.06 is proposed to be modified following the amendments to Rule 12.3, as a translation of the language-dependent free text of the sequence listing part of the description may be required. Similar changes are also made in paragraphs 15.14 and 15.14A.

Paragraph 2.10 is proposed to be modified following the amendments to Rule 13*ter*.1(a). In particular, the ISA may invite the applicant to furnish a compliant sequence listing if its language requirement for the sequence listing has not been met.

Paragraph 4.03 is proposed to be modified consequential to the modifications of Section 204(a) of the Administrative Instructions.

Paragraph 4.15 is proposed to be modified to clarify that, following the new standard provided for in Annex C of the Administrative Instructions (ST.26), a sequence listing should be furnished only where the international application contains disclosure of any nucleotide and/or amino acid sequences having ten or more specifically defined nucleotides or four or more specifically defined amino acids. Similar changes are also made in paragraphs 9.39, 15.12, 15.86, 16.26, 17.21 and 18.18.

In paragraph 9.39, it is clarified that failure to furnish a sequence listing in an accepted language may also lead to a conclusion that a meaningful search or preliminary examination cannot be conducted. The sentence on the possible requirement for a paper form sequence listing has become outdated and is thus deleted.

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Paragraph 15.12 is proposed to be modified to clarify the process for inviting the applicant to furnish a sequence listing or a translation thereof for the purposes of international search. Some other related changes are also proposed. Moreover, the penultimate sentence is proposed to be moved to the end of Chapter 22 as the sentence deals with administrative matters rather than examination considerations of the examiner.

Paragraph 15.13 is proposed to be deleted as a result of the amendments to Rule 5.2(b) and the deletion of Rule 13*ter*.1(f), as the free text will no longer be required to also appear in the main part of the description.

A new paragraph 15.14A is proposed to be introduced to provide detailed guidance for the ISA on how to examine the language aspects of a sequence listing and how to invite a translation if the requirement has not been met.

Paragraphs 15.86 and 15.87 concerning the supplementary international search procedure are proposed to be modified similarly and consequential to those changes made in paragraphs 15.12 concerning the international search procedure.

Paragraph 16.09 is proposed to be modified to reflect the new design of the international search report (Form PCT/ISA/210), wherein Box No. I, item 2 will be used to indicate that, although a compliant sequence listing or translation was required to be furnished but was not in fact furnished, the international search has nevertheless been carried out without such a sequence listing or translation. Corresponding changes referring to paragraph 15.12 are also made following the changes made in that paragraph.

Similarly, paragraph 16.26 is also proposed to be modified following the changes made in Form PCT/ISA/210 in respect of Box No. I.

Paragraph 17.21 is proposed to be modified following the changes made in the written opinion of the ISA (Form PCT/ISA/237), the written opinion of the IPEA (Form PCT/IPEA/408), and the international preliminary examination report (Form PCT/IPEA/409) in respect of the boxes concerning sequence listings. Among other things, a similar change to the above as explained in relation to paragraph 16.09 is made to allow for indicating that the opinion or report has been established without a compliant sequence listing or translation although it was required to be furnished.

Paragraph 17.37 is proposed to be modified to clarify that the failure to furnish the required translation of a sequence listing may also preclude any meaningful preliminary examination from being carried out.

In paragraph 18.12, it is proposed to correct an obsolete reference (in item (ii)) and also remove the reference to paper form of sequence listings (in item (vi)) as ST.26 only allows for electronic form.

In paragraph 18.17, similar changes as mentioned above are proposed to be made.

Paragraph 18.18 is proposed to be modified to clarify the process for inviting the applicant to furnish a sequence listing or a translation thereof for the purposes of international preliminary examination. Some other changes similar to above are also made.

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It is proposed to add a new section at the end of Chapter 22 to deal with the administrative procedures for the processing by the ISA and IPEA of sequence listings furnished specifically for the purposes of international search or preliminary examination. Specifically, two new paragraphs 22.60 and 22.61 are proposed to be added to reflect the administrative processing requirements provided for in the modified Sections 513(d) and (e) and 610(c) and (d) of the Administrative Instructions.

The paragraphs of the ISPE Guidelines which are proposed to be modified or added are set out in Annex II to this Circular. Certain paragraphs that are not proposed to be modified have been included for ease of reference.

III. Reminder

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The opportunity of this Circular is also taken to remind your Office, in its capacity as receiving Office, to notify the International Bureau of the language or languages of any language-dependent free text which it is prepared to accept under Rule 12.1(d) for the filing of the sequence listing part of the description in accordance with Section 332(a-bis) of the Administrative Instructions. Note that, if the accepted language of the language-dependent free text is not a language which your Office accepts for the filing of the main body of the international application, it must meet the requirements of Rule 12.1(b). The notification should also specify whether your Office permits the language-dependent free text to be filed in more than one language and, if so, any limitation on the second language. For more information, please refer to paragraphs 12 and 16 of Annex C of the Administrative Instructions.

IV. Comments on the proposed modifications of the RO Guidelines and the ISPE Guidelines

Your Office is invited to provide comments, if any, by June 10, 2022, by e-mail to: pct.legal@wipo.int.

Yours sincerely,

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Lisa Jorgenson

Deputy Director General

Patents and Technology Sector

Enclosures: Annex I — Proposed modifications of the PCT Receiving Office Guidelines

Annex II — Proposed modifications of the PCT International Search and Preliminary Examination Guidelines

PROPOSED MODIFICATIONS OF THE RECEIVING OFFICE GUIDELINES.

CHAPTER IV ARTICLE 11(1) CHECK; REQUIREMENTS FOR INTERNATIONAL FILING DATE

35 to 48. [No change]

Requirements for According an International Filing Date (Article 11(1))

39 to 40. [No change]

41. **Language**. The receiving Office checks whether the international application is in the prescribed language. For the purposes of according an international filing date, it is sufficient that the description, other than any sequence listing part thereof, and the claims are in the language, or one of the languages, which the receiving Office, under Rule 12.1(a), accepts for the filing of international applications. With regard to any sequence listing part of the description, see paragraph 56A. With regard to the language of the request, see paragraph 59. With regard to the language of the abstract and of any text matter of the drawings, see paragraph 62. With regard to any sequence listing part of the application, see paragraph 68. Where an international application is filed with a national Office, which acts as a receiving Office under the Treaty, by an applicant who is a resident or national of a Contracting State and the international application is not in a language accepted by that national Office but is in a language accepted by the International Bureau as receiving Office, Rule 19.4(a)(ii) applies (paragraphs 274 to 277).

42 to 54. [No change]

CHAPTER V LANGUAGE CHECK (ARTICLE 3(4)(i); RULES 12.1, 12.3, 12.4 AND 26.3 ter)

General

55. Pursuant to Article 3(4)(i), the international application (that is, all elements of the international application: request, description (other than any sequence listing part thereof), claims, abstract, any text matter of the drawings) must be in "a prescribed language." This requirement means that description (other than any sequence listing part thereof), claims, abstract and any text matter of the drawings must be in the language, or one of the languages, which the receiving Office, pursuant to Rule 12.1(a) and (d), accepts for the filing of international applications, and that the request must be in any language of publication which the receiving Office accepts for the filing of requests (Rule 12.1(c)). The languages of publication for

If the international application is filed with the United States Patent and Trademark Office as a receiving Office, all elements of the international application ether than any sequence listing part of the description (that is, request, description ether than any sequence listing part thereof, claims, abstract, any text matter of the drawings) must be in English (see Rule 20.1(c) and (d)). The language-dependent free text in any sequence listing part of the description may additionally be in a language other than English.

international applications are Arabic, Chinese, English, French, German, Japanese, Korean, Portuguese, Russian and Spanish (Rule 48.3(a)).

56. With regard to the description (other than any sequence listing part thereof) and claims, compliance with the requirement that the international application be in a prescribed language is a condition for according an international filing date (Article 11(1) and Rule 20.1(c)). If the description and/or the claims, or any part thereof (except for any sequence listing part of the description, see paragraphs 56A68 and 222), are not in such a language, the receiving Office must, subject to any required national security clearance and payment of any required fee, transmit the international application to the International Bureau as receiving Office (paragraphs 41 and 274 to 282).

56A. With regard to any sequence listing part of the description, the receiving Office is not required to check that the language-dependent free text is filed in a language accepted under Rule 12.1(d). Nevertheless, if the receiving Office notices that the language-dependent free text is not filed in an accepted language, the receiving Office transmits the international application under Rule 19.4(a)(ii) to the International Bureau as receiving Office (paragraphs 41 and 274 to 282).

57. [No change] With regard to the abstract, any text matter of the drawings and the request, compliance with requirements as to language is not a condition for according an international filing date. If the abstract or any text matter of the drawings does not comply with Article 3(4)(i) and Rule 12.3(a), that is, if those elements of the international application are not in the same language as the description and claims, the receiving Office proceeds as provided in Rule 26.3ter(a) (paragraph 63). If the request does not comply with Article 3(4)(i) and Rule 12.1(c), the receiving Office proceeds as provided for in Rule 26.3ter(c) (paragraph 60).²

58 to 65. [No change]

Language(s) Accepted for the Purposes of International Search and International Publication

66. [No change]

67. [No change] *Language Not Accepted for the Purposes of International Search*. Where the language in which the international application is filed is not accepted by the competent International Searching Authority chosen by the applicant, the applicant must furnish to the receiving Office, within one month from the date of receipt of the international application by 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 was already filed in a language of publication.

67A. [No change] *Language Not Accepted for the Purposes of International Publication*. 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 must furnish to the receiving Office, within 14 months from the priority date, a translation of the international

If the international application is filed with the United States Patent and Trademark Office as receiving Office, all elements of the international application other than any sequence listing part of the description (that is, request, description other than any sequence listing part thereof, claims, abstract, any text matter of the drawings) must be in English (see Rule 20.1(c) and (d)). The language-dependent free text in any sequence listing part of the description may additionally be in a language other than English.

application into any language of publication which the receiving Office accepts for the purposes of international publication.

- 67B. For any sequence listing part of the description, the requirements relating to translation for the purposes of international search and of international publication only apply to the language-dependent free text (Rules 12.3(a-bis) and 12.4(a-bis)).
- 68. The requirements relating to the translation for the purposes of international search and of international publication do not apply to the request (Rules 12.3(b) and 12.4(b) and paragraphs 59 to 61)—or any sequence listing part of the description (Rules 12.3(b) and 12.4(b) and paragraph 222).

69 and 69A. [No change]

- 70. Checking of Translation. Where the receiving Office has received a translation for the purposes of international search or international publication, it indelibly marks, in the upper righthand corner of each sheet of that translation, the international application number (Section 308(b)) and, immediately below, the date of receipt. If the receiving Office notices, before the expiration of the applicable time limit (paragraphs 69 and 69A), what appears to be a significant inconsistency between the original text and the translation, for example, when comparing the number of pages, the number of claims, the titles, etc., it should draw the applicant's attention to that inconsistency and give the applicant an opportunity to make any necessary corrections within the applicable time limit (paragraphs 69 and 69A). Within the applicable time limit, the applicant is entitled to furnish a corrected version of the translation that should be stamped as provided for in Section 305bis(c) and 308(b). In case where the receiving Office has already sent the initial version of the translation to the International Bureau, the receiving Office should draw the attention of the International Bureau to the fact that these sheets should replace the previously transmitted version of the translation. For compliance with the requirements for satisfactory reproduction and/or reasonably uniform publication, see paragraphs 132 to 138. The receiving Office is not required to check the translation of any sequence listing.
- 71. [No change] *Failure to Furnish the Required Translation*. Where the receiving Office has sent to the applicant an invitation under Rule 12.3(c) or 12.4(c) and the applicant has not, within the applicable time limit under Rule 12.3(c)(ii) or 12.4(c), furnished the required translation, or the translation furnished does not comply with the above-mentioned requirements, or any required late furnishing fee has not been paid, the receiving Office declares (Form PCT/RO/117) the international application withdrawn, provided that any translation and any payment received before that declaration is made and before the expiration of 15 months (Rule 12.3(d)) or 17 months (Rule 12.4(d)), from the priority date are considered to have been received before the expiration of the applicable time limit (Rules 12.3(d) or 12.4(d)). A copy of that notification is sent to the International Bureau and to the International Searching Authority if the record copy and the search copy, respectively, have been transmitted.

CHAPTER VI ARTICLE 14 CHECK AND OTHER FORMAL REQUIREMENTS

72 to 138. [No change]

139. Arrangement of Elements and Numbering of Sheets. The elements of the international application must be placed in the following order: the request, 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), the claim(s), the abstract,—and the drawings (if any), and, where applicable, the sequence listing part of the description. All sheets constituting the international

application must be numbered in consecutive Arabic numerals with the following separate series of numbering: the first applying to the request only and commencing with the first sheet of the request; the second series commencing with the first sheet of the description and continuing through the claims until the last sheet of the abstract; and if applicable, a third series applying to the sheets of the drawings only; and, for any sequence listing filed in page-based format (on paper or as image file(s)), a further series applying to the sequence listing part of the description commencing with the first sheet of that part. The number of each sheet of the drawings must consist of two sets of Arabic numerals separated by a slant, the first set being the sheet number and the second set being the total number of sheets of drawings (for example, 1/3, 2/3, 3/3); see Rule 11.7 and Section 207. While Rule 11.7(b) indicates that the numbers must be centered at the top or bottom of the sheet, but not placed in the margin, objections to non-compliance with this specific limitation is unnecessary where the numbers appear in the top or bottom margins but do not interfere with the areas where the receiving Office stamps the sheets with the international application number, date of receipt and any indications relating to substitute sheets. Any sequence listing part of the description must be presented as a separate ST.26 XML file.

- 140. [No change] Where sheets filed on the international filing date but not numbered as part of the international application are intended to be part of the international application, the receiving Office may renumber the sheets *ex officio* (paragraphs 161 to 165), failing which the International Bureau will do so.
- 141. Writing of Text Matter. The request, the description, the claims, and the abstract and any sequence listing part of the description filed in page-based format (on paper or as image file(s)) shall be typed or printed in a dark indelible color (Rule 11.9; for the request see also the Notes to the request form). This is very important for the description, claims and abstract because these parts are subject to OCR which does not work effectively on handwriting or light colored text. However, graphic symbols, chemical and mathematical formulae and certain characters in the Chinese or Japanese languages may be hand drawn. The text must be printed in letters the capitals of which are not less than 0.28cm high (Rule 11.9(d)). This equates to approximately 12 point text in Times New Roman font and is important because smaller text is much less reliable for image scanning and OCR. Rule 11.9(c) requires that the typing is 1½ spaced, but this need only be enforced to the extent that the lines of text are clearly separated from one another such that there is a definite vertical gap between the tops of letters and the lower part of letters on the line above. Moreover, indications (in particular, the marking of check-boxes) in the request form, that are, not machine printed should not be objected to if they are legible. Although the request is not published as such, details such as applicant/inventor's names and addresses are captured by OCR at the International Bureau for the purposes of international publication; therefore, Receiving Offices should, in their contacts with applicants, encourage them to respect similar guidelines for text matter in the request as in the description, claims and abstract, but without going as far as objecting to text matter in the request form, provided that it is sufficiently legible so as to allow correct data capture.

142 to 147. [No change]

Matter Appearing Not to be Part of the International Application

148. Apart from the request form (Rule 4.19), the PCT makes no provision for matter which does not appear to be a part of the international application such as appendices or annexes. Where such matter is submitted together with the international application, the receiving Office may contact the applicant by telephone or invite the applicant to clarify within a reasonable time limit whether these sheets are intended to be part of the international application. If the sheets are intended to be part of the application, they should be renumbered so as to comply with Section 207 under a heading which makes their status clear (paragraphs 139 and 140). If the applicant has not confirmed within the time limit set in the invitation that the sheets concerned should form part of the international application, the sheets concerned may be disregarded and therefore should not be considered part of the record copy or be sent to the International Bureau

(paragraph 294). As to sheets containing references to deposited biological material, see paragraphs 230 to 232, and sheets containing As to any separate electronic file disclosing nucleotide and/or amino acid sequences in a file format other than ST.26 XML listing and/or table(s) relating thereto, see paragraphs 222A to 222C227.

Check List

149. Indications Made by the Applicant. The purpose of the check list in Box No. IX of the request, which should be completed by the applicant, is to allow the receiving Office to verify whether all sheets and any sequence listing in ST.25 text format intended to constitute the international application and all items to accompany it were filed. The receiving Office checks whether the applicant has correctly completed the check list, failing which it makes the necessary annotations (Rule 3.3, Section 313, paragraphs 150 to 152 and 222 to 224). The actual number of sheets constituting each element of the international application as well as their total and the presence of sequence listing part of the description in ST.25 text ST.26 XML format (if any) on the international filing date should be indicated. Thus, the receiving Office counts the sheets of the record copy (which includes the request but not the fee calculation sheet) and checks whether the number of sheets of the international application and the items which accompany it correspond to the indications made by the applicant in Box No. IX of the request. As regards the request, there must be at least three sheets, namely, the "first sheet," the "second sheet" and the "last sheet." As regards any sequence listing part of the description in page-based format (on paper or as image file(s)), the number of sheets containing such sequence listing must be indicated separately (Rule 3.3(a)(i) and paragraph 224). For any sequence listing in ST.25 text format, the check list should reflect the presence of the electronic file (either as part of the description or as an accompanying item furnished only for search purposes), without any indication of the number of sheets (paragraphs 222A to 223). The language of filing of the application should be indicated; if it is not, the receiving Office should preferably make the indication ex officio (paragraphs 161 to 165); the applicant should subsequently be invited to indicate the language only if the receiving Office is not in a position to determine in which language the international application was filed.

150 to 203B. [No change]

Confirmation of Incorporation by Reference of Missing Parts or Correct Elements or Parts under Rule 20.6(a)

- 204. [No change] If, within the time limit under Rule 20.7, the receiving Office receives a notice confirming the incorporation by reference of a missing part or a correct element or part, it checks whether all the requirements of Rule 20.6 have been complied with, as outlined in the following paragraphs.
- 205. [No change] The receiving Office checks whether:
- (a) the request (Form PCT/RO/101) contains a statement under Rule 4.18 or, if such a statement was not in the request at the time of filing, if it was otherwise contained in, or submitted with, the international application;
- (b) sheets embodying the element or part concerned as contained in the earlier application have been submitted;
 - (c) the applicant had claimed priority of an earlier application at the time of filing;
- (d) the applicant has submitted the priority document for that earlier application or at least a simple copy of that earlier application;
- (e) under the circumstances of Rule 20.6(a)(iii), the applicant submitted a translation or translations of the earlier application (see Section 305*ter*); and

(f) in the case of a part of the description, claims or drawings, the applicant has submitted an indication as to where the part is contained in the earlier application and, where applicable, in any translation of the earlier application.

205A. The receiving Office checks whether the missing part or the correct element or part submitted by the applicant is completely contained in the earlier application. For that purpose, the Office compares the relevant element or part in the earlier application with the sheets submitted by the applicant under Rule 20.6(a)(i). For any sequence listing part of the description to be incorporated by reference, see paragraphs 227B and 227C. Where the later submitted sheets seem to go beyond the correction of formal defects and to modify the substantive content of the application, the receiving Office may, where applicable, invite the applicant to request the authorization of the rectification of an obvious mistake from the competent ISA under Rule 91(Form PCT/RO/108).

205B to 206. [No change]

CHAPTER IX NUCLEOTIDE AND/OR AMINO ACID SEQUENCE LISTING

General

222. Any sequence listing part of the description must comply with WIPO Standard ST.26 (Rule 5.2(a)). Under this Standard, sequence listings must be filed in XML format. The receiving Office examines the check list in Box No. IX of the request for reference to a sequence listings and checks whether any sequence listing in ST.26 XML file format has been filed as part of the description. If the applicant furnishes a single-sequence listing in ST.26 XML file format on the same date as the international application, but the check list contains no indication of the that a sequence listing forms—part of the description—international application, the receiving Office corrects the check list ex officio to reflect indicate that—the sequence listing as part of the description—forms part of the international application, in conformity with the requirement of Rule 5.2 that the international application shall contain a sequence listing where there is disclosure of one or more nucleotide and/or amino acid sequences (paragraph 26 of Annex C of the Administrative Instructions). If the sequence listing has been furnished on physical data carriers are as indicated on the check list. If there is any inconsistency, the receiving Office ex officio corrects the check list.

Where the applicant furnishes multiple sequence listings on the same day as the international application, but the check list contains no indication that one of the sequence listings forms part of the international application, the receiving Office should seek clarification from the applicant noting the requirement of Rule 5.2.

Procedure in the case of disclosure of sequences in a non-compliant file format

222A. Where the applicant furnishes a separate electronic file disclosing sequences in a file format other than ST.26 XML (e.g. ST.25 TXT or PDF) on the same date as the international application, the receiving Office seeks clarification from the applicant on whether the content of the file is intended to form part of the description and invites the applicant (Form PCT/RO/132) to furnish the content within a reasonable time limit in the format accepted for the main part of the description if necessary. For example, in the case of an ST.25 TXT file, the applicant may furnish the identical content as PDF sheets for inclusion in the main part of the description without affecting the international filing date. Alternatively, the receiving Office may convert the file into the acceptable format and invite the applicant to confirm that the content of the file is intended to

form part of the description and pay any applicable fee relating to the pages (Form PCT/RO/132). The receiving Office may additionally require a statement from the applicant that the content of the document resubmitted in the accepted format is identical to that of the electronic file originally submitted.

222B. If the applicant confirms that the content of the file is intended to form part of the description, the receiving Office marks in the upper right-hand corner of the furnished (or converted) sheets the international application number and the date on which it was received (or agreed to be converted). The receiving Office marks the middle of the bottom margin the words "SUBSTITUTE SHEET" and renumbers those sheets *ex officio* as pages of the description. The total number of pages indicated in the check list should be corrected and the payment of an additional fee for sheets in excess of 30 may be required (paragraphs 235 to 273). If the applicant fails to confirm or pay any applicable fee within the time limit, the content of the separate electronic file will not be considered as part of the international application.

222C. The receiving Office transmits any originally submitted electronic file disclosing sequences in a file format other than ST.26 XML to the International Bureau. The receiving Office checks that the check list reflects any originally submitted content not forming part of the description as an accompanying item in Box No. IX, item 9.

The receiving Office examines whether the check list appropriately indicates the relevant accompanying items in Box No. IX, items 8 and 9. If applicable, it also verifies that the type and number of physical data carriers on which the sequence listing is contained are as indicated. If there is any inconsistency, the check list may need to be corrected. The receiving Office transmits to the International Searching Authority any sequence listing (and any accompanying statement) furnished to it for the purposes of international search, whether submitted together with the international application or subsequent to the filing of the international application (Rule 23.1(c) and Section 313(c)), as outlined in paragraph 290.

Sequence Listing Furnished in ST.25 Text Format Checking for Compliance with WIPO Standard ST.26 and Other Defects

223. The receiving Office examines whether the check list in Bex No. IX of the request appropriately indicates the submission in electronic form (in ST.25 text format) of the sequence listing and checks that it was submitted by means accepted by the receiving Office. The receiving Office should only confirm the presence of an XML file appearing to be a sequence listing and need not examine for compliance of the sequence listing furnished in ST.25 text format with WIPO Standard ST.26 or the Rules and the prescribed requirements set out in the standard contained in Annex C of the Administrative Instructions since that check is made by the International Searching Authority (Rule 13 ter). However, if 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 by the International Bureau, the Office may notify the applicant accordingly (Form PCT/RO/132).

223A. If the receiving Office notices any discrepancy between the general information part of the sequence listing and the corresponding information in the request or the application body, the receiving Office may draw the fact to the applicant's attention (Form PCT/RO/132). The applicant may correct the discrepancy within the time limit provided for in Rule 26.2 but is not obliged to do so. The receiving Office processes the international application on the basis of the indications made in the request.

223B. Any correction of sequence listing under Rule 26 must be furnished as a complete sequence listing with an accompanying letter explaining the changes. The receiving Office is not required to check whether the correction is acceptable and simply makes the appropriate markings in the file name or metadata of the ST.26 XML file. If the correction under Rule 26 is furnished on physical data carrier(s), the receiving Office labels the carrier(s) "Sequence Listing"

Correction", together with the international application number. The receiving Office forwards
the corrected sequence listing with the accompanying letter to the International Searching
Authority and the International Bureau.

Sequence Listing Furnished in Page-Based Format (on Paper or as Image File(s))

224. <u>Deleted</u> The receiving Office examines whether the check list in Box No. IX of the request appropriately indicates "sequence listing part of the description" and checks whether the number of sheets of such sequence listing is indicated separately in the check list (Rule 3.3(a)(i)). If that number is not indicated separately, the receiving Office corrects the check list *ex officio* to indicate the appropriate number in items (b) and/or (f) as well as the total number of sheets (paragraphs 161 to 165) and invites the applicant to pay any required fee for sheets in excess of the previously calculated total number of sheets (paragraph 242). Form PCT/RO/102 or PCT/RO/133, as the case may be, is used for that purpose (paragraphs 252 to 265).

225. Deleted The receiving Office examines the sheets containing the sequence listing to a limited extent; it need not check the language of the sequence listing, compliance with requirements as to the presentation of the sequences, nor compliance with Rule 5.2. However, the receiving Office checks for compliance with the physical requirements necessary for the purpose of a reasonably uniform international publication as required by paragraph 3(i) of the said Annex C. Specifically, sheets of a sequence listing included in the international application must be presented as a separate part of the description (entitled "Sequence Listing") and should be sequentially numbered in a series separate from that used in numbering the sheets of the request (first series), the sheets of the description, claims and abstract (second series), and any sheets of drawings (third series) (Section 207 and paragraph 139). If sheets containing a sequence listing are not numbered or are incorrectly numbered, the receiving Office may either renumber them ex officio or invite the applicant under Rule 26 to do so by submitting replacement sheets (Rule 26.4 and paragraphs 153 to 159). Where sheets are renumbered, the total number of sheets indicated in the check list may need to be corrected and the receiving Office invites the applicant to pay any required additional fee for sheets in excess of the previously calculated total number of sheets (paragraphs 241 and 252 to 265).

226. <u>Deleted Tables related to a sequence listing contained in the international application must be included as an integral part of the description.</u> Pages containing such tables are counted as sheets of the international application (paragraph 243).

Subsequently Furnished Sequence Listing

227. Any sequence listing furnished after the filing of the international application would not normally be intended to form part of the international application. In case of doubt, the receiving Office should clarify with the applicant whether the sequence listing is intended to form part of the international application so as to complete or correct the international application (Rules 20.5 and 20.5 bis) or whether it is intended for search purposes (Rule 13ter.1). If the sequence listing is furnished for search purposes, the receiving Office promptly forwards the sequence listing and any accompanying statement to the International Searching Authority (see paragraph 290). However, where the applicant indicates to the receiving Office that the subsequently furnished sequence listing is intended to form part of the international application, for example, in response to an invitation for clarification whether the sequence listing was erroneously omitted from the international application, the procedure under Rule 20.5 applies (paragraphs 200 to 206). In other cases, the applicant may have erroneously submitted to the receiving Office corrections to the sequence listing intended for the International Searching Authority (Rule 13ter.1). In such case, the receiving Office transmits those corrections promptly to that Authority and informs the applicant accordingly (see Section 313(c) and paragraph 290).

227A. If the sequence listing intended for search purposes is furnished on a physical medium, the medium shall be labeled "SEQUENCE LISTING NOT FORMING PART OF THE

INTERNATIONAL APPLICATION", or its equivalent in the language of publication or of international preliminary examination, together with the international application number.

Incorporation by Reference; Missing and Erroneously Filed Parts

227B. Where the sequence listing is furnished to confirm incorporation by reference (Rule 20.6), the receiving Office may seek assistance from the International Bureau in comparing the sequence listing to be incorporated with the sequence listing from an earlier application.

227C. For any sequence listing incorporated by reference or furnished to complete or correct the international application after filing (Rules 20,5 and 20.5*bis*), the receiving Office makes the appropriate markings in the file name or metadata of the ST.26 XML file. If the receiving Office receives such a sequence listing on a physical medium, the receiving Office labels the medium with the words "SEQUENCE LISTING" together with other markings equivalent to those required for sheets (Sections 308(b) and 308*bis* to 310*ter*)

Transmission of Sequence Listing between Offices

227D. Where the sequence listing is transmitted online, the receiving Office encodes the international application number and type of sequence listing (as filed, corrected, for purpose of international search, etc.) in the filename, referencing XML or equivalent metadata appropriate to the means of online transmission. The content of the electronic file should not be changed.

227E. For any sequence listing received on a physical medium, the receiving Office may extract the file and transmit it online. In such a case, the receiving Office encodes the international application number and type of sequence listing in the filename or associated metadata in the same way as if the sequence listing had been received online. If the sequence listing is received on multiple data carriers, the receiving Office rejoins the extracted files to form one single contiguous file before transmitting it online.

CHAPTER XI FEES

235 to 240. [No change]

The International Filing Fee

241. [No change] *The International Filing Fee.* The amount of the international filing fee is set out (in Swiss francs) in the Schedule of Fees, which is annexed to the Regulations, and is payable in the currency or one of the currencies prescribed by the receiving Office. The amount of the international filing fee depends on the total number of sheets of the international application at the time of filing, which appears under "Total number of sheets" in Box No. IX (check list) of the request. If the international application contains more than 30 sheets, a supplement to the international filing fee must be paid for each sheet in excess of 30 (Rules 15.2(a) and 96 and the Schedule of Fees). This supplement is also due for the sheet containing the abstract, even where such abstract is missing at the time of filing the international application.

242. No fee is charged for any electronic file appearing to be a sequence listing in ST.26 XML format Where an international application containing a sequence listing is filed on paper³, any

Where the international application is filed in electronic form, the pages of the sequence listing part of the description will not be considered for the purposes of the calculation of the international filing fee if they are submitted in Annex C/ST. 25 compliant text format. However, if the sequence listing part is submitted in any other format (e.g. PDF), these pages of sequence listing will count as any other pages of the description for the purposes of calculating the international filing fee.

sheet of the sequence listing is counted as a regular page of the international application (Section 707).

243. Where tables, including those related to <u>the disclosure of sequences</u> a sequence listing, are contained in the international application, any sheet containing those tables is counted as a regular page of the description.

244 to 273. [No change]

CHAPTER XII TRANSMITTAL OF INTERNATIONAL APPLICATION TO INTERNATIONAL BUREAU AS RECEIVING OFFICE (RULE 19.4)

Transmittal of International Application for Reasons of Nationality and Residence of the Applicant or Language of the Application (Rule 19.4(a)(i) and (ii))

- 274. Where a purported international application is filed by an applicant who is a national or resident of a Contracting State with a national Office which acts as a receiving Office under the Treaty, but
- (i) that national Office is not competent for reasons of nationality or residence of the applicant to receive that purported international application (Rule 19.1 or 19.2), or
- (ii) the purported international application is not in a language accepted under Rule 12.1(a) or the language-dependent free text in the sequence listing part of the description is not in a language accepted under Rule 12.1(d) by that national Office but is in a language accepted under that Rule by the International Bureau as receiving Office (see Annex C (IB) of the PCT Applicant's Guide, for the language accepted by that Bureau), or
- (iii) all or part of the international application is filed in electronic form in a format not accepted by that national Office,

the national Office applies the procedure outlined in Rule 19.4(b).

275 to 282. [No change]

CHAPTER XIII RECORD COPY, SEARCH COPY AND HOME COPY

283 to 287. [No change]

Transmittal to the International Searching Authority of the Search Copy and Other Items

General

288 and 289. [No change]

290. Items to Accompany the Search Copy. Together with the search copy, the receiving Office transmits any sequence listing in electronic form (in ST.25 text format) (Rule 23.1(c)) or in page-based format (paper or as image file(s)) not forming part of the international application (Section 313(c)), any document concerning the deposit of biological material, any document concerning an earlier search, and a copy of any required power of attorney. Where the sequence listing furnished for the purposes of international search is received by the receiving Office after the transmittal of the search copy, the receiving Office it promptly transmits the sequence listing (and any accompanying statement) to the International Searching Authority (Rule 23.1(c) and Section 313(c)335(d)).

291 to 295. [No change]

CHAPTER XV RECTIFICATION OF OBVIOUS MISTAKES UNDER RULE 91

Request for Rectification Submitted to the Receiving Office

302 to 306. [No change]

Transmittal to Another Authority of a Request for Rectification

307. If the receiving Office receives a request for rectification of an obvious mistake in any part of the international application other than the request or in other papers or items (such as a nucleotide and/or amino acid sequence listing in ST. 25 text format), it transmits that request for rectification together with any proposed replacement sheet to the Authority competent to authorize the rectification (that is, the International Searching Authority, the International Preliminary Examining Authority or the International Bureau, as the case may be) and informs the applicant accordingly (Rule 91.1(b)(ii) to (iv)). It may, instead of transmitting the request for rectification, inform the applicant that the request for rectification should be sent to the Authority competent to rectify the mistake. For the language(s) in which such request for rectification must be submitted, see Rule 12.2(b).

Invitation to the Applicant to Request Authorization of Rectification

308. [No change]

[Annex II follows]

PROPOSED MODIFICATIONS OF THE INTERNATIONAL SEARCH AND PRELIMINARY EXAMINATION GUIDELINES

Chapter 2 Overview of the International Search Stage

2.01 to 2.04 [No change]

Preliminary Matters

Receipt of Search Copy from Receiving Office

2.05 [No change]

Rule 12

- 2.06 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 must furnish to the receiving Office a translation of the international application into a language which is all of the following:
 - (a) a language accepted by the International Searching Authority, and
 - (b) a language of publication, and
- (c) a language accepted by the receiving Office under Rule 12.1(a), unless the international application is filed in a language of publication.

However, no such translation is required of the request. For or any sequence listing part of the description, a translation may be required of only the language-dependent free text. Where the applicant is required to furnish such a translation, the international search will be carried out on the basis of that translation.

2.07 to 2.09 [No change]

The International Search Process

- 2.10 The role of the International Searching Authority is as follows, the details being considered in subsequent chapters referred to below:
- (a) to determine classification of the case, particularly to determine whether examiners specializing in other fields need to be consulted to ensure a proper search is carried out; this classification may need to be reconsidered in the light of fuller consideration, but a definitive classification must be made by the time that the international application is published (see Chapter 7);

Article 17(3); Rule 40

(b) to consider whether the application meets the requirement of unity of invention and, if not, whether the applicant should be invited to pay further search fees relating to the extra inventions (see Chapter 10);

Rule 39

(c) to consider whether some or all of the subject matter relates to subject matter which the Authority is not required to search (see Chapter 9);

Rules 4.12, 16.3, 41

(d) to determine whether to use the results of any earlier search, referred to by the applicant in the request form relating to the application, to establish the international search report, and to consequently authorize any appropriate refund;

Rule 13ter

(e) to determine whether to invite the applicant to provide a <u>sequence</u> listing if the international application contains disclosure of <u>one or more</u> nucleotide and/or amino acid sequences but does not include a sequence listing <u>in compliance complying</u> with the standard <u>for sequence listings in paper or electronic form</u> provided for in the Administrative Instructions <u>and in an accepted language</u> (see paragraphs 15.12 and <u>15.1315.14A</u>);

Articles 15, 17(2)

(f) to perform an international search to discover relevant prior art (see Chapter 11) taking into account that there may be subject matter such that the Authority is not obliged to search where the subject matter is such that the Authority is not obliged to do so (see Chapter 9), the description, claims or drawings fail to comply with the prescribed requirements to such an extent that no meaningful search could be carried out, (see Chapter 9 and paragraph 15.33) or else the claims relate to several different inventions and additional search fees, which the Authority has invited the applicant to pay, have not been paid (see Chapter 10);

Rules 37, 38

(g) to consider whether the abstract and title are appropriate and, in certain circumstances, to draft alternatives (see paragraphs 16.33 to 16.47);

Rule 43

(h) to establish a search report, indicating the results of the search and certain other information (see Chapter 16), or else make a declaration that a search was either not required or would not be meaningful (see Chapter 9);

Rule 43bis

(i) to establish a written opinion as to whether the international application appears to be novel, to involve an inventive step, to be industrially applicable and to comply with other requirements of the Treaty and Regulations insofar as they are checked by the International Searching Authority (see Chapter 17).

2.11 to 2.22 [No change]

Chapter 4 Content of the International Application (Other Than the Claims)

4.01 [No change]

Description

4.02 [No change]

Rule 5.1

4.03 The description should start with the same title that appears in the request (Form PCT/RO/101). The description should contain subheadings corresponding to those contained in Section 204 ("Technical Field", "Background Art", "Disclosure of Invention", "Brief Description of Drawings", "Best Mode(s) for Carrying Out the Invention", and "Industrial Applicability"—and, where appropriate, "Sequence Listing" and "Sequence Listing Free Text"). The use of such subheadings is strongly recommended in order to provide uniformity in publication and to facilitate access to the information contained in the international application. Some of the recommended subheadings are discussed in the following paragraphs.

4.04 to 4.14 [No change]

Nucleotide and/or Amino Acid Sequence Listings

Rule 5.2; Section 208; Al Annex C

4.16 to 4.32 [No change]

Appendix to Chapter 4

[No change]

Chapter 9 Exclusions from, and Limitations of, International Search and International Preliminary Examination

9.01 to 9.18 [No change]

Extent of Search and Preliminary Examination in Certain Situations

9.19 to 9.38 [No change]

Sequence Listings

Rule 13ter.1(a), (b); Section 208; Al Annex C 9.39 Another situation where a meaningful search or preliminary examination is not possible may arise where the international application contains disclosure of one or more nucleotide and/or amino acid sequences required to be included in a sequence listing but the International Searching Authority does not have available to it a copy of the sequence listing in electronic form complying with the standard provided for in Annex C of the Administrative Instructions and in an accepted language. The International Searching Authority requests the provision of such a sequence listing as soon as possible, before the search report and written opinion are established (see paragraphs 15.12 and 15.13-15.14A and paragraph 4.15). However if the listing is not provided or is not provided in the form required by the standard or in an accepted language, the Authority makes a meaningful search or preliminary examination to the extent that this is possible. For example, if a named protein is claimed, such a protein could be searched by its name rather than by its sequence. The same may occasionally apply also where a sequence listing is provided in paper (or image file) form which does not comply with the standard provided for in Annex C of the Administrative Instructions and the International Searching Authority requires such a paper (or image file) format for the purposes of the international search. Note that sequences having fewer than ten specifically defined nucleotides or fewer than four specifically defined amino acids are not required to be included in a sequence listing (see paragraph 4.15).

9.40 to 9.42 [No change]

Appendix to Chapter 9

[No change]

Chapter 15 The International Search

15.01 to 15.09 [No change]

Basis of the Search

Article 19: Rules 5.2, 13ter, 91.1; Section 208; Al Annex C

15.10 There is no right to amend the application until after the international search has been established, consequently the international search must be carried out on the basis of the search copy of the application as transmitted to the International Searching Authority by the receiving Office, except that obvious mistakes may be corrected (see Chapter 8).

15.11 to 15.11D [No change]

Rule 13ter.1; Section 513

If the application contains disclosure of one or more nucleotide and/or amino acid 15.12 sequences having ten or more specifically defined nucleotides or four or more specifically defined amino acids but does not contain a sequence listing complying with the relevant standard (see paragraph 4.15) or contains the sequence listing furnished is not in an accepted language only in paper (or image file) form, the International Searching Authority may invite the applicant (with Form PCT/ISA/225) to furnish, within a fixed time limit, a sequence listing in paper (or image file) form and/or in electronic form complying with the standard or, where applicable, a translation of the sequence listing in a language acceptable to it, for purposes of completion of the international search. The furnishing of a sequence listing or translation in response to an invitation by the International Searching Authority may be subject to the payment of a fee set by the International Searching Authority, which may not exceed 25% of the international filing fee (not taking into account any fee for each sheet of the international application in excess of 30 sheets). The International Searching Authority should not, however, require payment of any late furnishing fee if the absence of the sequence listing in a compliant form at the International Searching Authority was due to the receiving Office failing to forward an electronic sequence listing it had received for the purposes of Rule 13ter to the International Searching Authority, as required by Rule 23.1(c). If the applicant complies with the invitation, the International Searching Authority proceeds with the completion of the international search, the international search report or declaration of non-establishment of international search report, and the written opinion on the basis of the paper (or image file) and/or electronic forms of the compliant sequence listing or translation provided. However, any sequence listing not contained in the international application as filed will not, subject to Article 34, form part of the international application, but will be used as a search tool. The Authority marks in the upper right hand corner of the first sheet of any such listing provided in paper form "SUBSEQUENTLY FURNISHED SEQUENCE LISTING NOT FORMING PART OF THE INTERNATIONAL APPLICATION " or the equivalent in the language of publication of the international application. If the applicant does not comply with the invitation within the time limit or if the response to the invitation does not comply with the standard is defective, the International Searching Authority is required to search the international application only to the extent that a meaningful search can be carried out without the sequence listing (see paragraph 9.39).

Rules 5.2(b), 13ter.1(f); Section 513; Al Annex C

15.13 [Deleted] Where the sequence listing part of the description contains free text as defined in the standard provided for in Annex C of the Administrative Instructions, but that free text does not also appear in the main part of the description in the language thereof, the International Searching Authority invites the applicant (with Form PCT/ISA/233) to correct the application by adding the free text to the main part of the description. If the applicant

complies with the invitation, the International Searching Authority marks the replacement sheet with the words "SUBSTITUTE SHEET (RULE 13ter.1(f))" or their equivalent in the language of publication of the international application and the date of receipt, and transmits the substitute sheets containing that free text to the receiving Office and the International Bureau for inclusion of the sheets concerned in the home copy and the record copy, respectively; it keeps a copy of those sheets for inclusion in the search copy. If the applicant does not comply with the invitation, the International Searching Authority nevertheless continues to perform the international search.

Rules 12.3, 23.1(b)

15.14 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 should have supplied to the receiving Office a translation of the international application into a suitable language, howeverwhile no such translation is required of the request form or any sequence listing included as part of the description. The receiving Office sends this translation as part of the search copy and the international search will be carried out on the basis of this translation.

Rules 12.3, 13ter.1; Al Annex C

15.14A If the international application contains a sequence listing part of the description, only a translation of the language-dependent free text of the sequence listing may be required for the purposes of international search. Nevertheless, any such translation has to be provided in the form of a complete sequence listing containing all of the language-dependent free text in the required language. Note that the receiving Office may permit the language-dependent free text to be filed in more than one language according to the standard provided for in Annex C of the Administrative Instructions. If this is the case, as long as any one of the languages is accepted by the International Searching Authority, no translation of the sequence listing will be required. Where the language-dependent free text is not in a language accepted by the International Searching Authority but the receiving Office has not invited the applicant to furnish a translation under Rule 12.3, the International Searching Authority may invite the applicant to furnish a translation of the sequence listing into a language acceptable to it under Rule 13*ter*.1 (using Form PCT/ISA/225) and a late furnishing fee may be charged for this purpose (see paragraph 15.12).

15.15 to 15.75 [No change]

Supplementary International Search

15.76 to 15.84 [No change]

Basis of the Supplementary International Search

15.85 [No change]

15.86 If the application contains disclosure of one or more nucleotide and/or amino acid sequences having ten or more specifically defined nucleotides or four or more specifically defined amino acids but does not contain a sequence listing complying with the relevant standard (see paragraph 4.15) or the sequence listing furnished is not in an accepted language, the Authority may invite the applicant (with Form PCT/SISA/504) to furnish, within a fixed time limit, a sequence listing in written form and/or in electronic form complying with the standard or a translation of the sequence listing in a language acceptable to it, as the case may be, for purposes of completion of the supplementary international search. If the applicant complies with the invitation, the Authority proceeds with the completion of the supplementary international search on the basis of the written and/or electronic forms of the compliant sequence listing or translation provided. Any sequence listing not contained in the international application as filed will not, subject to Article 34, form part of the international

application, but will only be used as a search tool. If the applicant does not comply with the invitation within the time limit or if the response to the invitation does not comply with the standard, the Authority is not required to carry out the supplementary international search to the extent that such non-compliance has the result that a meaningful search cannot be carried out (see paragraph 15.87 (i)).

Claims Excluded from Supplementary International Search

Rule 45bis.5(c)-(e)

15.87 In addition to limitation of the supplementary international search due to a lack of unity of invention (see paragraph 15.89, below), the supplementary search may exclude:

Rule 45bis.5(c)

(i) any claims which would not be the subject of international search by the Authority carrying out the supplementary search, whether for reasons of clarity, subject matter or failure to provide, after a warning and opportunity to comply, a sequence listing in an appropriate form and language (see paragraphs 9.39, 15.12 and 15.33);

Rule 45bis.5(d), (e)

(ii) where the international search report or a declaration under Article 17(2)(a) has been established before the start of the supplementary search, any claims which were not the subject of the international search.

Rules 45bis.5(h), 45bis.9(a), (c)

(iii) certain claims, in accordance with a limitation or condition specified in the agreement between the Authority and the International Bureau under Article 16(3)(b) (in particular limitations to the effect that supplementary international searches will not extend to any claim beyond a certain number of claims).

15.88 to 15.97 [No change]

Chapter 16 International Search Report

16.01 to 16.07 [No change]

Form and Language of the International Search Report

International Search Report Form

16.08 [No change]

16.09 The "continuation of first sheet (1)" is used only when the international application includes acontains disclosure of nucleotide and/or amino acid sequences and indicates the sequence listing on the basis on of which the international search was carried out, since the relevant listings or related tables may be filed or furnished at different times and in different forms or, where a sequence listing or translation is required to be furnished (see paragraph 15.12), whether a meaningful search was carried out without such a compliant sequence listing or translation. The "continuation of first sheet (2) is used where an indication is made on the first sheet that claims were found unsearchable (item 2) and/or that unity of invention is lacking (item 3). The relevant indications are then made on that continuation sheet. The "continuation of first sheet (3)" contains the text of the abstract where an abstract or an amended abstract is established by the International Searching Authority (item 5) and an indication to that effect is made on the first sheet. The "continuation of second sheet" is to be used where the space on the second sheet is insufficient for the citation of documents. The "patent family annex," or alternatively a blank sheet, may be used for the indication of the members of patent families. The Form also includes an "extra sheet," which may be used whenever additional space is required to complete information from the other sheets. A sheet may be in paper form or may consist of the electronic equivalent of a paper sheet.

16.10 to 16.18 [No change]

Cases Where No, or Limited, Search Report is Established

Rules 39 and 67

- 16.19 No International Searching Authority is required to search or examine an international application to the extent that its subject matter is any of the following:
 - (i) scientific and mathematical theories.
- (ii) plant or animal varieties or essentially biological processes for the production of plants and animals, other than microbiological processes and the products of such processes,
- (iii) schemes, rules or methods of doing business, performing purely mental acts or playing games,
- (iv) methods for treatment of the human or animal body by surgery or therapy, as well as diagnostic methods,
 - (v) mere presentations of information,
- (vi) computer programs to the extent that the International Searching Authority is not equipped to search prior art concerning such programs.

Chapter 9 deals in detail with these exclusions from the search and examination, as well as other situations, such as lack of clarity, where it may not be possible to establish a meaningful international search in respect of some or all claims. See also paragraph 15.12,

which deals with the exclusion of claims where a sequence listing complying with the relevant standard in an accepted language is not provided as a result of non-compliance with the relevant standards for sequence listings. Supplementary international search reports may also exclude claims which were not the subject of the main international search.

16.20 to 16.21 [No change]

Filling Out the International Search Report (Form PCT/ISA/210)

16.22 to 16.24 [No change]

Basis of the Report

16.25 [No change] If the search has been conducted on the basis of a translation of the international application (see paragraph 15.14), this is indicated in item 1 of the first sheet of the international search report. This item also includes indications of whether a rectification of an obvious mistake has been taken into account, and a reference to any details relating to sequence listings used (see also paragraphs 15.15 to 15.17).

Nucleotide and/or Amino Acid Sequence Listings and Related Tables

16.26 Where the application discloses any nucleotide and/or amino acid sequence that has ten or more specifically defined nucleotides or four or more specifically defined amino acids, box 1.b 1.c of the first sheet is checked and Box No. I (appearing on "continuation of first sheet (1)") is used. Consequently, if the search was carried out on the basis of a sequence listing furnished, item 1 indicates the form (that is, whether in paper or electronic form) and status (that is, whether it was filed with as part of the international application or later, subsequently for the purposes of international search (in this case, also indicates whether it was accompanied by a statement that the sequence listing does not go beyond the disclosure in the international application as filed). of the sequence listing, and any related tables, that the search was carried out on If the applicant failed to furnish a sequence listing complying with the relevant standard in an accepted language and the search was carried out without the sequence listing, this fact is indicated in item 2. See paragraphs 4.15 and 15.12 for further details.

16.27 to 16.87 [No change]

Chapter 17 Content of Written Opinions and the International Preliminary Examination Report

17.01 to 17.08 [No change]

Content of the Opinion or Report

17.09 to 17.12 [No change]

Box No. I: Basis of the Written Opinion or Report

17.13 to 17.20 [No change]

- Nucleotide and/or Amino Acid Sequence Listings
- 17.21 With regard to any nucleotide and/or amino acid sequence listing, one or more of the following indications must be given with respect to the sequence listing, on which the examination is based, either in item 3 of Box No. I (for the written opinion of the International Searching Authority) or in item 1 of the Supplemental Box Relating to Sequence Listings (in written opinions of the International Preliminary Examining Authority or the international preliminary examination report):
- (a) forming part of the international application as filed (in the form of an Annex C/ST.25 text file, or on paper or in the form of an image file);
- (b) furnished together with the international application under Rule 13*ter*.1(a) for the purposes of international search only in the form of an Annex C/ST.25 text file;
- (eb) furnished subsequent to the international filing date for the purposes of international search and/or preliminary examination (in this case, also indicating whether it was accompanied by a statement that the sequence listing does not go beyond the disclosure in the international application as filed) (in the form of an Annex C/ST.25 text file, or on paper or in the form of an image file); and (in the case of international preliminary examination)
- (dc) furnished as an amendment under Article 34 (in the form of an Annex C/ST.25 text file, or on paper or in the form of an image file).

Where a sequence listing is required to be furnished (namely, for any sequence having ten or more specifically defined nucleotides or four or more specifically defined amino acids) but the applicant failed to furnish the sequence listing complying with the relevant standard in an accepted language (see paragraphs 15.12 and 18.18), Where more than one version or copy of a sequence listing related thereto has been filed, the check box either under item 4 of Box No. I (for the written opinion of the International Searching Authority) or under item 2 of the Supplemental Box Relating to Sequence Listings (for the written opinion of the International Preliminary Examining Authority or the international preliminary examination report) is used to indicate whether the written opinion or report was established to the extent that a meaningful opinion referred to in Article 33(1) could be formed without such a sequence listing whether the required statements were included, that the information in the subsequent or additional copies is identical to that in the application as filed or does not go beyond the application as filed. For further discussions of the nucleotide and/or amino acid sequence listings, refer to Chapter 18.

17.22 to 17.31 [No change]

Box No. III: Non-Establishment of Opinion with Regard to Novelty, Inventive Step and Industrial Applicability

17.32 to 17.36 [No change]

Nucleotide and/or Amino Acid Sequence Listings

Al Annexes C

17.37 A failure to supply furnish a nucleotide and/or amino acid sequence listing information, or have it complying with the standard provided for in Annex C of the Administrative Instructions standards and in an accepted language, may preclude any meaningful preliminary examination from being carried out. Refer to Chapter 15 (search stage) and Chapter 18 (examination stage) for discussion of the nucleotide and/or amino acid sequence listings. The Authority should make a meaningful search or preliminary examination to the extent that it is possible, but if some or all claims cannot be examined, the reasons are noted in the final check boxes of Box No. III, and details may be provided in the Supplemental Box if necessary.

17.38 to 17.73 [No change]

Chapter 18 Preliminary Procedure on Receipt of the Demand

18.01 to 18.09 [No change]

Documents, Etc., for the International Preliminary Examining Authority

18.10 to 18.11 [No change]

18.12 In the cases where the international search has been performed by an International Searching Authority which is not part of the same national Office or intergovernmental organization as the International Preliminary Examining Authority, the various elements of the file making up the international application will be supplied to the International Preliminary Examining Authority as follows:

Article 31(6)(a)

- (i) the demand: by the applicant;
- (ii) the request, description, drawings (if any), claims, and <u>any</u> sequence listing <u>part of the description</u> filed under the provisions of Section 801 (if applicable), as originally filed: by the International Bureau;

Rule 43bis

(iii) the international search report or the declaration under Article 17(2)(a), and the written opinion established under Rule 43*bis*.1: by the International Bureau;

Rule 55.2

(iv) where neither the language in which the international application is filed nor the language in which the international application is published is accepted by the International Preliminary Examining Authority, a translation of the international application into a language which is both a language accepted by the International Preliminary Examining Authority and a language of publication: by the applicant (see, however, paragraph 18.11);

Rule 62

(v) amendments and statement under Article 19 (if any): where the applicant has marked the appropriate check box in Box No. IV of the demand (Form PCT/IPEA/401) that amendments under Article 19 are to be taken into account, the International Preliminary Examining Authority indicates on the last sheet of the demand whether a copy of such amendments was actually received with the demand. Where no copy of the amendments under Article 19 was received with the demand, a copy of such amendment will be transmitted by the International Bureau promptly after that Bureau receives the demand. If no amendments under Article 19 have been made at the time when the demand is received by the International Bureau, the International Preliminary Examining Authority is so informed by the International Bureau. If, at the time of filing such amendments, the demand has already been submitted, the applicant should also submit a copy of such amendments to the International Preliminary Examining Authority. In any event, the International Bureau will promptly transmit a copy of any amendments under Article 19 to the International Preliminary Examining Authority;

Rule 13ter.1; Section 208; Al Annex C

(vi) nucleotide and/or amino acid sequence listing in paper and/or electronic form, both forms complying with the standard provided for in Annex C of the Administrative Instructions: where the International Searching Authority and the International Preliminary Examining Authority are part of the same national Office or intergovernmental organization, by the International Searching Authority; otherwise, by the applicant;

Rule 66.1

- (vii) amendments according to Article 34(2)(b): by the applicant;
- (viii) copies of any documents cited in the international search report which are not available from the databases of the International Preliminary Examining Authority: by the International Searching Authority;

Rule 66.7(a)

(ix) priority document: by the International Bureau;

Rule 66.7(b)

(x) translation of the priority document where required: by the applicant (subject to an invitation to furnish the translation having been made, see paragraph 18.16).

18.13 to 18.16 [No change]

Nucleotide and/or Amino Acid Sequence Listings

Section 208: Al Annex C

18.17 Where the international application contains disclosure of one or more nucleotide and/or amino acid sequences and a corresponding sequence listing complying with the standard provided for in Annex C of the Administrative Instructions and in an accepted language in paper (or image file) form and in electronic form for the purposes of international preliminary examination, (both forms complying with the standard provided for in Annex C of the Administrative Instructions) the International Preliminary Examining Authority carries out the international preliminary examination on the basis of those the sequence listings.

Rules 13ter.1, 13ter.2; Section 208; Al Annex C

18.18 Where the international application contains disclosure of one or more nucleotide and/or amino acid sequences having ten or more specifically defined nucleotides or four or more specifically defined amino acids but does not contain a corresponding sequence listing in paper (or image file) form and/or in electronic form complying with the standard provided for in Annex C of the Administrative Instructions or the sequence listing furnished is not in an accepted language, the International Preliminary Examining Authority may invite the applicant (with Form PCT/IPEA/441) to furnish to it, within a time limit fixed in the invitation, a sequence listing in paper (or image file) form and/or electronic form, as the case may be, complying with the standard or a translation of the sequence listing, as the case may be. The furnishing of a sequence listing or translation in response to an invitation by the International Preliminary Examining Authority may be subject to the payment of a fee set by the International Preliminary Examining Authority, which may not exceed 25% of the international filing fee (not taking into account any fee for each sheet of the international application in excess of 30 sheets). If the applicant complies with the invitation, the procedure outlined in the preceding paragraph applies. If the applicant does not comply with the invitation within the time limit or the response to the invitation is defective, the International Preliminary Examining Authority is required to carry out the international preliminary examination only to the extent that a meaningful examination can be carried out without the sequence listing (see paragraph 9.39).

Chapter 22 Clerical and Administrative Procedures

22.01 to 22.59 [No change]

<u>Processing of Nucleotide and/or Amino Acid Sequence Listings Furnished Specifically for the Purposes of International Search or Preliminary Examination</u>

Rules 13ter.1, 13ter.2; Sections 513, 610; Al Annex C

22.60 Where the international application contains disclosure of nucleotide and/or amino acid sequences and the applicant has furnished, either upon invitation or otherwise, a sequence listing to the International Searching Authority or the International Preliminary Examining Authority, as the case may be, specifically for the purposes of international search or preliminary examination, any such listing not contained in the international application as filed will not, subject to Article 34, form part of the international application, but will only be used for the purposes of the respective procedure. If such a sequence listing is furnished online, the purpose for which the sequence listing is filed and the international application number will be encoded in the filename or associated metadata without changing the contents of the file. If it is furnished on a physical medium, the Authority physically labels the medium with the words "SUBSEQUENTLY FURNISHED SEQUENCE LISTING NOT FORMING PART OF THE INTERNATIONAL APPLICATION" or the equivalent in the language of publication of the international application, together with the international application number.

Sections 513(e), 610(d); AI Annex C

22.61 The Authority, in addition to keeping a copy of such sequence listing in its files, transmits a copy thereof to the International Bureau so that it may be shared with the designated or elected Offices. If the sequence listing was received online, it is transmitted to the International Bureau online with the appropriate annotations but no change to its contents. If it was furnished on a physical medium, the Authority may either transmit a copy to the International Bureau online as if it had been received online, or alternatively, send a copy of the physical medium to the International Bureau. If the physical medium was furnished in less than the number of required copies, the Authority prepares the additional copy and may collect the corresponding fee from the applicant.

[End of Annexes and of Circular]