

Рабочая группа по Договору о патентной кооперации (РСТ)

**Одиннадцатая сессия
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ПЕРЕЧНИ ПОСЛЕДОВАТЕЛЬНОСТЕЙ

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РЕЗЮМЕ

1. Рабочей группе предлагается рассмотреть предварительный проект поправок к Инструкции к РСТ и изменений в Административной инструкции, необходимых для подачи и обработки международных заявок, включающих перечни последовательностей, в соответствии с новым стандартом ВОИС ST.26, с тем чтобы Международное бюро и Целевая группа по перечням последовательностей Комитета по стандартам ВОИС (КСВ) могли руководствоваться ими при разработке процедуры и формального предложения о внесении изменений в нормативную основу РСТ.

ОБЩАЯ ИНФОРМАЦИЯ

2. КСВ принял новый стандарт ВОИС ST.26 в отношении представления перечней последовательностей в формате XML. Целевая группа по перечням последовательностей рекомендовала провести работу в целях применения данного стандарта к национальным и международным заявкам, которые будут поданы начиная с 1 января 2022 г., при условии удовлетворительной разработки программных средств для подготовки, подачи и обработки перечней последовательностей.

3. Что касается процедуры РСТ, то основные различия между стандартами ST.25 и ST.26 заключаются в следующем:

(a) стандарт ST.26 определяет формат представления перечней последовательностей, которые могут представляться только в электронной форме (XML): ST.26 в отличие от ST.25 не предусматривает возможности представления перечней последовательностей на бумаге или в электронной форме в каком-либо ином формате, кроме XML, например в формате PDF. Таким образом, становится крайне предпочтительным представление перечней последовательностей вместе с подачей международной заявки в электронной форме. Если это не возможно, к международным заявкам, поданным на бумаге, должны будут прилагаться перечни последовательностей в электронной форме, представляемые на физических носителях;

(b) стандарт ST.26 более строго определяет, какие последовательности должны или не должны включаться в перечни последовательностей: так, должны включаться все последовательности, содержащие десять и более нуклеотидов, и неразветвленные последовательности, содержащие четыре и более аминокислот, а более короткие последовательности не должны включаться.

4. Основные детальные различия между стандартами будут учтены в специальной программе, разрабатываемой Международным бюро для обеспечения работы сервиса.

ПРОБЛЕМА

5. Что касается PCT, то для перехода от стандарта ST.25 к стандарту ST.26, помимо разработки процедур и создания вспомогательного инструментария, необходимо будет внести определенные поправки в Инструкцию к PCT и изменения в Административную инструкцию. В приложениях к настоящему документу содержатся следующие предварительные проекты предлагаемых изменений в нормативной основе PCT:

(a) приложение I содержит проект предлагаемых поправок к Инструкции к PCT (для удобства пользования в нем также содержатся некоторые положения, касающиеся перечней последовательностей, которые на данном этапе не предлагается менять);

(b) приложение II содержит проект предлагаемых изменений в основном тексте Административной инструкции к PCT; и

(c) приложение III содержит проект предлагаемого приложения С к Административной инструкции к PCT взамен существующего приложения С, включая несколько пояснительных комментариев. Предлагаемое новое приложение С имеет форму полного консолидированного пояснения всех соответствующих процедур подачи и обработки перечней последовательностей в рамках PCT. Поэтому некоторые его положения дублируют соответствующие положения Инструкции к PCT (приложение I) и основного текста Административной инструкции к PCT (приложение II), а также стандарта ВОИС ST.26. Кроме того, оно содержит ряд положений, которые строго с юридической точки зрения, возможно, не являются необходимыми, но содержат справочную информацию, разъясняющую цель некоторых положений. Приложение было составлено таким образом, что в случае дублирующих положений четко показано, основано ли определенное требование на соответствующем правиле Инструкции к PCT или разделе основного текста Административной инструкции к PCT или же оно является новым требованием, вводимом непосредственно в приложении.

6. Проект предложений призван четко показать, какие вопросы будут нуждаться в детальном рассмотрении в ближайшие годы в Международном бюро и Целевой группе по перечням последовательностей КСВ с целью подготовки формального предложения в будущем. Особое внимание по-прежнему требуется уделить вопросам, касающимся

свободного текста (см., в частности, комментарии, приведенные после пункта 9 приложения III), и обеспечению процедур, допускающих эффективную обработку международных заявок, даже поданных на бумаге или в электронной форме, не полностью согласующейся со стандартом.

7. Рабочей группе предлагается принять к сведению предварительные изменения в нормативной основе РСТ, приведенные в приложениях к настоящему документу, и дать указания Международному бюро и проинформировать КСВ относительно вопросов, требующих дальнейшего изучения.

[Приложения следуют]

ПРЕДВАРИТЕЛЬНЫЙ ПРОЕКТ ПОПРАВОК К ИНСТРУКЦИИ К РСТ

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Правило 5

Описание изобретения

5.1 [Без изменений]

5.2 Раскрытие последовательностей нуклеотидов и/или аминокислот

(а) Если международная заявка включает раскрытие одной или нескольких последовательностей нуклеотидов и/или аминокислот, которые в соответствии с Административной инструкцией должны быть указаны в перечне последовательностей, то описание изобретения содержит отдельную часть описания («часть описания, содержащую перечень последовательностей»), в которой указывается перечень ~~этих~~ последовательностей, соответствующий данной ~~который должен соответствовать стандарту, предусмотренному в Административной инструкции, и который и~~ представленный в виде ~~отдельной части описания в соответствии с этим стандартом~~ отдельного электронного файла, также соответствующего данной инструкции («соответствующий требованиям перечень последовательностей»).

[КОММЕНТАРИЙ: Новый стандарт по сути главным образом основан на стандарте ВОИС ST.26 (в отличие от существующего текста, в котором стандарт полностью воспроизводится в приложении С к Административной инструкции). Тем не менее, предлагается, чтобы ссылка в тексте делалась на Административную инструкцию, а не непосредственно на стандарт ST.26, с тем чтобы можно было более четко прописать отдельные детали, связанные с управлением версиями, а также применением соответствующей процедуры и выполнением требований, касающихся РСТ. Термин «соответствующий требованиям перечень последовательностей» предлагается для использования в последующих положениях при том понимании, что некоторые получающие ведомства будут осуществлять лишь весьма ограниченные проверки перечней последовательностей на предмет их соответствия требованиям, если вообще будут их осуществлять, но такие проверки могут проводиться или требоваться международными органами и указанными или выбранными ведомствами.]

(a-bis) Любой содержащийся в поданной международной заявке файл, заявленный как перечень последовательностей или имеющий вид перечня последовательностей, считается частью описания независимо от того, указан ли данный перечень в основной части описания или заявки.

[КОММЕНТАРИЙ: Данное предложение не связано напрямую с переходом от стандарта ВОИС ST.25 к стандарту ВОИС ST.26 и имеет своей целью свести к минимуму риск того, что перечень может не рассматриваться как часть поданной заявки вследствие того, что он был неправильно назван, при том что данный риск возрастает, если собственно заявка подана на бумаге, а перечень последовательностей в электронной форме – на физическом.]

(b) [Без изменений] Если часть описания, содержащая перечень последовательностей, содержит какой-либо [зависящий от языка](#) свободный текст, как это определено в ~~стандарте, предусмотренном в~~ Административной инструкции, то этот [зависящий от языка](#) свободный текст приводится и в основной части описания изобретения на языке этого описания.

[КОММЕНТАРИЙ: См. дополнительное пояснение к пунктам 6-9 в приложении III.]

Правило 12

Язык международной заявки и переводы для целей международного поиска и международной публикации

12.1 Языки, допустимые для подачи международных заявок

(a) Международная заявка подается на любом из языков, которые Получающее ведомство допускает для этой цели.

(b) Каждое Получающее ведомство для целей подачи международных заявок допускает, по меньшей мере, один язык, который одновременно является:

(i) языком, допустимым Международным поисковым органом, или, где это применимо, по меньшей мере, одним из Международных поисковых органов, компетентным проводить международный поиск по международным заявкам, поданным в это Получающее ведомство, и

(ii) языком публикации.

(c) Несмотря на пункт (a), заявление подается на любом из языков публикации, которые Получающее ведомство допускает для целей настоящего пункта.

(d) Несмотря на пункт (a), любой текстовой материал в части описания, содержащей перечень последовательностей, ~~упомянутый в правиле 5.2(a)~~, представляется в соответствии со стандартом, предусмотренным в Административной инструкции.

12.1bis - 12.2 *[Без изменений]*

12.3 *Перевод для целей международного поиска*

(a) [Без изменений] Если язык, на котором подается международная заявка, не допускается Международным поисковым органом, который проводит международный поиск, то заявитель в течение одного месяца с даты получения международной заявки Получающим ведомством представляет в это ведомство перевод международной заявки на язык, отвечающий всем следующим требованиям:

(i) языком, допустимым этим Органом, и

(ii) язык является языком публикации, и

(iii) язык допускается Получающим ведомством в соответствии с правилом 12.1(a), если только международная заявка не подана на языке публикации.

(b) [Без изменений] Пункт (a) не применяется ни в отношении заявления, ни в отношении части описания, содержащей перечень последовательностей.

[КОММЕНТАРИЙ: Как представляется, вышеприведенное положение не нуждается в изменении.]

(c) - (e) [Без изменений]

12.4 *Перевод для целей международной публикации*

(a) [Без изменений] Если язык, на котором подана международная заявка, не является языком публикации и не требуется перевода в соответствии с правилом 12.3(a), то заявитель в течение 14 месяцев с даты приоритета представляет в Получающее ведомство перевод международной заявки на любой из языков публикации, которые Получающее ведомство допускает для целей настоящего пункта.

(b) [Без изменений] Пункт (a) не применяется ни в отношении заявления, ни в отношении части описания, содержащей перечень последовательностей.

[КОММЕНТАРИЙ: Как представляется, вышеприведенное положение не нуждается в изменении.]

(c) - (e) [Без изменений]

Правило 13ter

Перечни последовательностей нуклеотидов и/или аминокислот

13ter.1 Процедура, применяемая Международным поисковым органом

(а) Если международная заявка содержит раскрытие одной или нескольких последовательностей нуклеотидов и/или аминокислот, которые в соответствии с Административной инструкцией должны быть включены в перечень последовательностей, но поданная международная заявка не содержит соответствующего требованиям перечня последовательностей, то Международный поисковый орган может предложить заявителю представить для целей международного поиска соответствующий требованиям перечень последовательностей ~~в электронной форме, соответствующий стандарту, предусмотренному в Административной инструкции~~, если только такой перечень ~~в электронной форме~~ уже не является доступным ему приемлемым для него способом и в приемлемой для него форме, а также этот Орган может предложить уплатить, когда это применимо, пошлину за позднее представление перечня, упомянутую в пункте (с), в срок, установленный в предложении.

[КОММЕНТАРИЙ: Положение изменено, так как новый стандарт более детально определяет, какие последовательности должны быть или не должны быть указаны в перечне последовательностей, а также потому, что перечень по определению должен представляться в электронной форме.]

~~(b) — Если по меньшей мере часть международной заявки подана на бумаге и Международный поисковый орган устанавливает, что описание не соответствует правилу 5.2(а), то он может предложить заявителю представить для целей международного поиска перечень последовательностей на бумаге, соответствующий стандарту, предусмотренному в Административной инструкции, если только такой перечень на бумаге уже не является доступным ему приемлемым для него способом и в приемлемой для него форме, независимо от того, предложено ли в соответствии с пунктом (а) представить перечень последовательностей в электронной форме, а также~~

~~этот Орган может предложить уплатить, когда это применимо, пошлину за позднее представление перечня, упомянутую в пункте (с), в срок, установленный в предложении.~~

[КОММЕНТАРИЙ: Вышеприведенный пункт представляется ненужным, так как соответствующий требованиям перечень последовательностей нельзя представить на бумаге.]

(с) Представление перечня последовательностей в ответ на предложение в соответствии с пунктом (а) ~~или (б)~~ может сопровождаться уплатой Международному поисковому органу, в его пользу, пошлины за позднее представление перечня, размер которой определяется Международным поисковым органом, но не превышает 25% от размера международной пошлины за подачу, упомянутой в пункте 1 Перечня пошлин, без учета пошлины за каждый лист международной заявки свыше 30, ~~при условии, что уплата пошлины за позднее представление перечня может быть предусмотрена или в соответствии с пунктом (а), или в соответствии с пунктом (б), но не в соответствии с двумя пунктами сразу.~~

(d) Если заявитель в срок, установленный в предложении в соответствии с пунктом (а) ~~или (б)~~, не представит ~~требуемый~~ соответствующий требованиям перечень последовательностей и не уплатит требуемую пошлину за позднее представление перечня, то Международный поисковый орган проводит поиск по международной заявке в той мере, в какой возможно проведение полноценного поиска без соответствующего требованиям перечня последовательностей.

(е) Любой перечень последовательностей, не содержащийся в международной заявке при ее подаче, независимо от того, представлен ли он в ответ на предложение в соответствии с пунктом (а) ~~или (б)~~, или как-то иначе, не является частью международной заявки; ~~не~~ однако в соответствии со статьей 34(2)(b) данный пункт не запрещает заявителю изменять описание в отношении раскрытия любых перечня последовательностей нуклеотидов и/или аминокислот, содержащихся в международной

заявке при ее подаче, независимо от того, были ли эти последовательности включены в соответствующий требованиям перечень последовательностей ~~в соответствии со статьей 34(2)(b).~~

[КОММЕНТАРИЙ: Поправки представляются необходимыми для того, чтобы более четко отразить тот факт, что «перечни последовательностей» получают более узкое определение, чем прежде, и возможно внесение поправок, вследствие которых раскрытие последовательностей производится в формате, соответствующем перечню последовательностей, если только это не ведет к включению дополнительного объекта.]

(f) [Без изменений] Если Международный поисковый орган устанавливает, что описание не соответствует правилу 5.2(b), то он предлагает заявителю представить необходимое исправление. Правило 26.4 *mutatis mutandis* применяется к любым исправлениям, представленным заявителем. Международный поисковый орган пересылает исправления Получающему ведомству и Международному бюро.

13ter.2 *[Без изменений] Процедура, применяемая Органом международной предварительной экспертизы*

Правило 13ter.1 применяется *mutatis mutandis* к процедуре, применяемой Органом международной предварительной экспертизы.

13ter.3 *[Без изменений] Перечень последовательностей для указанного ведомства*

Ни одно указанное ведомство не может требовать от заявителя представления какого-либо иного перечня последовательностей, кроме перечня, соответствующего стандарту, предусмотренному в Административной инструкции.

Правило 49

Копия, перевод и пошлина в соответствии со статьей 22

49.1 - 49.4 *[Без изменений]*

49.5 *Содержание перевода и требования к его оформлению*

(a) *[Без изменений]* Для целей статьи 22 перевод международной заявки должен содержать описание (с учетом пункта (a-bis)), формулу изобретения, любые надписи на чертежах, и реферат. Если это требуется указанным ведомством, то перевод также, с учетом пунктов (b), (c-bis) и (e):

(i) содержит заявление;

(ii) содержит как формулу изобретения в том виде, в каком она подана, так и измененную формулу изобретения, если формула изобретения была изменена в соответствии со статьей 19 (измененная формула изобретения представляется в форме перевода полного набора пунктов формулы изобретения, представленного в соответствии с правилом 46.5(a) взамен всей первоначально поданной формулы изобретения), и

(iii) сопровождается копией чертежей.

(a-bis) *[Без изменений]* Ни одно указанное ведомство не может требовать, чтобы заявитель представил ему перевод текстового материала, содержащегося в той части описания изобретения, которая содержит перечень последовательностей, если такая часть удовлетворяет требованиям правила 12.1(d) и если описание изобретения удовлетворяет требованиям правила 5.2(b).

[КОММЕНТАРИЙ: Это важный принцип, который должен остаться без изменений, хотя вопросы в отношении того, что следует считать свободным текстом, могут привести к некоторым изменениям. См. комментарий после пункта 9 приложения III.]

(b) - (l) [Без изменений]

49.6 [Без изменений]

[Приложение II следует]

PRELIMINARY DRAFT MODIFICATIONS
TO THE PCT ADMINISTRATIVE INSTRUCTIONS

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Section 101

Abbreviated Expressions and Interpretation

(a) In these Administrative Instructions:

(i) to (xi) [No change]

(xii) the expressions “sequence listing”, “sequence listing forming part of the international application” and “sequence listing not forming part of the international application” have the same meaning as in Annex C.

[COMMENT: The exact group of expressions which should be defined at this point will be considered following further consideration of the substantive changes which may be required.]

(b) [No change]

Section 204

Headings of the Parts of the Description

(a) The headings of the parts of the description shall preferably be as follows:

(i) to (vi) [No change]

(vii) [Deleted] ~~for matter referred to in Rule 5.2(a), “Sequence Listing”;~~

[COMMENT: It would only be possible to submit sequence listings as separate electronic files. Consequently, there will be no purpose for a section with a heading “Sequence Listing”. Any description of or reference to the sequence listing could be placed elsewhere in the main part of the description.]

(viii) for matter referred to in Rule 5.2(b), “Sequence Listing Free Text.”

(b) [No change]

Section 207

Arrangement of Elements and Numbering of Sheets of the International Application

(a) In effecting the sequential numbering of the sheets of the international application in accordance with Rule 11.7, the elements of the international application shall be placed in the following order:

(i) the request;

(ii) 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 referred to in [Rule 5\(2\)\(a\)](#) ~~item (vi) of this paragraph~~);

(iii) the claims;

(iv) the abstract;

(v) if applicable, the drawings;

(vi) [Deleted] ~~if applicable, the sequence listing part of the description.~~

(b) The sequential numbering of the sheets shall be effected by using the following separate series of numbering:

(i) the first series applying to the request only and commencing with the first sheet of the request;

(ii) the second series commencing with the first sheet of the description (as referred to in paragraph (a)(ii)) and continuing through the claims until the last sheet of the abstract;

(iii) if applicable, a further series applying to the sheets of the drawings only and commencing with the first sheet of the drawings; the number of each sheet of the drawings shall consist of two Arabic numerals separated by a slant, the first being the sheet number and the second being the total number of sheets of drawings (for example, 1/3, 2/3, 3/3);

~~(iv) if applicable, a further series applying to the sequence listing part of the description, commencing with the first sheet of that part.~~

(c) Any sequence listing shall be presented as a compliant sequence listing in the form of an electronic file in XML format, which is not a page-based format and thus does not require page numbering.

[COMMENT: The above paragraph is not strictly necessary as it is of a merely explanatory nature. However, it may be worth considering in order to avoid concern that a section of the international application might have been omitted accidentally.]

Section 208

Sequence Listings

Any sequence listing, ~~whether on paper or in electronic form,~~ whether forming part of the international application or not forming part of the international application, shall comply with Annex C.

Section 313

Documents Filed with the International Application; Manner of Marking the Necessary Annotations in the Check List

(a) Any power of attorney, any priority document, any fee calculation sheet and any separate sheet referred to in Section 209(a) containing indications as to deposited biological material, filed with the international application shall accompany the record copy; any other document referred to in Rule 3.3(a)(ii) shall be sent only at the specific request of the International Bureau. If any document which is indicated in the check list as accompanying the international application is not, in fact, filed at the latest by the time the record copy leaves the receiving Office, that Office shall so note on the check list and the said indication shall be considered as if it had not been made.

(b) Where, under Rule 3.3(b), the receiving Office itself completes the check list, that Office shall enter, in the margin, the words "COMPLETED BY RO" or their equivalent in the language of publication of the international application. Where only some of the indications are completed by the receiving Office, the said words and each indication completed by that Office shall be identified by an asterisk.

~~(c) [Deleted] Any sequence listing not forming part of the international application, whether on paper or in electronic form, that is furnished for the purposes of the international search to the receiving Office together with the international application or subsequent to the filing of the international application, shall be transmitted to the International Searching Authority together with the search copy. Where such a sequence listing is received by the receiving Office after the transmittal of the search copy, that sequence listing shall be promptly transmitted to the International Searching Authority.~~

[COMMENT: According to proposed Rule 5.2(a-bis), all sequence listings filed together with the international application would be considered part of the description – there would be no need or possibility to file a second sequence listing, not forming part of the description, for the purposes of international search.]

(c) Where an international application is filed on paper, any sequence listing shall be filed on a physical medium in accordance with the procedures set out in Annex C. Each receiving Office shall notify the International Bureau of the forms of physical media accepted for this purpose. The International Bureau shall promptly publish details of the notification in the Gazette.

(d) Paragraph (c) shall apply *mutatis mutandis* to international applications filed in electronic form where any sequence listings in the application were not included within the package containing the remainder of the international application.

Section 513
Sequence Listings

(a) Where the International Searching Authority receives a correction of a defect under Rule 13^{ter}.1(f), it shall:

(i) indelibly mark, in the upper right-hand corner of each replacement sheet, the international application number and the date on which that sheet was received;

(ii) indelibly mark, in the middle of the bottom margin of each replacement sheet, the words "SUBSTITUTE SHEET (Rule 13^{ter}.1(f))" or their equivalent in the language of publication of the international application;

(iii) indelibly mark on the letter containing the correction, or accompanying any replacement sheet, the date on which that letter was received;

(iv) keep in its files a copy of the letter containing the correction or, when the correction is contained in a replacement sheet, the replaced sheet, a copy of the letter accompanying the replacement sheet, and a copy of the replacement sheet;

(v) promptly transmit any letter and any replacement sheet to the International Bureau, and a copy thereof to the receiving Office.

[COMMENT: The procedures concerning the sequence listing free text in the main part of the description would remain unchanged.]

(b) Where the international search report and the written opinion of the International Searching Authority are based on a [compliant](#) sequence listing not forming part of the international application but furnished for the purposes of the international search, the international search report and the written opinion of the International Searching Authority shall so indicate.

(c) Where a meaningful international search cannot be carried out and a meaningful written opinion, as to whether the claimed invention appears to be novel, to involve an inventive step (to be non-obvious) and to be industrially applicable, cannot be established because a [compliant](#) sequence listing is not available to the International Searching Authority ~~in the required form~~, that Authority shall so state in the international search report or declaration referred to in Article 17(2)(a), and in the written opinion.

(d) ~~The International Searching Authority shall indelibly mark, on the first sheet of any sequence listing on paper which does not form part of the international application but was furnished for the purposes of the international search, the words “SEQUENCE LISTING NOT FORMING PART OF THE INTERNATIONAL APPLICATION” or their equivalent in the language of publication of the international application.~~ Where ~~such~~ [a](#) sequence listing [for the purposes of the international search](#) is furnished ~~in electronic form~~ on a physical medium, that Authority shall physically label that medium [in accordance with the procedures in Annex C](#) ~~accordingly~~.

[COMMENT: It is not necessary to regulate the metadata used internally by International Searching Authorities to identify the different types of sequence listing which have been transmitted electronically, rather than submitted on physical media; the means of identifying the files for the purpose of exchange with the International Bureau or other Offices are set out in Annex F and/or the “minspec” document exchange specification.]

(e) The International Searching Authority shall:

(i) keep in its files one copy of any sequence listing, ~~whether on paper or in electronic form,~~ which does not form part of the international application but was furnished for the purposes of the international search; and

(ii) ~~where the sequence listing which does not form part of the international application but was furnished for the purposes of the international search is in electronic form,~~ transmit one copy thereof to the International Bureau together with the copy of the international search report. If that listing ~~in electronic form~~ is filed on a physical medium in less than the number of copies required by the International Searching Authority, that Authority shall be responsible for the preparation of the additional copy and shall have the right to fix a fee for performing that task and to collect such fee from the applicant.

(f) ~~Any~~ Each International Searching Authority ~~which requires, for the purposes of the international search, the furnishing of a sequence listing in electronic form~~ shall notify the International Bureau ~~accordingly. In that notification, the Authority shall specify~~ of the means of transmittal of the sequence listing ~~in electronic form~~ accepted by it in accordance with Annex F. The International Bureau shall promptly publish details of the notification in the Gazette.

[COMMENT: It would be mandatory for all International Searching Authorities to accept sequence listings in electronic form, though this could be limited to physical media.]

Section 610

Sequence Listings

(a) Where the written opinion of the International Preliminary Examining Authority or the international preliminary examination report is based on a [compliant](#) sequence listing not forming part of the international application but furnished for the purposes of the international preliminary examination, the written opinion and the international preliminary examination report of the International Preliminary Examining Authority shall so indicate.

(b) Where a meaningful written opinion of the International Preliminary Examining Authority cannot be established, or a meaningful international preliminary examination cannot be carried out, as to whether the claimed invention appears to be novel, to involve an inventive step (to be non-obvious) and to be industrially applicable, because a [compliant](#) sequence listing is not available to the International Preliminary Examining Authority ~~in the required form~~, that Authority shall so state in the written opinion and in the international preliminary examination report.

(c) ~~The International Preliminary Examining Authority shall indelibly mark, on the first sheet of any sequence listing on paper which does not form part of the international application but was furnished for the purposes of the international preliminary examination, the words “SEQUENCE LISTING NOT FORMING PART OF THE INTERNATIONAL APPLICATION” or their equivalent in the language of publication of the international application.~~ Where ~~such a~~ [sequence listing for the purposes of the international preliminary examination](#) is furnished in ~~electronic form~~ on a physical medium, that Authority shall physically label that medium [in accordance with the procedures in Annex C](#) ~~accordingly~~.

[COMMENT: As for Section 513(d).]

(d) The International Preliminary Examining Authority shall keep in its files one copy of any sequence listing, ~~whether on paper or in electronic form,~~ which does not form part of the international application but was furnished for the purposes of the international preliminary examination.

(e) ~~Any~~ Each- International Preliminary Examining Authority ~~which requires, for the purposes of the international preliminary examination, the furnishing of a sequence listing in electronic form~~ shall notify the International Bureau ~~accordingly. In that notification, the Authority shall specify~~ of the means of transmittal of the sequence listing ~~in electronic form~~ accepted by it in accordance with Annex F. The International Bureau shall promptly publish details of the notification in the Gazette.

[COMMENT: As for Section 513(f).]

(f) Where the national Office or intergovernmental organization that acted as the International Searching Authority also acts as the International Preliminary Examining Authority, any compliant sequence listing not forming part of the international application but furnished to that Office or organization for the purposes of the international search shall be considered to have been furnished to it also for the purposes of the international preliminary examination.

Section 703

Filing Requirements; Basic Common Standard

(a) An international application may, subject to this Part, be filed in electronic form if the receiving Office has notified the International Bureau in accordance with Rule 89*bis*.1(d) that it is prepared to receive international applications in such form.

(a-bis) All receiving Offices shall be required, in the circumstances referred to in Section 313(c), to accept the filing of sequence listings in electronic form on physical media and shall specify at least one form of physical medium in accordance with Annex F which it accepts for the filing of such sequence listings. Preferably, such media shall include at least one form of medium accepted by each International Searching Authority which is competent for searching international applications filed with it.

[COMMENT: Given the difficulties of obtaining notifications from all receiving Offices, most of which would never actually receive such a physical medium, it may be appropriate to indicate a default, where in the absence of a notification the receiving Office must accept a sequence listing on a physical medium of a type accepted by the relevant International Searching Authority. Consideration might be given to an amendment to Rule 19.4, allowing receiving Offices which do not wish to deal with physical media to forward the international application to the International Bureau to act as receiving Office.]

(b) to (f) [No change]

Section 707

Calculation of International Filing Fee and Fee Reduction

(a) Where an international application is filed in electronic form, the international filing fee shall, subject to paragraph (a-bis), be calculated on the basis of the number of sheets that the application would contain if presented as a print-out complying with the physical requirements prescribed in Rule 11.¹

(a-bis) Where ~~a sequence listing is contained in an~~ the international application as filed contains a sequence listing ~~in electronic form~~, the calculation of the international filing fee shall, in the calculation of the number of sheets, not take into account any ~~sheet of the sequence listing if that listing is presented as a separate part of the description in accordance with Rule 5-2(a) and is in the electronic document format specified in paragraph 40 of Annex C~~ material contained in an electronic file which appears to the receiving Office to be a sequence listing.

[COMMENT: The receiving Office would not be required to perform any checks on the format of the sequence listings – notably, receiving Offices which have no electronic filing systems and simply accept the listing on a physical medium may assume that any appropriately labeled disk is a compliant listing. This is intended simply to allow page fees to be collected in cases where a file is provided which is clearly not intended to be a sequence listing, for example if a PDF file of further description or drawings had been attached, mislabeled as sequence listings.]

(b) Item 4(b), (c) and (d) of the Schedule of Fees annexed to the Regulations shall apply to reduce the fees payable in respect of an international application filed in electronic form with a receiving Office which has notified the International Bureau under Section 710(a) that it is prepared to receive international applications in electronic form or which has decided to receive such an application in accordance with Section 703(d).

¹ *Editor's Note:* Noting that Rule 11 leaves some flexibility as to the margins of the sheets (see Rule 11.6) and the size of the characters (see Rule 11.9(d)), the international filing fee should be calculated on the basis of the number of sheets that the application would contain if presented as a print-out complying with the minimum margin and character size requirements. In practice, however, the receiving Office should not print out the international application but rather rely on the number of pages of the international application as calculated by the electronic filing software and indicated in the request.

Section 710

Notification and Publication of Receiving Offices'

Requirements and Practices

(a) A notification by a receiving Office to the International Bureau under Rule 89*bis*.1(d) and Section 703(a) that it is prepared to receive international applications in electronic form shall indicate, where applicable:

(i) the electronic document formats (including, where applicable, the versions of such electronic document formats), means of transmittal, types of electronic packages, electronic filing software and types of electronic signature specified by it under Section 703([a-bis](#)), (b)(i) to (iv) and (c), and any options specified by it under the basic common standard;

(ii) the conditions, rules and procedures relating to electronic receipt, including hours of operation, choices for processes to verify or acknowledge receipt, choices for electronic communication of invitations and notifications, any methods of online payment, details concerning any help desks, electronic and software requirements and other administrative matters related to the filing in electronic form of international applications and related documents;

(iii) the kinds of documents which may be transmitted to or by the Office in electronic form;

(iv) whether and under what conditions the Office accepts the filing under Section 706(a) and (f), of documents in pre-conversion formats and the electronic document format(s) (including, where applicable, the versions of such electronic document format(s)) accepted by it under that Section;

(v) procedures for notification of applicants and procedures which applicants may follow as alternatives when the electronic systems of the Office are not available;

(vi) the certification authorities that are accepted by the Office, and the electronic addresses of the certificate policies under which certificates are issued;

(vii) the procedures relating to access to the files of international applications filed or stored in electronic form.

(b) The receiving Office shall notify the International Bureau of any change in the matters previously indicated by it in a notification under Section 705*bis*(a) or paragraph (a) of this Section.

(c) The International Bureau shall promptly publish in the Gazette any notification received by it under Section 705*bis*(a) or paragraph (a) or (b) of this Section.

(d) The effective date of any change notified under paragraph (b) shall be as specified by the receiving Office in the notification, provided that any change which restricts filing options shall not be effective earlier than two months after the date of publication of the notification of the change in the Gazette.

[Annex III follows]

PRELIMINARY DRAFT REPLACEMENT FOR
ANNEX C OF THE PCT ADMINISTRATIVE INSTRUCTIONS

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ANNEX C
INSTRUCTIONS RELATING TO THE PRESENTATION
OF NUCLEOTIDE AND AMINO ACID SEQUENCE LISTINGS
IN INTERNATIONAL PATENT APPLICATIONS UNDER THE PCT

INTRODUCTION

1. This Annex provides Instructions for the procedures involved in the filing and processing of sequence listings in international applications. The requirements for the presentation of the listings are set out in WIPO Standard ST.26, subject to the specific requirements set out below.

DEFINITIONS

2. For the purposes of these Instructions:

(i) the expression “sequence listing” has the same meaning as defined in WIPO Standard ST.26, having regard to paragraph 3, below;

(ii) “sequences”, “nucleotides” and “amino acids” have the same meanings as in WIPO Standard ST.26.

(iii) the expression “sequence listing forming part of the international application” means a sequence listing contained in the international application as filed, including any sequence listing or part thereof which is included in the international application under Rule 20.5(b) or (c), which is considered to have been contained in the international application under Rule 20.6(b), or which has been corrected under Rule 26, rectified under Rule 91 or amended under Article 34(2); or a sequence listing included in the international application by way of an amendment under Article 34(2)(b) of the description in relation to sequences contained in the international application as filed;

(iv) the expression “sequence listing not forming part of the international application” means a sequence listing which does not form part of the international application but is furnished for the purposes of the international search or international preliminary examination.

RELATIONSHIP WITH WIPO STANDARD ST.26

3. Following any revision of WIPO Standard ST.26, the Director General shall decide a date from which the revised version of the Standard shall apply to international applications and publish that information in the Gazette. Sequence listings shall be presented in accordance with the version of WIPO Standard ST.26 so applicable to international applications on the international filing date.

SEQUENCES WHICH MUST BE PRESENTED IN A LISTING

4. In accordance with WIPO Standard ST.26, a sequence for which inclusion in a sequence listing is required for the purposes of Rule 5.2 is one that is disclosed anywhere in an international application by enumeration of its residues and can be represented as:

(a) an unbranched sequence or a linear region of a branched sequence containing ten or more specifically defined nucleotides, wherein adjacent nucleotides are joined by:

(i) a 3' to 5' (or 5' to 3') phosphodiester linkage; or

(ii) any chemical bond that results in an arrangement of adjacent nucleobases that mimics the arrangement of nucleobases in naturally occurring nucleic acids; or

(b) an unbranched sequence or a linear region of a branched sequence containing four or more specifically defined amino acids, wherein adjacent amino acids are joined by peptide bonds.

5. In accordance with WIPO Standard ST.26, a sequence listing must not include, as a sequence assigned its own sequence identification number, any sequences having fewer than ten specifically defined nucleotides, or fewer than four specifically defined amino acids.

[COMMENT: This is a fundamental aspect of what must and must not be included in a sequence listing and is very unlikely to change between versions of ST.26. It is also fundamentally different from most of the formatting issues in that it needs to be actively understood by the applicant, rather than being a matter which will be handled transparently by the software used for preparing the listing. As such, it seems useful to expressly include these

provisions within this Annex, rather than expecting applicants to find the reference within WIPO Standard ST.26.]

PRESENTATION OF SEQUENCE LISTINGS AND FREE TEXT

6. A sequence listing compliant with WIPO Standard ST.26 takes the form of an electronic file in XML format. In accordance with Rule 5.2, the sequence listing part of the description shall be presented as separate from the main part of the description. It is unnecessary and usually undesirable to set out the sequences themselves elsewhere in the description.

7. According to WIPO Standard ST.26, qualifiers are used to supply information about features in addition to that conveyed by the feature key and feature location. There are three types of value formats to accommodate different types of information conveyed by qualifiers: (i) free text; (ii) controlled vocabulary or enumerated values (for example, a number or date); and (iii) sequences. Free text is a type of value format for certain qualifiers (as indicated in Annex I to WIPO Standard ST.26) that is presented in the form of a descriptive text phrase that should preferably be in the English language. In any case, such text phrases shall only use characters from the Unicode Basic Latin code table (excluding certain reserved characters defined in WIPO Standard ST.26), which precludes including free text in several of the PCT languages of publication.

8. The qualifiers indicated in Annex I of WIPO Standard ST.26 as being “free text” fall into several categories. Some are entirely language independent since, while being described as free text and not controlled by the schema, the expected format is specified as a number or code which does not vary between languages. Some may be effectively language-independent because the expected values are personal names or internationally used terms for an organism (for example “homo sapiens”). Some are always language dependent, taking the form of genuinely free text comments. Where the sequence listing part of the description contains any language-dependent free text, that free text shall also appear in the main part of the description in the language thereof. It is recommended that the free text in the language of the main part of

the description be put in a specific section of the description called “Sequence Listing Free Text”.

9. For the purposes of Rule 49.5(a-bis), a sequence listing filed as part of the international application shall be considered to comply with Rule 12.1(d) only if the language-dependent free text is in English. However, the International Searching Authority and International Preliminary Examining Authority shall not require the applicant to furnish a sequence listing for the purposes of international search or preliminary examination solely because the listing forming part of the international application contains free text in a language other than English, provided that the free text is included in the “sequence listing free text” part of the description in the language of the international application or the translation provided for publication, international search or international preliminary examination, as the case may be.

[COMMENT: One of the key objectives of WIPO Standard ST.26 was to permit the sequences to be imported efficiently by database suppliers, who expect any language-dependent annotations to be in English, even where that is not the main language of the country in which they are based. It is not practical to strictly require this in the international phase because amendment is only possible using Chapter II and most receiving Offices would not be capable of making the checks which would be necessary.

The above provisions are intended to allow the application to proceed efficiently within the international phase, but for English language listings to be required in the national phase where it appears appropriate in order to provide high quality information to database providers.

A final version of this section of the Annex may need to include guidance on how best to set out the free text within the sequence listing free text part of the description, based on the experience gained in extracting and presenting the information as part of development of the relevant IT tool.

Examples of the different types of free text qualifier from WIPO Standard ST.26 include the following. It will be noted that all qualifiers defined as free text within WIPO Standard ST.26 currently include the note “this value may require translation for National/Regional purposes” irrespective of the type of free text involved:

(i) “Free text” is actually a number in a specific format – not language-dependent, nor free text in the normal sense

6.16.	Qualifier	EC_number
	Definition	Enzyme Commission number for enzyme product of sequence
	Value format	free text
	(NOTE: this value may require translation for National/Regional procedures)	

Example	<pre><INSDQualifier_value>1.1.2.4</INSDQualifier_value> <INSDQualifier_value>1.1.2.-</INSDQualifier_value> <INSDQualifier_value>1.1.2.n</INSDQualifier_value></pre>
Comment	valid values for EC numbers are defined in the list prepared by the Nomenclature Committee of the International Union of Biochemistry and Molecular Biology (NCIUBMB) (published in Enzyme Nomenclature 1992, Academic Press, San Diego, or a more recent revision thereof). The format represents a string of four numbers separated by full stops; up to three numbers starting from the end of the string may be replaced by dash "-" to indicate uncertain assignment. Symbol "n" may be used in the last position instead of a number where the EC number is awaiting assignment. Please note that such incomplete EC numbers are not approved by NC-IUBMB.

(ii) "Free text" is usually a personal or internationally used form of name (but may be a local species name, which would be language dependent)

6.10.	Qualifier	collected_by
	Definition	name of persons or institute who collected the specimen
	Value format	free text
		(NOTE: this value may require translation for National/Regional procedures)
	Example	<pre><INSDQualifier_value>Dan Janzen</INSDQualifier_value></pre>
6.44.	Qualifier	organism
	Definition	scientific name of the organism that provided the sequenced genetic material, if known, or the available taxonomic information if the organism is unclassified; or an indication that the sequence is a synthetic construct
	Value format	free text
		(NOTE: this value may require translation for National/Regional procedures)
	Example	<pre><INSDQualifier_value>Homo sapiens</INSDQualifier_value></pre>

(iii) "Free text" is truly free text and will always be language dependent

6.40.	Qualifier	note
	Definition	any comment or additional information
	Value format	free text
		(NOTE: this value may require translation for National/Regional procedures)
	Example	<pre><INSDQualifier_value>A comment about the feature</INSDQualifier_value></pre>

Further consideration of these issues will be needed as part of the development of the IT tools, possible further modification of WIPO Standard ST.26, what is appropriate to ask of PCT applicants in terms of extracting and translating text and what "free text" within the main body of the application may be useful and what may be active barriers to effective reading by patent information users. Issues include:

- (i) the extent to which non-latin characters may be accepted by the validation tool despite being forbidden by the standard;

- (ii) the way in which terms requiring translation can be extracted by the software tool for inclusion into the sequence listing free text part of the description and whether this should always include all qualifiers designated as free text within ST.26;
- (iii) whether the software tools should provide features to assist the replacement of free text originally in a language not in English with an English language translation, either to create a new sequence listing file or by creating a translation file to accompany the original sequence listing which can map the translated texts to the correct points within the original XML;
- (iv) whether the frequency of use of qualifiers which are described as free text but are in fact highly regulated would justify the sub-division of free text into “language-dependent” and “language-independent” categories; and
- (v) if it is desirable to separate the free text into different categories, whether the software tool can offer a sufficiently simple interface to deal with the qualifiers which are sometimes, but not always, language-dependent.]

SEQUENCE LISTINGS AND SEQUENCES FORMING PART OF THE INTERNATIONAL APPLICATION AS FILED

10. In accordance with Rule 5.2(a-bis), any file contained in the international application as filed, purporting or appearing to be a sequence listing shall be considered to be part of the description, whether or not a listing is referred to in the main part of the request and whether or not the file is in fact compliant with WIPO Standard ST.26.

International Applications Filed in Electronic Form

11. International applications containing a sequence listing shall preferably be filed in fully electronic form. Preferably, the sequence listing shall form part of a package filed in accordance with Annex F with the listing indexed in accordance with the standards in that Annex.

[COMMENT: The relationship between Annexes C and F will need to be given further consideration once the required principles are clear.]

12. Nevertheless, any receiving Office may accept a sequence listing as a file provided separately from the main package on the date of filing and shall accept such a separate listing in any case where it is not practical for the applicant to include the listing as part of the main

package, for example because the file size is too large to be handled by the software used for preparing or receiving the main part of the international application.

International Applications Filed on Paper

13. Where the international application is filed on paper, the receiving Office shall accept a sequence listing filed on a separate physical medium of a type accepted by that Office.

Sequence Listings Filed on Physical Media

14. Any physical media on which a sequence listing is filed together with an international application filed on paper or separately from the main part of an international application filed in electronic form shall be clearly labeled "Sequence Listing", or its equivalent in the language of publication, and the receiving Office shall add the international application number. Preferably, the physical media used for a sequence listing forming part of the international application as filed shall be of a type accepted by both the receiving Office and the International Searching Authority.

[COMMENT: It does not appear necessary to have special provisions for dealing with the case where a sequence listing and the main part of the application are received by the receiving Office on different days. These would be handled in exactly the same way as cases where other parts of an international application are received on different ways in accordance with Article 11 and Rule 20.5(c) – that is, the application would be accorded an international filing date according to the date of the later received part.]

Purported Sequence Listings Not Compliant with the Standard

15. The receiving Office shall not be required to validate whether a sequence listing is compliant with WIPO Standard ST.26. However, where 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 for the purpose by the International Bureau, the Office shall notify the applicant accordingly.

16. For the purposes of section 707(a-bis), any file which appears to be a sequence listing shall not be taken into account for the purpose of calculating the number of pages for the filing fee. Page fees should, however, be charged if it is seen that a file in fact contains material which is clearly not a sequence listing, such as PDF pages of description or drawings mislabeled as a sequence listing.

[COMMENT: This is basically intended to say that anything which is properly trying to be a sequence listing should not be treated as pages for the purpose of the filing fee even if there are minor defects, but that proposed Rule 5.2(a-bis) cannot be used to add normal description (for example, as a PDF file) into the application while avoiding the associated page fees.]

ACCEPTED TYPES OF PHYSICAL MEDIA

17. Each receiving Office and International Authority shall notify the International Bureau of at least one of the physical media types referred to in Appendix IV of Annex F which it accepts for the purpose of the receipt of sequence listings. The International Bureau shall promptly publish any such notification in the Gazette. In the absence of such a notification, the Office or Authority shall accept physical media of any type which has been the subject of a notification in accordance with Section 710(a) or (b), or else any of the media referred to in Appendix IV of Annex F.

EXTREMELY LARGE FILES

18. Where a sequence listing is too large to include on a single physical medium, it may be split such that the files can be rejoined to form one single contiguous file without any missing or repeating contents in accordance with the procedures set out in paragraphs 2(c) and (c-bis) of Appendix IV to Annex F of these Administrative Instructions. In addition to the physical labeling appropriate to the type of sequence listing, the physical media shall each be numbered, for example "DISK 1/3", "DISK 2/3", "DISK 3/3".

[COMMENT: This requirement may be modified in the course of development of the IT tools if it emerges that a different method of splitting the file would be more effective for either creating or processing very large listings.]

SEQUENCE LISTINGS FURNISHED FOR THE PURPOSES OF INTERNATIONAL SEARCH OR PRELIMINARY EXAMINATION

19. Any sequence listing furnished under Rule 13*ter*, 45*bis*.5(c) or 76.5 to an International Authority for the purposes of international search or preliminary examination shall, where possible, in compliance with WIPO Standard ST.26, maintain the original numbering of the sequences in the application as filed, using “intentionally skipped sequence” identifiers where necessary. Otherwise, the sequences shall be numbered in compliance with that Standard in the order in which they appear in the international application.

[COMMENT: WIPO Standard ST.26 requires sequences to have consecutive numbering. Usually, the sequences in the application as filed will either have no numbering (in which case they should be numbered in the order in which they appear) or else they will have sequential numbering which can be reused in the sequence listing for the purposes of international search or preliminary examination. However, in exceptional cases (typing errors or incorporation by reference), there may be repeated numbers or other situations which would require an alternative approach to be used.]

20. In accordance with Rule 5.2, any sequence listing referred to in paragraph 14, above, shall contain all the sequences in the international application as filed which meet the criteria referred to in paragraph 4 above and shall not go beyond the disclosure as filed. The listing shall be accompanied by a statement to that effect.

21. Where such a listing is furnished on physical media, the media shall be labeled “Sequence Listing Not Forming Part of the International Application”, or its equivalent in the language of publication, together with the international application number.

CORRECTION, RECTIFICATION AND AMENDMENT OF SEQUENCE LISTINGS

22. Any correction under Rule 26, rectification under Rule 91 or amendment under Article 34(2)(b) of the description submitted in relation to a sequence listing contained in the international application as filed and any sequence listing included in the international application by way of an amendment under Article 34(2)(b) of the description in relation to sequences contained in the international application as filed shall be made using a complete

sequence listing compliant with WIPO Standard ST.26 including the relevant correction, rectification or amendment. The nature of the correction, rectification or amendment shall be clearly explained in an accompanying letter.

23. The sequences in any sequence listing referred to in paragraph 17 shall, where possible, in compliance with WIPO Standard ST.26, maintain the original numbering of the sequences in the application as filed, using “intentionally skipped sequence” identifiers where necessary.

Otherwise, the sequences shall be numbered in compliance with that Standard in the order in which they appear in the international application.

24. Where the sequence listing as proposed to be corrected, rectified or amended is presented on physical media, the media shall be labeled “Sequence Listing – Correction”, “Sequence Listing – Rectification” or “Sequence Listing – Amendment”, as the case may be, or the equivalents in the language of publication, together with the international application number.

PROCEDURE BEFORE DESIGNATED AND ELECTED OFFICES

25. For the purposes of the procedure before a designated or elected Office before which the processing of an international application which contains the disclosure of one or more nucleotide and/or amino acid sequences has started (see Rule 13*ter*.3):

(i) any reference to the receiving Office or the competent authority shall be construed as a reference to the designated or elected Office concerned;

(ii) any reference to a sequence listing which is included in the international application by way of a rectification under Rule 91 or an amendment under Article 34(2)(b) of the description in relation to sequences contained in the application as filed shall be construed to also include any sequence listing included in the application, under the national law applied by the designated or elected Office concerned, by way of a rectification (of an obvious mistake) or amendment of the description in relation to sequences contained in the application as filed;

(iii) any reference to a sequence listing furnished for the purposes of international search or international preliminary examination shall be construed to also include any such listing furnished to the designated or elected Office concerned for the purposes of national search or examination by that Office;

(iv) the designated or elected Office concerned may invite the applicant to furnish to it, within a time limit which shall be reasonable under the circumstances, for the purposes of national search and/or examination, a sequence listing in electronic form complying with this Standard, unless such listing in electronic form is already available to that Office in a form and manner acceptable to it.

[COMMENT: This paragraph is a direct copy of paragraph 42 of existing Annex C. It is not intended to change the principles involved regarding the processing of sequence listings at designated and elected Offices, except for the fact that the Offices should be required to accept sequence listings according to WIPO Standard ST.26 rather than ST.25 for international applications filed on or after the date on which the new provisions come into force. However, the paragraph does not read well onto the other proposed modifications to the Administrative Instructions and further consideration will be required on drafting once the substance of the remainder is agreed.]

[Конец приложения III и документа]