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MEETING OF INTERNATIONAL AUTHORITIES
UNDER THE PATENT COOPERATION TREATY (PCT)

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AVAILABILITY OF SEQUENCE LISTINGS IN ELECTRONIC FORM

Document prepared by the International Bureau

1. The Appendix to this document contains a copy of a preliminary draft which has been published informally on the PCT Reform electronic forum for comment, prior to a formal document being prepared for the seventh session of the Working Group on Reform of the PCT. This draft follows up discussion in earlier sessions of the Working Group of proposals for a central deposit system for sequence listings and suggests that little further legal or technical provision is required at the International Bureau for the improved handling of sequence listings in electronic form. Rather, procedures and inter-Office communication arrangements must be considered.

2. *The Meeting is invited to comment on aspects of the preliminary draft document in the Appendix which affect the operation of the International Authorities, and to indicate whether further action is required to facilitate the electronic transfer of sequence listings between the International Bureau and the International Authorities.*

[Appendix follows]

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APPENDIX

COPY OF PRELIMINARY DRAFT DOCUMENT FOR THE SEVENTH SESSION
OF THE WORKING GROUP ON REFORM OF THE PCT

SUMMARY

1. Already today, a system is in place under which all applicants have the option of filing sequence listings in electronic form as part of the international application. Furthermore, already today, such sequence listings are kept by, and available from, a central source, namely, the International Bureau. What appears to be lacking, in practice, however, are operational arrangements which would ensure that International Authorities and designated/elected Offices take advantage of the fact that sequence listings in electronic form are available from a central source and obtain copies of such sequence listings from that central source rather than from the applicant. This document thus contains proposals to improve the operational arrangements (necessitating only a minor amendment of the Regulations under the PCT¹) regarding access by Authorities and Offices to sequence listings filed in electronic form as part of the international application rather than, as proposed in previous documents presented to the Working Group, to establish a separate central system for the deposit of sequence listings filed in electronic form.

BACKGROUND

2. 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).

3. For the fourth session of the Working Group, the International Bureau submitted a document containing proposals for amendment of the Regulations so as to establish a central electronic deposit system for sequence listings. Having regard to the time available, discussions on that document were, however, deferred until the fifth session (see the summary of the fourth session of the Working Group by the Chair, document PCT/R/WG/4/14, paragraph 104).

4. At its fifth session, the Working Group discussed 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 Working Group's discussions are outlined in document PCT/R/WG/5/13, paragraphs 74 to 82:

¹ References in this document to "Articles" and "Rules" are to those of the Patent Cooperation Treaty (PCT) and the Regulations under the PCT ("the Regulations"), or to such provisions as proposed to be amended or added, as the case may be. References to "national laws," "national applications," "the national phase," etc., include reference to regional laws, regional applications, the regional phase, etc.

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“74. Discussions were based on document PCT/R/WG/5/3.

“75. Many delegations expressed great interest in the proposals contained in the document, noting that there was a real need to provide systems enabling sequence listings to be efficiently filed and made available to International Authorities, designated and elected Offices and third parties, and to avoid the need to handle extraordinarily voluminous applications filed on paper. It was noted that the problem was an international one concerning national patent applications as well as international applications. While the specific proposals made represented a step in the right direction, a number of comments, concerns and suggestions were made, as outlined in the following paragraphs.

“76. Several delegations were concerned that, for the purposes of disclosure of the invention, a reference to a deposited sequence listing might not serve the same function for the purposes of national law as the inclusion of the sequence listing part of the description as a part of the international application itself, and that proposed Rule 5.2(a)(ii) might not be sufficient to address this issue. Any solution would need to avoid inconsistency with, for example, Articles 3, 5 and 11.

“77. Several delegations suggested that an alternative approach be considered, whereby a sequence listing in electronic form (only) would first be filed with the receiving Office as part of the international application (even if filed on paper); such a procedure had already been established in Part 8 of the Administrative Instructions. That sequence listing could be transmitted by the receiving Office to a sequence listing data bank which would then make it available, in accordance with the usual requirements and restrictions set out in the Treaty as to access to documents, to Authorities, designated and elected Offices and third parties. Even though the remaining part of the international application comprising the request, written description, claims and drawings (if any) might be received in a different format (on paper) and stored separately, the two parts would together be considered to constitute the application. For such a system to be workable, the data bank would of course need to be willing and able to meet the procedural and other requirements of the PCT.

“78. It was agreed that, before a decision could be made as to the desirability of a deposit system of the kind proposed, the benefits which would accrue to different users would need to be established. It would need to be clear that the system would meet the requirements of users, including applicants, receiving Offices, the International Bureau, International Authorities, designated and elected Offices, and third parties with different interests, noting the different times and reasons for which a sequence listing would need to be available for different purposes. The data bank would need to allow reliable access to those in respect of whom access to the information was required or permitted at any particular time. It should permit easy downloading of sequence listings to the search databases used for search purposes by patent Offices including International Authorities. The means for both uploading and downloading information would need to be studied carefully, since normal Internet connections might be inadequate for very large sequence listing files. It would also need to offer flexible access, including the selection of specific sequences in cases where a sequence listing contained more than

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one sequence. The necessary hardware and software requirements (including communication means as well as storage) would need to be studied.

“79. Concerning the possibility that such a data bank might be established and operated by the International Bureau, a number of delegations and representatives of users raised the question of the cost of setting up and running the necessary systems and associated infrastructure.

“80. One delegation suggested that an existing sequence listing database institution might be able to provide such a facility. The Secretariat noted that the proposal expressly mentioned that possibility, although the main existing sequence listing data banks had in the past not been in a position to undertake all the necessary patent-related functions, such as storage of listings with a guarantee of legal certainty as to their content on the filing date of the application and ensuring that the provisions of the Treaty concerning access and publication would be met.

“81. The costs associated with various possibilities for the establishment and maintenance of such a data bank would, in particular, need to be identified and justified in the light of the potential benefits, as would the means by which it might be financed.

“82. The Working Group agreed that the Secretariat, in consultation with the Meeting of International Authorities under the PCT, should prepare a revised proposal, including a study of the practical as well as legal considerations mentioned above, for submission to the Working Group at a future session.”

SEQUENCE LISTINGS FILED IN ELECTRONIC FORM AS PART OF THE INTERNATIONAL APPLICATION

5. Today, an increasing number of sequence listings are filed in electronic form as part of the international application, either under Part 7 of the Administrative Instructions (as part of an international application filed in electronic form) or under Part 8 of the Administrative Instructions (as part of an international application whose other elements are filed on paper). More and more receiving Offices allow for such filings, and all applicants have the option of filing a sequence listing in electronic form as part of the international application, either under Part 7 or Part 8 of the Administrative Instructions, with the International Bureau as receiving Office. In both cases, whether filed in electronic form under Part 7 or under Part 8 of the Administrative Instructions, the sequence listing in electronic form, being part of the international application as filed, is transmitted by the receiving Office to the International Bureau and kept by the International Bureau as part of the record copy.

6. It would thus appear that, already today, a system is in place under which all applicants are able to file sequence listings in electronic form as part of the international application and these sequence listings are kept by, and available from, a central source, namely, the International Bureau. What appears to be lacking, in practice, however, are operational arrangements (necessitating only minor amendments to the Regulations) which would ensure that International Authorities and designated/elected Offices take advantage of the fact that sequence listings in electronic form are available from a central source and obtain copies of such sequence listings from that central source rather than from the applicant.

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7. It is thus proposed to improve the operational arrangements regarding access by Authorities and Offices (and third parties) to sequence listings filed in electronic form as part of the international application, similar to the “alternative approach” suggested by several delegations during the fifth session of the Working Group (see paragraph 77 of the summary by the chair (document PCT/R/WG/6/12), reproduced in paragraph 4, above), rather than, as in previous documents presented to the Working Group, to establish a separate central system for the deposit of sequence listings filed in electronic form. The main features of the proposed new system are outlined in the following paragraphs.

Availability of Sequence Listings Filed in Electronic Form as Part of International Applications in Electronic Form Filed Under Part 7 of the Administrative Instructions

8. *Availability to the International Searching Authority.* At present, where a sequence listing is filed in electronic form as part of an international application filed in electronic form under Part 7 of the Administrative Instructions, such sequence listing in electronic form is available to the International Searching Authority as part of the search copy, but only where that Authority has notified the International Bureau that it is prepared to process international applications in electronic form (see Section 705(d) of the Administrative Instructions) and thus receives the search copy in electronic form. Unfortunately, to date, none of the International Searching Authorities has so notified the International Bureau, so that, at present, search copies related to international applications filed in electronic form under Part 7 of the Administrative Instructions (including a sequence listing) are sent to the International Searching Authority in the form of a print-out on paper. The International Searching Authority then has to rely on the procedure under Rule 13^{ter}² to obtain from the applicant another copy of the sequence listing in electronic form for the purposes of international search.

9. In order to overcome this (from the viewpoint of the applicant, unacceptable) situation, it is proposed to set up a system under which the International Searching Authority, even if not (yet) prepared to process the entire international applications in electronic form (see Section 705(d) of the Administrative Instructions), would receive from the receiving Office, in addition to the search copy on paper, a copy of the sequence listing in electronic form, in a similar way as is presently the case for sequence listings filed under Part 8 of the Administrative Instructions. Alternatively, should the receiving Office not be prepared to do so, a copy of the sequence listing in electronic form could also be made available to the International Searching Authority by the International Bureau, for example, on a physical medium or via secure online transmission (similar to the existing non-secure view/download service for sequence listings filed under Part 8 of the Administrative Instructions (see <http://www.wipo.int/pct/en/sequences/index.htm>)). The International Searching Authority would then not need (or be entitled) to require the applicant to furnish it, under Rule 13^{ter}, with a copy of the sequence listing in electronic form where such listing, complying with the standard provided for in the Administrative Instructions, was available to it from the receiving Office or the International Bureau. As at present, the procedure under

² References in this document to Rule 13^{ter} are to the text of Rule 13^{ter} as proposed to be amended, as agreed by the sixth session of the Working Group on Reform of the PCT with a view to its submission to the PCT Union Assembly for adoption at its next session in September/October 2004 (see document PCT/A/33/2).

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Rule 13^{ter}.1 would only apply where the sequence listing in electronic form available to the International Searching Authority did *not* comply with the standard provided for in the Administrative Instructions.

10. *International Publication; Availability to Third Parties.* At present, international applications filed in electronic form under Part 7 of the Administrative Instructions are not published in fully electronic form but only in paper form (and are also available, after publication, in an electronic image format). Consequently, third parties do not have access to a sequence listing in a searchable electronic form filed as part of an such international application (other than by way of access to the file held by the International Bureau). Pending a possible move in the near future to international publication in electronic form of all international applications, so as to improve the present situation, it is proposed that sequence listings filed in electronic form as part of an international application filed in electronic form under Part 7 of the Administrative Instructions should, similar as is presently provided for sequence listings filed under Part 8 of the Administrative Instructions, be made available in electronic form, on a dedicated WIPO website, for viewing and downloading via ftp (see, for example, the existing view/download service for sequence listings filed under Part 8 of the Administrative Instructions under <http://www.wipo.int/pct/en/sequences/index.htm>), and/or, upon request, on CD-ROMs/DVDs.

11. *Availability to the International Preliminary Examining Authority.* As regards availability to the International Preliminary Examining Authority of a sequence listing filed in electronic form as part of an international application filed in electronic form under Part 7 of the Administrative Instructions, the situation is very similar to the situation outlined in paragraph 8, above. Since, to date, no International Preliminary Examining Authority has notified the International Bureau that it is prepared to process international applications in electronic form, at present, copies of international applications filed in electronic form under Part 7 of the Administrative Instructions (including international applications which contain a sequence listing in electronic form) are sent to the International Preliminary Examining Authority, for the purposes of international preliminary examination, in the form of a print-out on paper (see Section 420). Again, the International Preliminary Examining Authority then has to rely on the procedure under present Rule 13^{ter} to obtain from the applicant yet another copy of the sequence listing in electronic form for the purposes of international preliminary examination (only, of course, where the International Preliminary Examining Authority is not part of the same national Office or intergovernmental organization as the International Searching Authority).

12. Under the new system as proposed in this document, the International Preliminary Examining Authority, where that Authority is part of the same national Office or intergovernmental organization as the International Searching Authority, would obtain a copy of the sequence listing in electronic form from the International Searching Authority (to which it is available as outlined in paragraph 9, above). Were the International Preliminary Examining Authority is not part of the same national Office or intergovernmental organization as the International Searching Authority, it would obtain a copy of the sequence listing in electronic form from the International Bureau (see Section 420) (on a physical medium or via secure online transmission (similar to the existing non-secure view/download service for sequence listings filed under Part 8 of the Administrative Instructions (see <http://www.wipo.int/pct/en/sequences/index.htm>)). No such Authority would need (or be entitled) to require the applicant to furnish it (under Rule 13^{ter}) with a copy of the sequence

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listing in electronic form, unless the sequence listing in electronic form available to it from the International Searching Authority or the International Bureau does not comply with the standard provided for in the Administrative Instructions.

13. *Availability to designated/elected Offices.* As regards availability to designated/elected Offices of a sequence listing filed in electronic form as part of an international application filed in electronic form under Part 7 of the Administrative Instructions, again, the situation is very similar to the situation outlined in paragraph 8, above. While the International Bureau will soon be in a position to communicate under Article 20, to any designated/elected Office which so wishes, a copy in fully electronic form of an international application filed in fully electronic form under Part 7 of the Administrative Instructions (including any sequence listing in electronic form), to date, no designated/elected Office has notified the International Bureau (see Rule 89bis.1(d)) that it is prepared to process in electronic form international applications filed in electronic form. Consequently, at present, designated/elected Offices receive, under Article 20, a copy of an international application filed in fully electronic form under Part 7 of the Administrative Instructions (including any sequence listing) either in paper form or, if so specified, in an electronic image format. Designated/elected Offices thus again have to rely on the procedure under Rule 13ter to obtain, from the applicant, a copy of the sequence listing in (searchable) electronic form for the purposes of national phase processing.

14. In order to overcome this (from the viewpoint of the applicant, again, unacceptable) situation, it is proposed to set up a system under which any designated/elected Office, even if not (yet) prepared to process the entire international applications in electronic form (see Section 705(d) of the Administrative Instructions), would receive from the International Bureau, if so wished, in addition to the Article 20 communication on paper or in an electronic image format, a copy of the sequence listing in electronic form, in a similar way as is presently the case for sequence listings filed under Part 8 of the Administrative Instructions (that is, by using the view/download service for sequence listings and/or requesting copies to be sent on CD-ROMs/DVDs). No such Office would be entitled to require the applicant to furnish it (under Rule 13ter) with a copy of the sequence listing in electronic form, unless the sequence listing in electronic form available to it from the International Bureau does not comply with the standard provided for in the Administrative Instructions (see the proposed minor amendment of Rule 13ter.3 in the Annex to this document).

Availability of Sequence Listings in Electronic Form Filed Under Part 8 of the Administrative Instructions as Part of International Applications Filed on Paper

15. *Availability to the International Searching Authority.* Already at present, a sequence listing in electronic form filed under Part 8 of the Administrative Instructions, with the remainder of the international application being filed on paper, is available to the International Searching Authority as part of the search copy (see Section 804), so no change of the present system appears to be needed. As at present, the procedure under Rule 13ter.1 would apply where the sequence listing in electronic form available to the International Searching Authority as part of the search copy does *not* comply with the standard provided for in the Administrative Instructions.

16. *International Publication; Availability to Third Parties.* Already at present, where a sequence listing in electronic form is filed under Part 8 of the Administrative Instructions, with the remainder of the international application being filed on paper, the sequence listing in

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electronic form is published in electronic form (only) and thus available to third parties in a searchable electronic form. The sequence listing is not included in the published paper pamphlet, which contains, on the front-page, a reference to the fact that the sequence listing has been filed in electronic form and that the sequence listing in electronic form is available, upon request, from the International Bureau. This may be done by using the view/download service for sequence listings filed under Part 8 of the Administrative Instructions under <http://www.wipo.int/pct/en/sequences/index.htm>), and/or requesting copies to be sent on CD-ROMs/DVDs.

17. *Availability to the International Preliminary Examining Authority.* Already at present, a sequence listing in electronic form filed under Part 8 of the Administrative Instructions, with the remainder of the international application being filed on paper, is available to the International Preliminary Examining Authority, where that Authority is part of the same national Office or intergovernmental organization as the International Searching Authority, from the International Searching Authority (to which it is available as outlined in paragraph 15, above). Where the International Preliminary Examining Authority is not part of the same national Office or intergovernmental organization as the International Searching Authority, the sequence listing in electronic form is available to it from the International Bureau as part of the copy of the international application sent to it under Section 420, so no change of the present system appears to be needed. As at present, the procedure under Rule 13*ter*.1 would apply where the sequence listing in electronic form available to the International Preliminary Examining Authority does *not* comply with the standard provided for in the Administrative Instructions.

18. *Availability to Designated/Elected Offices.* Already at present, where a sequence listing in electronic form is filed under Part 8 of the Administrative Instructions, with the remainder of the international application being filed on paper, the sequence listing in electronic form is available to designated/elected Offices in a searchable electronic form. While not included in the Article 20 communication of the international application to designated/elected Offices, the pamphlet used for Article 20 communication contains, on the front-page, a reference to the fact that the sequence listing has been filed in electronic form and that the sequence listing in electronic form is available to designated/elected Offices, upon request, from the International Bureau. This may be done by using the view/download service for sequence listings filed under Part 8 of the Administrative Instructions under <http://www.wipo.int/pct/en/sequences/index.htm>), and/or requesting copies to be sent on CD-ROMs/DVDs. While it would thus appear that no change of the present system is needed, a minor amendment of Rule 13*ter*.3 is proposed in the Annex to this document, so as to clarify that, if the sequence listing in electronic form is available to the designated/elected Office in a manner and form acceptable to it, that Office is not entitled to require the applicant to furnish it with such sequence listing, unless the sequence listing in electronic form available to it from the International Bureau does not comply with the standard provided for in the Administrative Instructions.

19. *The Working Group is invited to consider the proposals contained in this document and in the Annex to this document.*

[Annex follows]

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ANNEX

PROPOSED AMENDMENTS OF THE PCT REGULATIONS:³

AVAILABILITY OF SEQUENCE LISTINGS IN ELECTRONIC FORM

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³ Proposed additions and deletions are indicated, respectively, by underlining and striking through the text concerned. Certain provisions that are not proposed to be amended may be included for ease of reference.

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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 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”](#)).

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

(b) [No change]

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Rule 13^{ter}⁴

Nucleotide and/or Amino Acid Sequence Listings

13^{ter}.1 [No change] *Procedure Before the International Searching Authority*

(a) [No change] Where the international application contains disclosure of one or more nucleotide and/or amino acid sequences, the International Searching Authority may invite the applicant to furnish to it, for the purposes of the international search, a sequence listing in electronic form complying with the standard provided for in the Administrative Instructions, unless such listing in electronic form is already available to it in a form and manner acceptable to it, and to pay to it, where applicable, the late furnishing fee referred to paragraph (c), within a time limit fixed in the invitation.

(b) [No change] Where at least part of the international application is filed on paper and the International Searching Authority finds that the description does not comply with Rule 5.2(a), it may invite the applicant to furnish, for the purposes of the international search, a sequence listing in paper form complying with the standard provided for in the Administrative Instructions, unless such listing in paper form is already available to it in a form and manner acceptable to it, whether or not the furnishing of a sequence listing in electronic form is invited under paragraph (a), and to pay, where applicable, the late furnishing fee referred to in paragraph (c), within a time limit fixed in the invitation.

⁴ The present text is that of amended Rule 13^{ter} as proposed to be amended, as agreed by the sixth session of the Working Group on Reform of the PCT with a view to its submission to the PCT Union Assembly for adoption at its next session in September/October 2004 (see document PCT/A/33/2).

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[Rule 13ter.2, continued]

(c) [No change] The furnishing of a sequence listing in response to an invitation under paragraph (a) or (b) may be subjected by the International Searching Authority to the payment to it, for its own benefit, of a late furnishing fee whose amount shall be determined by the International Searching Authority but shall not exceed 25% of the international filing fee referred to in item 1 of the Schedule of Fees, not taking into account any fee for each sheet of the international application in excess of 30 sheets, provided that a late furnishing fee may be required under either paragraph (a) or (b) but not both.

(d) [No change] If the applicant does not, within the time limit fixed in the invitation under paragraph (a) or (b), furnish the required sequence listing and pay any required late furnishing fee, the International Searching Authority shall only be required to search the international application to the extent that a meaningful search can be carried out without the sequence listing.

(e) [No change] Any sequence listing not contained in the international application as filed, whether furnished in response to an invitation under paragraph (a) or (b) or otherwise, shall not form part of the international application, but this paragraph shall not prevent the applicant from amending the description in relation to a sequence listing pursuant to Article 34(2)(b).

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[Rule 13ter.1, continued]

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

13ter.2 [No change] *Procedure Before the International Preliminary Examining Authority*

[No change] Rule 13ter.1 shall apply *mutatis mutandis* to the procedure before the International Preliminary Examining Authority.

13ter.3 *Sequence Listing for Designated Office*

Once the processing of the international application which contains disclosure of one or more nucleotide and/or amino acid sequences has started before a designated Office, that Office may invite the applicant to furnish to it, for the purposes of national processing, a sequence listing in electronic form complying with the standard provided for in the Administrative Instructions, unless such listing in electronic form is available to it in a form and manner acceptable to it. No designated Office shall require the applicant to furnish to it a sequence listing other than a sequence listing complying with the standard provided for in the Administrative Instructions.

[End of Appendix and of document]