

## **Patent Cooperation Treaty (PCT) Working Group**

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### **TREATMENT OF A SEQUENCE LISTING SUBMITTED IN AN INTERNATIONAL APPLICATION ON THE INTERNATIONAL FILING DATE**

*Document submitted by the United States of America*

#### **SUMMARY**

1. This document is directed to the issue of an incorrect or non-existent indication by applicant of a sequence listing as forming part of an international application and whether the current framework provides an adequate remedy. The issue was first discussed at the twenty-first session of the Meeting of International Authorities (MIA) held in Tel Aviv in February 2014 (see document PCT/MIA/21/11).

#### **BACKGROUND**

2. Proper characterization of an image or text format sequence listing for an international application can be confusing for applicants. Too frequently, applicants are unaware of the need to indicate that a sequence listing is part of the international application in the Check List of the Request, or improperly indicate it as an accompanying item only. When the error is recognized during the pendency of the international application, the receiving Office (RO) may make an *ex officio* correction or allow the applicant to make a correction of the Check List. However, often the error is not recognized until national or regional phase, when the RO would not normally allow correction, since the international phase has concluded. Such an error may have fatal consequences in the national or regional phase where the disclosure does not otherwise provide sufficient information regarding the sequences.

3. Proper characterization of an image or text format sequence listing for an international application can also be confusing for International Searching, Supplementary International Searching, and International Preliminary Examining Authorities. The sequence listing portion of

forms issued by these authorities should indicate whether the sequence listing was filed or furnished "in the international application as filed," "together with the international application in electronic form," or subsequently to this Authority for the purposes of search (and/or examination)." This indication is, with some frequency, inconsistent with the indications on the Request. The United States Patent and Trademark Office (USPTO) has proposed changes to the language used in these forms.

4. Additionally, proper characterization of an image or text format sequence listing seems to be an area of confusion also for the International Bureau regarding publication of the international application. On occasions, international applications have been incorrectly published: (a) without any indication of a sequence listing part of the international application; (b) with a sequence listing indicated as part of the application, when it was not indicated as such on the Request; or (c) with an indication of the wrong format, i.e. image or text, as part of the application.

5. The issue of incorrect or non-existent indications concerning sequence listings, which are recognized only after national or regional phase entry, was first discussed at the most recent session of the MIA. While it was noted at that time that this situation had so far not occurred in many cases and had not posed major problems for most national Offices, it seems that perhaps the situation has occurred, but may simply have not been recognized.

6. The USPTO has reviewed twelve applications of which we have become aware that contain errors related to the initially filed sequence listing. While most of those applications were filed by US applicants in the RO/US, two of the applications were filed in a receiving Office (RO) other than the RO/US. This would seem to indicate that it is not only U.S. applicants who are confused about the proper indication of sequence listings on the Request, but other applicants as well. In seven of the twelve applications, applicant's error was not recognized until after national phase entry. Information is not yet available for most of the seven applications as to where national or regional phase may have been entered; however, two of the applications have entered national or regional phase in at least four Offices other than the United States. The error in the remaining five applications was recognized prior to national phase entry, including three that were discovered on the 30-month deadline.

7. In seven applications, the sequence listing was provided on the international filing date, but was indicated incorrectly as an accompanying item only; in four additional applications, the Request contained no indication as to status. Nevertheless, the publication indicated that the sequence listing was part of the application in half (six) of the applications. Finally, in one application, the Request indicated only the PDF sequence listing as part of the application, but in contrast, PATENTSCOPE indicated that both the PDF and the TXT sequence listings were part of the application.

8. Consequently, while inconsistencies in the status of the sequence listing exist between the publication/PATENTSCOPE and the Request in half of the applications reviewed, these inconsistencies would not have been obvious to any national or regional Office that relied solely on the publication/PATENTSCOPE for status determination, without reference to the Request.

9. Therefore, in view of the potential fatal defect trap to applicants and the potential confusion for offices as to what properly constitutes the International Application as filed, the United States is proposing that any sequence listing filed on the international filing date, but which is not specifically indicated as forming part of the international application in the Request, be treated as part of the international application. It is believed that this change can be achieved through a simple modification of the RO Guidelines. However, the United States is open to consideration of amending the regulations should the Member States decide that is necessary.

## LEGAL PROVISIONS

10. The following provisions are of particular relevance:

### PCT Rule 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 ... presented as a separate part of the description ...

### PCT Rule 3.3 *Check List*

(a) The request shall contain a list indicating:

(i) the total number of sheets constituting the international application and the number of sheets of each element of the international application: ... description (separately indicating the number of sheets of any sequence listing part of the description) ...

(b) The list shall be completed by the applicant, failing which the receiving Office shall make the necessary indications ...

### PCT Receiving Office Guidelines

225. If the applicant furnishes sheets containing a sequence listing on the same date as the international application, but separately from the international application, the receiving Office, if in doubt, clarifies with applicant whether the sequence listing forms part of the international application. If the applicant so confirms, the receiving Office corrects the check list *ex officio* and invites applicant to pay any required fee for sheets in excess of the previously calculated total number of sheets ...

11. The combination of the above provisions dictates that a sequence listing *shall* form part of the application, and that the indication of such by the applicant in the Request is simply a formality that is correctable by the RO.

## ISSUES

12. The following filing scenarios should be considered:

(i) One sequence listing is provided in either paper/image or text format on the international filing date, but:

(a) The sequence listing is incorrectly indicated as an Accompanying Item only, or

(b) The sequence listing is not indicated at all on the Request;

(ii) Two sequence listings are provided in both paper/image and text format on the international filing date, but:

(a) Both sequence listings are incorrectly indicated as Accompanying Items only,

(b) Both sequence listings are not indicated at all on the Request,

(c) One of the sequence listings is indicated as part of the application, and the other sequence listing is not indicated at all on the Request.

## POLICY CONSIDERATIONS

13. The first scenario, a single sequence listing provided on the international filing date but not indicated as part of the application, directly contradicts the direction of PCT Rule 5.2 that the description *shall* contain a sequence listing. Therefore, consideration of either a paper/image or a text format sequence listing provided on the international filing date as part of the application is simply the logical extension of the regulation, regardless of whether the sequence listing is indicated as an Accompanying Item or is not indicated at all.

14. The second scenario, where multiple sequence listings are provided on the international filing date but are not indicated as part of the application, is not quite as straightforward; however, a strong argument can be made that the outcome should be similar to the first scenario, i.e. that each of the multiple sequence listings should be considered part of the application.

15. The scenario described in paragraph 12(ii)(a) and (b) above, where no sequence listing is indicated as part of the application is similar to the first scenario, in that it directly contradicts the direction of PCT Rule 5.2 that the description *shall* contain a sequence listing. The question then arises as to whether only a single sequence listing or multiple sequence listings should be considered part of the application. No PCT Regulation, Administrative Instruction, or receiving Office Guideline provides direction as to which of two sequence listings should be considered part of the application in the absence of any direction from applicant. Historically, only a single sequence listing has been considered part of the application; however, no PCT Regulation or Administrative Instruction actually prohibits more than one sequence listing forming part of the application. In fact, no harm arises from more than one sequence listing forming part of the application, whereas harm could result where only one of multiple sequence listings is considered to be part of the application and the multiple sequence listings are not identical. Despite best efforts on behalf of the applicant, mistakes are made. Recently, an application was filed with a PDF sequence listing as part of the application, together with a statement of identity to the text sequence listing for search purposes; however, when the ISA recognized that the two were completely different, verification was requested and received from the RO that the text sequence listing transmitted was that provided by applicant, although it did not match the PDF sequence listing part of the application.

16. Currently, where a paper or image sequence listing forms part of the application, then a text file not forming part of the application must be provided for search purposes only, together with a statement that the two are identical. In the scenario described in paragraph 12(ii)(a) and (b) above, likely no such statement would have been provided. However, if both the paper/image and text format of the sequence listing were considered to form part of the application, then such a statement would not be necessary. Any difference discovered during examination would then be handled as any other contradiction between disclosures made in the application on the international filing date, as dictated by national/regional law.

17. The scenario described in paragraph 12(ii)(c) above, where one of the sequence listings is indicated as part of the application, and the other is not indicated at all on the Request, does not directly contradict the direction of PCT Rule 5.2, since a sequence listing forms part of the application. However, as discussed above, applicants do make mistakes – it is possible that the two sequence listings are not identical – and the wrong sequence listing was indicated as part of the application. No identity statement is needed, and no harm arises if more than one sequence listing forms part of the application. On the other hand, harm could definitely result where the second sequence listing is not considered part of the application.

18. One final consideration is that where the sequence listing was provided on the international filing date in paper or as an image, fees for excess sheets may not have been paid during the international phase. However, where the error is not discovered until after completion of the international phase, an invitation to pay additional fees or the collection thereof would be inappropriate.

## PROPOSED CHANGE TO THE PCT RECEIVING OFFICE GUIDELINES

19. Therefore, to protect applicants from reaching the national stage with a fatal defect in their applications and to eliminate confusion on the part of the national offices as to what constitutes the disclosure in the international application, it is proposed to treat any sequence listing filed on the international filing date, but which is not specifically indicated as forming part of the international application in the Request, as part of the international application as filed. As discussed above, the combination of PCT Rule 5.2, PCT Rule 3.3, and RO Guidelines paragraph 225 dictates that a sequence listing *shall* form part of the application, and that the indication of such by the applicant in the Request is simply a formality that is correctable. As such, it would seem that no change is needed in the PCT Regulations, but simply that RO Guidelines paragraph 225 could be clarified as follows:

225. If the applicant furnishes sheets, [an image file, and/or a text file](#) containing a sequence listing on the same date as the international application, but separately from the international application, ~~the receiving Office, if in doubt, clarifies with applicant whether the sequence listing forms part of the international application. If the applicant so confirms,~~ the receiving Office corrects the check list *ex officio* [to indicate that the sequence listing forms part of the international application](#) and invites applicant to pay any required fee for sheets in excess of the previously calculated total number of sheets ...

20. *The Working Group is invited to consider and comment on:*

(a) *whether one or more sequence listings provided on the international filing date should be considered part of the international application despite the absence of any indication as such; and*

(b) *whether the proposed change to the PCT Receiving Office Guidelines is sufficient to effect the proposed change to practice.*

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