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COOPERATION TREATY (PCT)**

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**CENTRAL ELECTRONIC DEPOSIT SYSTEM FOR
NUCLEOTIDE AND AMINO ACID SEQUENCE LISTINGS**

Document prepared by the International Bureau

BACKGROUND

1. At its third session, the Working Group agreed that, in order to facilitate the processing of sequence listings for the purposes of the international and the national phase of the PCT procedure, the International Bureau should further investigate the possibility of establishing a central electronic deposit system for such listings (see the summary of the session by the Chair, document PCT/R/WG/3/5, paragraph 58).

2. The Annex to this document contains proposals for amendment of the Regulations under the PCT so as to establish a central electronic deposit system for sequence listings for the purposes of disclosure of the invention and to facilitate access to deposited sequence listings by Offices and Authorities and also third parties. The main features of the proposed new system are outlined in the following paragraphs.

DEPOSIT OF SEQUENCE LISTINGS

3. The idea of establishing a central electronic deposit system for sequence listings is not new. Previous discussions on this issue in the 1990s focused on the need to establish a data bank containing sequence listings of all published applications in a standardized form suitable for patent search purposes (the issue was discussed, for example, at the fifth session of the

Meeting of International Authorities under the PCT; see document PCT/MIA/V/3, paragraphs 27 to 32). At that time it was envisaged that, where the International Searching Authority had received a sequence listing in computer readable form from the applicant, it would make that sequence listing available, promptly after international publication, to one of the existing sequence listing database institutions. Those institutions would then have served as data repositories for future access to the sequence listing, including by the International Preliminary Examining Authorities, designated/elected Offices and third parties. No such Authority or Office would have been entitled to ask the applicant to furnish it with a copy of the sequence listing in computer readable form where it was available from such an institution. However, the idea was not proceeded with when it was ascertained that the procedures followed by the institutions concerned did not meet certain general needs of the patent procedure (for example, in respect of guaranteeing the documentary integrity of sequence listings as originally filed).

4. In practice, the Trilateral Patent Offices, for example, systematically place sequence listings with public sequence listing database institutions: the European Patent Office with the European Bioinformatics Institute (EBI); the Japan Patent Office with the DNA Databank of Japan (DDBJ); and United States Patent and Trademark Office with the National Center for Biotechnology Information (NCBI). This applies in the case of sequences disclosed in patents and published patent applications, both in national/regional applications and in international applications for which the Office concerned acts as International Searching Authority.

5. A distinction needs to be drawn between three related purposes for which sequence listings in electronic form might usefully be stored in data banks:

(i) *international search (and international preliminary examination)*: a sequence listing in electronic form is needed to enable the International Searching Authority to carry out the international search, and provision of a listing in such form is the subject of present Rule 13ter; for this purpose, it is presently envisaged, although not expressly mentioned in Rule 13ter, that a sequence listing in electronic form which is furnished by the applicant to the International Searching Authority will be placed by that Authority in a sequence listing database in such a way that it can be searched using highly sophisticated algorithms designed to aid the examiner in deciding whether the invention is novel and involves an inventive step; similar considerations apply in the case of international preliminary examination;

(ii) *disclosure*: another purpose, not presently catered for, would be to enable the applicant to disclose the invention by way of reference to a deposit, so that there would be no need to file, as part of the international application, a sequence listing requiring up to many thousands of sheets of paper or even on a CD as is presently provided for under Part 8 (Sections 800 to 806) of the Administrative Instructions under the PCT;

(iii) *access*: patent Offices, PCT Authorities and third parties may need or wish to have access to deposited sequence listings for a number of purposes, including scientific research, technical information, international search and ascertaining the exact nature of the disclosure contained in a patent application as originally filed.

6. The presently available database institutions do not cater fully for all of those purposes. Their operations are geared towards practical needs for technical information for research purposes. While they are certainly useful or even essential for the carrying out of searches of the prior art in relation to patent applications, they are not designed or maintained in a way

which meets certain more specialized needs of the patenting procedure, notably in relation to establishing the precise nature of the disclosure made on a certain date (normally, in the case of a patent application, the filing date) in a way which would meet evidentiary requirements in the event that the nature or date of the disclosure is contested in court proceedings. The proposals made in the present document are for a deposit system intended to meet those more specialized needs.

7. It is thus proposed to set up a system, similar in certain ways to the system for the deposit of biological material with a depositary institution under the Budapest Treaty, under which a reference to a sequence listing in electronic form deposited with a prescribed sequence listing data bank would replace the need to include such listing in the description itself. Provided that the International Searching Authority has access to such a deposited sequence listing, there would then also be no need for the applicant to furnish a separate listing in electronic form to the International Searching Authority for the purposes of the international search (and similar considerations would apply to the procedure before the International Preliminary Examining Authority and designated/elected Offices).

8. Since the deposited sequence listing would replace a listing which would otherwise have to be handled by the International Bureau, whether in form of a sequence listing part of the description (on paper) or as a listing in electronic form separately furnished under Part 8 of the Administrative Instructions, and since its storage in the data bank would be for the purposes of disclosure and simple access rather than research or patent searching, it would appear to be logical for the functions of the data bank to be carried out by the International Bureau, while still allowing for the possibility that other data banks may also be prescribed. However, a study of the feasibility of such a possibility would need to be undertaken.

9. The main features of the proposed system would be as follows:

(i) the applicant would have the option, if so wished, to deposit, for the purposes of the PCT procedure in relation to an international application, a sequence listing in electronic form with a prescribed sequence listing data bank (which may include the International Bureau, as mentioned in paragraph 8, above);

(ii) in order to attract the operation of the provisions outlined further below, the sequence listing would have to be deposited on or before the international filing date and to comply with the standard prescribed in the Administrative Instructions (see present Annexes C and C-*bis*, which would have to be modified accordingly);

(iii) a reference in the description to a deposited sequence listing would replace the need to include such listing in the description itself (“sequence listing part of the description” – see present Rule 5.2(a));

(iv) a reference to a deposited sequence listing would replace the need to furnish, for the purposes of international search, the listing in electronic form to the International Searching Authority (and the International Preliminary Examining Authority and designated/elected Offices) as under present Rule 13*ter*;

(v) the deposited sequence listing would be published in electronic form only, similar as is presently provided for under Part 8 (Section 805) of the Administrative Instructions under the PCT;

(vi) access to the deposited sequence listing would be restricted, until the international publication of the international application concerned, in a similar way as access to the application itself;

(vii) Authorities and Offices would be entitled to access the deposited sequence listing, including for the purposes of search and examination, as they would be entitled to access the international application itself;

(viii) third parties would be entitled to access the deposited sequence listing on the same basis as they would be entitled to access the international application itself (that is, in general, only after the international publication of the international application concerned).

10. Details concerning the making of deposits (including details concerning submission of corrections under Rule 26.3, rectifications of obvious errors under Rule 91 and amendments under Article 34 in respect of a deposited sequence listing), the prescribing of data banks and the obligations of and procedures to be followed by prescribed data banks would be set out in the Administrative Instructions.

11. Adoption of proposals for amendment of the Regulations to implement such a system would necessitate consequential modifications of the Administrative Instructions to set out procedural details, and consequential modifications would be needed to Part 7 and Annex C of the Instructions. The procedures set out in Part 8 and Annex C-bis of the Instructions would probably be completely superseded by, or incorporated into, the new system and would thus be deleted.

8. The Working Group is invited to consider the proposals contained in this document.

[Annex follows]

ANNEX

PROPOSED AMENDMENTS OF THE PCT REGULATIONS:

DEPOSIT OF SEQUENCE LISTINGS

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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, the description shall contain, at the option of the applicant, either:

(i) a sequence listing complying with the standard provided for in the Administrative Instructions and presented as a separate part of the description in accordance with that standard (“sequence listing part of the description”); or

[COMMENT: Clarification only; for the standard provided for in the Administrative Instructions, see Section 208 and Annex C to the Administrative Instructions.]

(ii) a reference complying with Rule 13ter.2(a) to a sequence listing in electronic form complying with the standard provided for in the Administrative Instructions that was deposited with a prescribed sequence listing data bank in accordance with Rule 13ter.1 (“deposited sequence listing”) on or before the international filing date.

[COMMENT: See paragraphs 5(ii), 7 and 9 of the Introduction to this document. The Working Group may wish to consider whether an indication that a sequence listing has been deposited in accordance with Rule 5.2(a)(ii) should also be provided for in the request form (Rule 4 would have to be amended accordingly).]

[Rule 5.2, continued]

(b) Where the sequence listing part of the description [or the deposited sequence listing](#) contains any free text as defined in the standard provided for in the Administrative Instructions, that free text shall also appear in the main part of the description in the language thereof.

[COMMENT: Consequential on proposed amendment to Rule 5.2(a), above.]

Rule 13ter

Nucleotide and/or Amino Acid Sequence Listings

13ter.1 Sequence Listing Deposits

A deposit of a sequence listing in electronic form for the purposes of Rule 5.2(a)(ii) shall be made in accordance with the Administrative Instructions.

[COMMENT: See paragraphs 10 and 11 of the Introduction to this document.]

13ter.2 References to Sequence Listings: Contents; Failure to Include Reference or Indication

(a) Any reference to a deposited sequence listing for the purposes of Rule 5.2(a)(ii) shall indicate:

(i) the name and address of the sequence listing data bank with which the deposit was made;

(ii) the date of the deposit; and

(iii) the number given to the deposit by that sequence listing data bank.

[Rule 13ter.2, continued]

(b) Where the international application contains disclosure of one or more nucleotide and/or amino acid sequences and the description as filed:

(i) does not contain a sequence listing part of the description or a reference to a deposited sequence listing; or

(ii) contains a reference to a deposited sequence listing but any of the indications referred to in paragraph (a) is not included in that reference;

the International Searching Authority shall invite the applicant to file a correction by furnishing a reference to a deposited sequence listing complying with Rule 5.2(a)(ii) or the missing indication within a time limit fixed in the invitation. 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. Any reference or indication furnished within the time limit fixed in the invitation shall be considered by any designated Office to have been furnished in time.

[COMMENT: Similar to the situation under Rule 13bis.4 with regard to the furnishing of a reference to deposited biological material, where the international application as filed does not contain a sequence listing part of the description and also does not contain a reference to a deposited sequence listing, or where any of the indications required under Rule 13ter.2(a) is missing from a reference contained in the international application as filed, the applicant would be given the opportunity, upon invitation by the International Searching Authority, to make the required correction by furnishing such a reference or the missing indication within the time limit fixed in the invitation. If furnished within that time limit, any designated Office would have to consider any such reference or indication to have been furnished in time. Note that, in practice, the invitation under Rule 13ter.2(b) would be combined with the invitation under Rule 13ter.3(a) (see below): the applicant would have the option either to comply with the invitation under Rule 13ter.2(b), in which case the deposited sequence listing referred to

[Rule 13ter.2(b), continued]

in the description would be used for the purposes of disclosure, international search and international preliminary examination, and access (see paragraph 5 in the Introduction to this document, above); or, alternatively, to comply with the invitation under Rule 13ter.3(a), in which case the sequence listing in electronic form furnished to the International Searching Authority would be used for the purposes of international search only. Note that any sequence listing deposited after the international filing date would not comply with the requirements of Rule 5.2(a)(ii) and thus not be accepted as a correction under Rule 13ter.2(b); any sequence listing deposited after the international filing date would also not be taken into account for the purposes of international search (see Rule 13ter.3(a), below).]

(c) ~~13ter.1(d)~~ Where the International Searching Authority finds that the description does not comply with Rule 5.2(b), it shall invite the applicant to file the required correction within a time limit fixed in the invitation. 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.

[COMMENT: Clarification only.]

13ter.3 ~~13ter.1~~ *Sequence Listings Required for the Purposes of International Search or International Preliminary Examination* ~~for International Authorities~~

(a) Where the international application contains disclosure of one or more nucleotide and/or amino acid sequences and the description does not contain a reference to a deposited sequence listing, or the description contains a reference to a deposited sequence listing but the deposited sequence listing does not comply with Rule 5.2(a)(ii), the International Searching Authority may require that the applicant furnish to that Authority, for the purposes of the

[Rule 13ter.3(a), continued]

international search, a sequence listing in electronic form complying with the standard provided for in the Administrative Instructions. Where such a listing is so required but has not been furnished by the applicant, the International Searching Authority may invite the applicant to furnish such a listing within a time limit fixed in the invitation.

[COMMENT: A sequence listing in electronic form is needed to enable the International Searching Authority to carry out the international search. Provided that the International Searching Authority has access to a deposited sequence listing complying with the standard provided for in the Administrative Instructions, there is no need for the applicant to furnish a separate listing in electronic form to the International Searching Authority for the purposes of international search. In all other cases, that is, in cases where the International Searching Authority does not have access to a deposited sequence listing complying with the standard provided for in the Administrative Instructions, the International Searching Authority would be entitled to invite the applicant to furnish such separate listing in electronic form. Any such listing in electronic form furnished by the applicant would not form part of the international application (see Rule 13ter.3(d), below). In practice, the invitation under Rule 13ter.3(a) would be combined with the invitation under Rule 13ter.2(b) (see Comment on Rule 13ter.2(b), above). Note that proposed new Rule 13ter.3(a) would no longer provide for an invitation to furnish a sequence listing in paper format (as present Rule 13ter.1(a) does), taking into account that such listing in paper format would not allow a meaningful search to be carried out by the International Searching Authority. Note further that that proposed new Rule 13ter.3(a) would not provide for an applicant to furnish, in response to an invitation under that Rule, a reference to a sequence listing deposited with a sequence listing data bank.]

~~[13ter.1](a) Where the International Searching Authority finds that the international application contains disclosure of one or more nucleotide and/or amino acid sequences but:~~

~~(i) the international application does not contain a sequence listing complying with the standard provided for in the Administrative Instructions, that Authority may invite the applicant to furnish to it, within a time limit fixed in the invitation, a sequence listing complying with that standard;~~

[Rule 13ter.3(a), continued]

~~(ii) the applicant has not already furnished a sequence listing in computer readable form complying with the standard provided for in the Administrative Instructions; that Authority may invite the applicant to furnish to it, within a time limit fixed in the invitation, a sequence listing in such a form complying with that standard.~~

(b) ~~[13ter.1](e)~~ If the applicant does not comply with an invitation under paragraph (a) within the time limit fixed in the invitation, the International Searching Authority shall not be required to search the international application to the extent that such non-compliance has the result that a meaningful search cannot be carried out.

(c) ~~[13ter.1](e)~~ Paragraphs (a) and (b) ~~(e)~~ shall apply *mutatis mutandis* to the procedure before the International Preliminary Examining Authority.

(d) ~~[13ter.1](f)~~ Any sequence listing in electronic form furnished pursuant to paragraphs (a) to (c) ~~not contained in the international application as filed~~ shall not, ~~subject to Article 34,~~ form part of the international application.

[COMMENT: The proposed amendment of present Rule 13ter.1(f) (new paragraph (d)) is consequential on the proposed deletion of present Rule 13ter.1(a) (see above) and the fact that Rule 13ter.3(a) as proposed to be amended would no longer provide for an invitation to furnish a sequence listing in paper format (see Comment on Rule 13ter.3(a), above).]

13ter.4 ~~13ter.2~~ Sequence Listings for Designated Offices

Once the processing of the international application has started before a designated Office, Rules 13ter.2(b) and 13ter.3(a) ~~13ter.1(a)~~ shall apply *mutatis mutandis* to the procedure before that Office. No designated Office shall require the applicant to furnish to it:

(i) a sequence listing where a reference to a deposited sequence listing complying with Rule 5.2(a)(ii) is included in the description;

(ii) a sequence listing other than a sequence listing complying with the standard provided for in the Administrative Instructions.

[COMMENT: Proposed amendment of present Rule 13ter.2 (new Rule 13ter.4) is consequential on the proposed creation of a central electronic deposit system for sequence listings under which a sequence listing data bank would serve as a data repository for future access to the sequence listing, including by the designated/elected Offices.]

13ter.5 Prescribed Sequence Listing Data Banks

The Administrative Instructions shall set out the sequence listing data banks that are prescribed for the purposes of Rules 5.2(a)(ii) and 13ter.1 and the provisions and requirements in relation to deposited sequence listings, including but not limited to, provisions and requirements in relation to [the status of sequence listing data banks, making of deposits, issuance of receipts for deposits, recognition and effect of a deposit, storage of deposited sequence listings, furnishing of copies of deposited sequence listings, and fees].

[Rule 13ter.5, continued]

[COMMENT: The Administrative Instructions may, subject to further study of the feasibility (see paragraph 8 of the Introduction to this document) prescribe the International Bureau as a data bank. In that case, a deposit with the International Bureau as data bank should be possible by way of filing the sequence listing in electronic form together with the international application with the receiving Office, in which case it would be considered to have been deposited with the International Bureau on the date of receipt by the receiving Office.]

[End of Annex and of document]