



PCT/MIA/IV/6 Rev. 1 ORIGINAL: English DATE: June 27, 1994

WORLD INTELLECTUAL PROPERTY ORGANIZATION GENEVA

INTERNATIONAL PATENT COOPERATION UNION (PCT UNION)

MEETING OF INTERNATIONAL AUTHORITIES UNDER THE PCT

Fourth Session Geneva, June 27 to July 1, 1994

PROPOSAL CONCERNING THE ESTABLISHMENT OF A UNIFORM FORMAT FOR NUCLEOTIDE AND/OR AMINO ACID SEQUENCE LISTINGS

Document prepared by the International Bureau

Introductory Comment

- 1. The present revised document takes more clearly into consideration PCT Rule 13*ter*.1(b) than the original one. Changes are indicated by a vertical line in the margin.
- 2. The Annex to this document contains comments on and proposals by the European Patent Office and the United States Patent and Trademark Office concerning the establishment of a uniform format for nucleotide and/or amino acid sequence listings, in connection with the following items:
 - --Sections 207(b)(ii), 208, 313(c) and 513 of the Administrative Instructions; and
 - -- Form PCT/ISA/225.
- 3. These comments and proposals, which will serve as a topic for discussion at the fourth session of the Meeting of International Authorities under the PCT, are hereby provided to all International Authorities for information and comment.

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ANNEX

SEQUENCE LISTINGS

Comments and proposals by the European Patent Office concerning the Administrative Instructions under the PCT

a) Numbering of sheets of the international application

Section 207(b)(ii):

For the sequence listing (SL) filed with the international application **independent numbering of sheets** might be advisable (if not problems for the international publication).

b) Section 208:

For subsequently filed **SL** independent numbering of sheets from the numbering of the international application as filed is advisable.

- c) As a clarification it is suggested that the SL printed as well as in machine readable form must be sent together with the Search copy to the ISA (Section 313(c)).
- d) Section 513: Addition of a paragraph a(bis) concerning the marking sheets of a subsequently filed SL.

The following wording is suggested:

"Where the ISA receives a sequence listing furnished separately from the international application/ it shall indelibly mark in the middle of the bottom margin of each sheet, the words 'SUBSEQUENTLY FURNISHED SL'."

Furthermore, a new section d) is proposed:

"(d) Where a SL does not comply with the prescribed standard (Section 208) but nevertheless has been accepted by the ISA for the purpose of carrying out the international search, the international search report shall so indicate.

This requires the ISA that is using a "bad" SL to inform the applicant and the downstream offices accordingly.

e) The EPO is working on a **Trilateral/PCT common standard** for SL and therefore will come back on this item in due course.

SEQUENCE LISTINGS

1. Comments relating to the EPO/USPTO proposal for amendment of Form PCT/ISA/225

Recent experience has shown that Form PCT/ISA/225 needs improvement.

The proposed amended form is annexed. [see pages 4 and 5 of this Annex]

The purpose of the proposed amendments is as follows:

- (a) The second and third boxes in Item 2 of the current Form have been merged together to remove duplicated information.
- (b) Item 3 has been extended to cover more statement possibilities.
- (c) An annex to the Form may be necessary in certain cases. More specifically an ISA may wish to attach to the invitation to correct a detailed report to inform the applicant of irregularities in the sequence listing.

2. Statement that the written sequence listing and the sequence listing in machine-readable form are identical

- (a) Under EPO practice, each sequence listing (SL) in machine-readable form must be accompanied by a statement by the applicant that the information so recorded is identical to the information contained in the SL on paper. This requirement applies not only to subsequently filed FD (Rule 13ter.1(b) PCT) but also where the FD is furnished on filing the application (see Rule 27a(2) EPC and the decision of the President of the EPO dated 11 December 1992, Supplement No. 2 to OJ EPO 12/1992, p. 1, annexed hereto). [See pages 6 and 7 of this Annex]
- (b) This requirement avoids the EPO having to check the content of the diskette before the search and thus divests the EPO of any responsibility for the quality of the search if the paper and electronic form of the SL are not identical. In fact, such a comparative check would in practice be impossible.
- (c) Therefore in the procedure under the PCT, and for the case where the applicant has not included the statement on filing, the EPO suggests introducing that requirement of identity also. To ensure legal certainty, it would be advisable to incorporate the requirement in Rule 5.2 as follows:

"Where the International Searching Authority competent for the international application requires that, in addition to the written sequence listing, a machine readable form complying with the standard prescribed in the Administrative Instructions be filed, such data carrier shall be accompanied by a statement by the applicant that the information so recorded is identical to the written sequence listing."

Until this can be done, the EPO proposes to complement Section 208 of the Administrative Instructions by a corresponding paragraph.

An invitation to furnish the statement has been included in the draft Form PCT/ISA/225/ under Item 3, second box.

(d) In order to facilitate the provision of the statement of identity, in the case where the sequence listing is supplied in machine-readable form with the international application, the EPO proposes that the statement be incorporated in the Request Form. This would require an additional box, similar to Box 31 in the EPO Request Form 1001, a copy of which is enclosed herewith. [See page 8 of this Annex]

A specific sub-paragraph should be inserted into Rule 4 PCT which permits the insertion of a specific box in the PCT Request. Until this can be done, the EPO proposes to add a corresponding specific paragraph in Section 208 of the Administrative Instructions.

3. Wording of the statements

To help applicants phrase the statements, the EPO proposes to add on Form PCT/ISA/225, on the Annex sheet, two notes showing a "standard form" for each statement.

The statements proposed are as follows:

- (a) In the case of a sequence listing filed or corrected subsequent to filing of the application/
 - "It is hereby stated that the sequence listing does not include matter which goes beyond the content of the application as filed."
- (b) In the case of a sequence listing in machine readable form:
 - "It is hereby stated that the information recorded in machine readable form is identical to the written sequence listing."

PATENT COOPERATION TREATY

EPO / USPTO Draft (April 1994)

From the INTERNATIONAL SEARCHING AUTHORITY	שעשות וושוקא אוונג אוענו	
To:	PCT	
3000 gg	INVITATION TO FURNISH NUCLEOTIDE AND/ OR AMINO ACID SEQUENCE LISTING	
	(PCT Rule 13ter.1))	
	Date of mailing (day/month/year)	
Applicant's or agent's file reference	REPLY DUE within months/days from the above date of mailing	
International application No.	International filing date (day/month/year)	
Applicant		
 The International Searching Authority has found that the sequence(s) and that the sequence(s) are not presente Administrative Instructions. 	e international application discloses nucleotide and/or amino acided as a listing complying with the standard prescribed by the	
Administrative Instructions, in accordance with to pay to this Authority the cost of the transcription	omplying with WIPO Standard ST.23. In a machine readable form as provided, under Section 208 of the Annex C thereof. In on of the sequence listing into a machine readable form provided, as of the Administrative Instructions, in accordance with Annex C	
	(amount/currency).	
accompanied by a statement to the effect that that listing does no international application as filed.	sequence listing furnished in response to this invitation must be of include matter which goes beyond the disclosure in the time readable form, a statement that the information recorded on ritten sequence listing.	
4. see annex(es)		
 Failure to comply with this invitation may result in this that no meaningful search can be carried out. 	s Authority not carrying out the international search to the extent	
Name and mailing address of the ISA/	Authorized officer	
Facsimile No.	Telephone No.	

Form PCT/ISA/225 (April 1994)

Annex to Form	PCT/ISA/225	International application No.
The sequences disclosed are r	submitted does not comply with the r not all included in the sequence listing y items is/are not indicated in the sequence e not represented in accordance with V	ence listing
The machine readable form that has Section 208 and Annex C of the Ad	s been submitted does not comply with Iministrative Instructions	n WIPO ST. 24,
The machine-readable form has bee	en found to be damaged and/or unread:	able.
Other	7.78	200
Report attached		
	, in the second	

Decision of the President of

the European Patent Office

dated 11 December 1992 con-

Beschluß des Präsidenten des Europäischen Patentamts vom 11. Dezember 1992 über die Darstellung von Nucleotid- und Aminosäuresequenzen in Patentanmeldungen und die Einreichung von Sequenzprotokollen*

Der Präsident des Europäischen Patentamts, gestützt auf Artikel 10 EPÜ Regeln 27a (1) und (2) und 49 (1) EPÜ sowie Regel 13^{ter} PCT, beschließt:

Standardisierte Darstellung von Nucleotid- und Aminosäureseguenzen in europäischen Patentanmeldungen

Hat die in einer europäischen Patentanmeldung offenbarte Erfindung Nucleotid- oder Aminosäuresequenzen zum Gegenstand, so hat die Beschreibung ein Sequenzprotokoll zu enthalten, das dem in Anhang I wiedergege-benen WIPO-Standard ST, 23 entspricht.

Artikel 2

Einreichung von Sequenzprotokollen auf elektronischem Datenträger

- (1) Zusätzlich ist ein Datenträger mit dem Sequenzprotokoll gemäß Artikel 1 einzureichen, der den in Anhang II enthaltenen Vorschriften entspricht.
- (2) Wird ein Sequenzprotokoll nach seiner Einreichung beim Europäischen Patentamt berichtigt, so ist ein neuer Datenträger mit dem Sequenzprotokoll in der geänderten Fassung einzurei-
- (3) Jedem Datenträger ist eine Erklärung des Anmelders beizufügen, daß die auf dem Datenträger gespeicherte Information mit dem schriftlichen Sequenzprotokoll übereinstimmt
- (4) Ist ein Datenträger beschädigt oder aus einem anderen Grund nicht lesbar, so hat der Anmelder einen neuen, einwandfrei lesbaren Datenträger einzureichen

Beseitigung von Mängeln

Wird den in Regel 27a EPÜ und in den Artikeln 1 und 2 dieses Beschlusses genannten Erfordernissen nicht entsprochen, so teilt die Eingangsstelle dies dem Anmelder mit und fordert ihn auf, die festgestellten Mängel innerhalb einer nicht verlängerbaren Frist von zwei Monaten zu beseitigen (Regel 41 (1) EPÜ)

Office, having regard to Article 10 EPC, Rules 27a(1) and (2) and 49(1) EPC and Rule 13ter PCT, has decided as follows:

Article 1

Standardised representation of nucleotide and amino acid sequences in European patent applications

If the subject-matter of the invention disclosed in a European patent application is nucleotide or amino acid sequences, the description shall contain a sequence listing complying with WIPO Standard ST.23 reproduced in Annex I.

Article 2

Filing of sequence listings on electronic data carriers

- 1) In addition, a data carrier shall be filed containing the sequence listing under Article 1 and complying with the rules laid down in Annex II.
- (2) If a sequence listing is corrected after being filed with the European Patent Office, a new data carrier containing the amended sequence listing shall be filed.
- (3) Each data carrier shall be accompanied by a statement by the applicant that the information recorded on the data carrier is identical to the written sequence listing.
- (4) If a data carrier is damaged or unreadable for some other reason, the applicant shall submit a new, perfectly readable data carrier.

Article 3

Rectification of deficiencies

If the requirements laid down in Rule 27a EPC and Articles 1 and 2 of this Decision are not met, the Receiving Section shall inform the applicant accordingly and invite him to remedy the disclosed deficiencies within a non-extendable period of two months (Rule 41(1) EPC)

Le Président de l'Office européen des brevets, vu l'article 10 CBE, les règles 27bis(1) et (2) et 49 (1) CBE ainsi que la règle 13^{ter} PCT, décide:

Article premier

Représentation normalisée de séquences de nucléotides et d'acides aminés dans les demandes de brevet européen

Si l'invention exposée dans une demande de brevet européen a pour obiet des séquences de nucléotides ou d'acides aminés, la description doit contenir une liste de séquences conforme à la norme ST.23 de l'OMPI. reproduite en Annexe I.

Article 2

Dépôt de listes de séquences sur support électronique de données

- (1) En outre, il y a lieu de déposer un support de données contenant la liste de séquences visée à l'article premier et satisfaisant aux prescriptions figurant à l'Annexe II.
- (2) Si une liste de séquences est rectifiée après avoir été déposée auprès de l'Office européen des brevets, il y a lieu de déposer un nouveau support de données contenant la liste de séquences modifiée
- (3) Tout support de données doit être accompagné d'une déclaration du demandeur selon laquelle l'information figurant sur ce support est identique à celle que contient la liste écrite
- (4) Si un support de données est endommagé ou rendu illisible pour toute autre raison, le demandeur doit déposer un nouveau support de données parfaitement lisible

Article 3

Correction d'irrégularités

S'il n'est pas satisfait aux exigences visées à la règle 27bis CBE et aux articles premier et 2 de la présente décision, la section de dépôt le signale au demandeur et l'invite à remédier aux irrégularités constatées dans un délai non prorogeable de deux mois (règle 41(1) CBE).

cerning the representation of nucleotide and amino acid sequences in patent applications and the filing of sequence listings* The President of the European Patent

Décision du Président de l'Office européen des brevets, en date du 11 décembre 1992, relative à la représentation de séquences de nucléotides et d'acides aminés dans les demandes de brevet et au dépôt de listes de séauences*

Siehe dazu den Beschluß des Verwaltungsrats vom 5. Juni 1992 zur Änderung der Ausführungs-ordnung zum EPU, ABI, EPA 1992, 342, sowie die Mitteilung des EPA vom 11. Dezember 1992 in dieser Beilage zum Amtsblatt auf Seite 3.

^{*} See the Decision of the Administrative Council of 5 June 1992 amending the Implementing Regulations to the EPC, OJ EPO 1992, 342, and the Notice from the EPO dated 11 December 1992 in this Supplement to the Official Journal page 3

^{*}Voir à ce propos la décision du Conseil d'admi-nistration du 5 juin 1992 modifiant le reglement d'exécution de la CBE. JO OEB 1992, 342, et le communiqué de l'OEB, en date du 11 decembre 1992, publié dans le présent supplément au Journal officiel, page 3.

Artikel 4

Einreichung von Sequenzprotokollen beim EPA als Internationaler Recherchenbehörde

In bezug auf internationale Anmeldungen nach dem PCT, für die nach Regel 5.2 PCT ein Sequenzprotokoll vorgeschrieben ist, verfährt das Europäische Patentamt als Internationale Recherchenbehörde nach Regel 13ter. 1 PCT und den Abschnitten 208 und 513 der Verwaltungsrichtlinien zum PCT. Artikel 2 (2) bis (4) dieses Beschlusses ist entsprechend anzuwenden.

Artikel 5

Veröffentlichung von Sequenzprotokol-

Ein am Anmeldetag der europäischen Patentanmeldung eingereichtes Sequenzprotokoll wird als Bestandteil der Beschreibung zusammen mit den Anmeldungsunterlagen veröffentlicht. Ein nach dem Anmeldetag, jedoch innerhalb der vom Amt bestimmten Frist eingereichtes oder berichtigtes Sequenzprotokoll wird, wenn es vor dem Zeitpunkt vorliegt. zu dem die technischen Vorbereitungen für die Veröffentlichung als abgeschlossen gelten, als Anlage zu den Anmeldungsunterlagen, andernfalls, bei Patenterteilung, als Anlage zur europäischen Patentschrift veröffentlicht.

Artikel 6

Inkrafttreten

Dieser Beschluß tritt am 1. Januar 1993 in Kraft.

Geschehen zu München, am 11. Dezember 1992.

PAUL BRAENDLI Präsident

Article 4

Filing of sequence listings with the EPO as International Searching Authority

With regard to international applications under the PCT, for which a sequence listing is prescribed under Rule 5.2 PCT, the European Patent Office shall act as International Searching Authority in accordance with Rule 13^{iot}.1 PCT and Sections 208 and 513 of the PCT Administrative Instructions. Article 2(2) to (4) of this Decision shall apply *mutatis mutandis*.

Article 5

Publication of sequence listings

A sequence listing filed on the date of filing of the European patent application shall be published together with the application documents as part of the description. A sequence listing filed or corrected after the date of filing but within the period specified by the Office shall be published as an annex to the application documents, provided it is received before the date on which the technical preparations for publication are deemed to have been completed; otherwise, it shall be published as an annex to the European patent specification when the patent is granted.

Article 6

Entry into force

This decision shall enter into force on 1 January 1993.

Done at Munich, 11 December 1992.

PAUL BRAENDLI President

Article 4

Dépôt de listes de séquences auprès de l'OEB agissant en qualité d'administration chargée de la recherche internationale

En ce qui concerne les demandes internationales déposées au titre du PCT pour lesquelles la règle 5.2 PCT prescrit une liste de séquences. l'Office européen des brevets, agissant en qualité d'administration chargée de la recherche internationale, procède conformément aux dispositions de la règle 13^{ter}.1 PCT et des instructions administratives 208 et 513 du PCT. L'article 2(2) à (4) de la présente décision s'applique.

Article 5

Publication de listes de séquences

Une liste de séquences déposée à la date de dépôt de la demande de brevet européen est publiée comme élément de la description avec les documents de la demande. Une liste de sé-quences déposée ou rectifiée après la date de dépôt, mais dans le délai imparti par l'Office, est, pour autant qu'elle soit disponible avant la date à laquelle les préparatifs techniques entrepris en vue de la publication de la demande sont réputés achevés, publiée en annexe aux documents de la demande, ou, si ce n'est pas le cas, au moment de la délivrance du brevet, en annexe au fascicule du brevet européen.

Article 6

Entrée en vigueur

La présente décision entre en vigueur le 1° janvier 1993.

Fait à Munich, le 11 décembre 1992.

PAUL BRAENDLI Président

EPC-Request Form	
NUCLEOTID-UND AMINOSÄURESEQUENZEN	İ
NUCLEOTIDE AND AMINO ACID SEQUENCES	31
SEQUENCES DE NUCLEOTIDES ET D'ACIDES AMINES	jes
Die Beschreibung enthält ein Sequenzprotokoll nach Regel 27a(1). The description contains a sequence listing in accordance with Rule 27a(1). La description contient une liste de séquences selon la règle 27bis(1)	
Der vorgeschriebene maschinenlesbare Datenträger ist beigefügt. The prescribed machine readable data carrier is enclosed. Le support de données prescrit déchiffrable par machine est annexé.	
Es wird hiermit erklärt, daß die auf dem Datenträger gespeicherte Information mit dem schriftlichen Sequenzprotokoll übereinstimmt (Regel 27a(2)). It is hereby stated that the information recorded on the data carrier is identical to the written sequence listing (Rule 27a(2)). Il est déclaré par la présente que l'information figurant sur le support de données est identique à celle que contient la liste de séquences écrite (règle 27bis (2)).	
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EPA/EPO/OEB Form 1001.3 07.94 (Excerpt)