

## 专利合作条约（PCT） 工作组

第十二届会议  
2019年6月11日至14日，日内瓦

### 序列表——实施产权组织标准 ST. 26

国际局编拟的文件

#### 概 述

1. 请工作组指导国际局为从现行的 PCT 序列表标准转向新的产权组织标准 ST. 26 所需的 PCT 法律框架修改制定正式提案，以供相关 PCT 机构于 2020 年审议。还请工作组对国际局就以下方面应向产权组织标准委员会（CWS）序列表工作队提供的意见提供指导：进一步修改产权组织标准 ST. 26 的潜在需要，和根据该标准开发为编制、提交和处理序列表提供支持的软件工具。

#### 背 景

2. 在 2016 年 3 月举行的第四届会议续会上，产权组织标准委员会（CWS）通过了产权组织标准 ST. 26 “关于用 XML（可扩展标记语言）表示核苷酸和氨基酸序列表的推荐标准”。在 2017 年 5 月/6 月举行的第五届会议和 2018 年 10 月举行的第六届会议上，标准委员会进一步修订了 ST. 26。产权组织标准 ST. 26 的最新版本（版本 1.2），可见产权组织网站上的《工业产权信息与文献手册》第三部分。<sup>1</sup>

3. 在 2017 年 5 月/6 月举行的第五届会议上，标准委员会商定，2022 年 1 月 1 日为从产权组织标准 ST. 25 向 ST. 26 过渡的日期，ST. 26 适用于在此日或此后提出的任何国家或国际申请，标准委员会还要求序列表（SEQL）工作队（见文件 CWS/5/21，该届会议主席总结第 18 段）：

<sup>1</sup> <https://www.wipo.int/export/sites/www/standards/en/pdf/03-26-01.pdf>。

- (a) 为国际局提供支持，提供用户对编著和验证工具的要求和反馈意见；
  - (b) 就《PCT 行政规程》的相应修订为国际局提供支持；并且
  - (c) 根据标准委员会的要求为产权组织标准 ST. 26 编制必要的修订。
4. 针对 2022 年 1 月 1 日或此后提交的国际申请实施产权组织标准 ST. 26，将需要《PCT 实施细则》的修正在 2020 年 9 月/10 月的 PCT 大会上得到通过，并在 2022 年 1 月 1 日生效，还需对《行政规程》进行重大修改。
5. 在预期从 PCT 序列列表标准转向产权组织标准 ST. 26 的背景下需处理的关键问题包括：
- (a) 与《行政规程》附件 C 规定的现行 PCT 序列列表标准不同，产权组织标准 ST. 26 不适合以纸件形式或除 XML 以外的电子格式（如 PDF）提交序列列表。因此，最好是把序列列表作为电子格式的国际申请的一部分来提交。如果做不到，以纸件提交的国际申请需附上以物理介质提交的电子格式的序列列表，实质上是将“混合模式”申请重新引入 PCT。
  - (b) 为保持 PCT 目前对序列列表中语种相关“自由内容”的语言要求所采取的做法（PCT 要求与语种相关的“自由内容”在国际申请说明书的主要部分以撰写说明书所用的语言进行重复），需要明确定义允许在序列列表中使用的任何此类“自由内容”是（完全或实际上）“与语种无关”还是“与语种相关”，如与语种相关，可能因此需要为国家阶段处理提供译文（关于与序列列表相关的 PCT 语言要求的具体解释，见下文第 12 段至第 28 段）。
  - (c) 受理局将无需对据称的序列列表文件的内容进行任何检查，而国际单位将会检查这些内容。然而，很可能大多数包含序列列表的国际申请将会使用在线申请系统提交，受理局则会在该阶段看到自动检验的结果。需要考虑申请人、受理局和国际单位检验序列列表是否符合产权组织标准 ST. 26 各项要求时可使用的工具，不同阶段检验失败的结果，以及进行改正的可选项。
6. 在 2018 年举行的第十一届会议上，工作组就预期转向产权组织标准 ST. 26 的背景下需解决的问题进行了第一轮讨论，主席总结对此进行了概述（文件 PCT/WG/11/26，第 105 段至第 107 段），内容如下：
- “105. 讨论依据文件 PCT/WG/11/24 和 24 Cor. 进行。
- “106. 代表团注意到关于引入产权组织标准 ST. 26 的若干问题仍有待最终确定。主管局需要时间完成其准备工作。针对之前申请中以 ST. 25 格式提交的序列列表，在之后提出优先权要求的申请中需要以 ST. 26 格式提交的情况，需要评估其法律影响；此种情况也需要软件工具协助申请人和主管局。还需要进一步探讨增加和删除序列的问题。软件工具需要以多种语言提供给用户。需要评估期望纸件提交的序列列表以物理介质提交的实务和法律影响。应考虑在国际申请提交时省略序列列表的情况下，关于改变提交日期或援引加入的规范条款是否会按预期发挥作用的问题。关于基于语言的自由文本翻译，和 IT 工具可能提供的帮助的问题仍然存在。会议注意到，需要改进起草工作，以确保所有条款确实实现既定目标。
- “107. 工作组注意到文件 PCT/WG/11/24 和 24 Cor. 的内容，请国际局继续推进在 PCT 执行产权组织标准 ST. 26 的工作，该标准将生效并与国家局的需求相符合。”

## 提案初稿

7. 为 PCT 的目的，从《行政规程》附件 C 规定的 PCT 序列列表标准过渡到产权组织标准 ST. 26，将需要修正《PCT 实施细则》，修改《行政规程》，并开发程序和支持性工具。结合工作组在第十一届会议上的讨论和标准委员会序列列表工作队在此之后的进一步讨论，以及本文件正文部分列出的考虑，本文件附件载列了以下内容的初稿：

- (a) 《PCT 实施细则》拟议修正案（见附件一）；
- (b) 《PCT 行政规程》正文部分的拟议修改（见附件二）；和
- (c) 《行政规程》附件 C 的拟议修改（见附件三）；

详细解释见各附件中对具体细则的拟议修正和《行政规程》具体条款的拟议修改的“说明”。

8. 与现行的 PCT 序列列表标准类似，新的标准寻求让申请人能够在专利申请中制定一份国际、地区和国家程序都接受的序列列表。此外，其目的在于提升序列列表表示的准确性和质量，以方便传播。这将会方便序列数据的检索，使电子格式的序列数据能够进行交换并被纳入由序列数据库提供商托管的计算机数据库中。

9. 鉴于以上目标，本文件附件中所载的提案初稿旨在建立处理包含序列列表的国际申请的实际方法。特别是，本文件强调了需要国际局和标准委员会序列列表工作队在未来一年进一步详细审议的问题，以期编制一份正式提案，供工作组在 2020 年上半年审议，并供 PCT 大会在 2020 年 9 月/10 月批准通过。

10. 附件 C 的拟议修改以完整的形式重新起草了该附件。所采用的方法是以合并的形式对涉及提交和处理序列列表的整个 PCT 程序进行解释。为此，它所载的内容与《PCT 实施细则》（附件一）和《PCT 行政规程》正文部分（附件二）中所列的某些条款有些重复，与产权组织标准 ST. 26 也有重复。此外，它所载的某些条款，从严格的法律角度来看，可能不是必须的，但为澄清某些条款的目的提供了背景信息。在起草这部分时，如出现重复内容，则清楚地说明某一具体要求是基于《PCT 实施细则》中的某一具体细则、《PCT 行政规程》正文部分的某一条，还是该附件中具体列出的一条新规程。

11. 在从 PCT 序列列表标准转向产权组织标准 ST. 26 的背景下，与序列列表中所含“自由内容”相关的语种要求似乎是一个值得特别注意的问题。该问题在以下段落中进行了进一步阐述。

## 关于语种的要求

### 现行做法

12. 在考虑条约第 11 条（1）（ii）对申请日的要求，即国际申请须根据细则 12.1（a）以受理局接受的语言提交时，国际申请说明书中的序列列表部分是一种特殊情况，下文第 13 段至第 17 段对此进行了进一步解释。一般来说，受理局在检查国际申请是否符合条约第 11 条（1）（ii）中与申请日相关的语言要求时，只会检查说明书的主要部分是否符合条约第 11 条（1）（ii），而不会检查说明书的任何序列列表部分（见细则 20.1（c））。

13. 然而，这并不意味着，在提交和处理序列列表时语言要求不重要。一般来说，在国际阶段，国际检索单位和国际初步审查单位（在任何第二审程序期间）必须能够理解说明书的任何序列列表部分所含任何与语种相关的自由内容，才能进行国际检索，以及在适用的情况下，进行国际初步审查。与此相似，在国家阶段，申请进入其国家阶段的指定局和选定局能够理解任何此类文字也同样重要。此外，

作为公开要求的一部分，在序列表进行国际公布后，公众必须能够理解序列表中所含任何与语种相关的自由内容。

14. 为此，现行的 PCT 序列表标准（载于《行政规程》附件 C 中）规定必须使用“受控词表”（列于附件 C 附录二）来描述说明书序列表部分所含的序列。该“受控词表”“与语种无关”，或被视为“与语种无关”，所以并未出现需要为国际检索或初步审查或国家阶段目的而进行翻译的问题。

15. 另一方面，除规定使用“受控词表”之外，现行的 PCT 序列表标准还允许使用“自由内容”作为值格式，来描述序列表的某些特征。根据标准第 33 段，“[自]由内容一词描述的是，数字标识符 <223>（其他信息）下不使用与语种无关的词汇的序列特征”。根据第 35 段，任何此类“自由内容”都最好以英文提交（但也可以以任何其他语言提交）。

16. 现行的细则 5.2 (b) 要求任何此类“自由内容”在说明书主要部分以国际申请所用的语言进行重复。该要求确保，国际阶段的国际检索单位和国际初步审查单位以及国家阶段的指定局和选定局将总是能够以其所接受的语种获取“自由内容”，分别供国际检索或国际初步审查以及国家阶段处理所用，无论是作为所提交国际申请的一部分（或是根据细则 13 之三.1 (f) 提交的改正），还是作为国际或国家阶段处理所需国际申请译文的一部分（包括在说明书主要部分以撰写说明书所用的语言进行重复的任何“自由内容”）。因此，申请人通常将只需在提交国际申请时编制一次序列表，无需仅因需要以国际单位或任何指定局或选定局接受的语言翻译表中所含任何与语种相关的“自由内容”而向该单位或该局提交新的序列表。

17. 另一方面，如果任何此类与语种相关的“自由内容”并未在说明书的主要部分以撰写说明书所用的语言进行重复，相关国际单位则需请申请人提交一份改正，以撰写说明书所用的语言将此类“自由内容”纳入说明书的主要部分（见现行的细则 13 之三.1 (f) 和 13 之三.2）。这一要求主要是为了方便申请人，而不是为了方便国际单位（即便与语种相关的“自由内容”已经为国际检索或国际初步审查目的以其所接受的语种提供，该要求仍然适用）。如果在说明书主要部分继而在其任何译文中重复了任何与语种相关的“自由内容”，申请人将无需以国家阶段处理所接受的语言提交含有任何“自由内容”的新序列表（细则 49.5 (a 之二)）。

#### 转向产权组织标准 ST.26 之后的语种要求

18. 与现行的 PCT 序列表标准类似，产权组织标准 ST.26 规定，在描述序列的特征，也就是该标准附件一列出的相关区域或位点注释时，必须使用“受控词表”。这一“允许的”受控词表包括：核苷酸编码（附件一第 1 节）；经修饰的核苷酸缩略词（附件一第 2 节）；氨基酸编码（附件一第 3 节）；经修饰的氨基酸缩略词（附件一第 4 节）；核苷酸序列特征关键词（附件一第 5 节）；核苷酸序列限定符（附件一第 6 节）；氨基酸序列特征关键词（附件一第 7 节）；以及氨基酸序列限定符（附件一第 8 节）。

19. 根据该标准，使用“限定符”来提供由特征关键词和特征位置所传递的特征之外的特定信息。允许的“值格式”有多种类型，以适应由限定符传递的不同类型的信息，包括特定术语、枚举值（例如，时间或日期）、“自由内容”和序列。

20. 在描述序列特征时允许使用的受控词表中（见上文第 18 段），以下与语种无关，或被视为与语种无关：

- (a) 该标准附件一第 1 节列出的核苷酸编码和第 3 节列出的氨基酸编码；

(b) 第 2 节列出的经修饰的核苷酸缩略词和第 4 节列出的经修饰的氨基酸缩略词，作为特定限定符允许的仅有的值；

(c) 第 5 节和第 7 节列出的特征关键词名称以及第 6 节和第 8 节列出的限定符名称，尽管许多允许的特征关键词和限定符名称是英文的或英文缩略词（例如，见特征关键词 5.1 “C-region” 和 7.18 “MOD\_RES”（“modification of a residue” 的缩略词）；以及限定符 6.5 “cell\_type” 和 8.3 “ORGANISM”）；

(d) 第 5、6、7、8 节列出的允许适用于“自由内容”以外的限定符所传递的不同类型信息的所有“值格式”（即，特定术语、日期或时间等枚举值以及序列），尽管很多允许的“值格式”都含有英文或英文缩略语元素，或可以看出是由英文或拉丁词衍生而来（例如，值格式为“left, right or both”的限定符 6.15 “direction”）。

21. 目前，未出现需要为国际检索或初步审查或国家阶段目的而翻译任何此类“与语种无关的受控词表”的问题。

22. 另一方面，和现行的 PCT 序列列表标准一样，产权组织标准 ST. 26（附件一第 6 节和第 8 节）也允许在序列列表中使用“自由内容”作为特定限定符的值格式。根据该标准第 85 段，“[自]由内容是特定限定符的一种值格式（如附件一所示），表现形式为描述性的、最好以英文写成的文本短语”。

23. 与现行的 PCT 序列列表标准不同，产权组织标准 ST. 26 要求电子序列列表包含的所有信息，除“申请人名称”、“发明人名称”和“发明标题”部分提供的信息之外，都必须由 Unicode 统一字符基本拉丁语代码表中的可打印字符组成（产权组织标准 ST. 26 定义的特定保留字符除外；也不许使用带重音的拉丁字符）。这意味着，如果提交的序列列表中含有任何与语种相关的“自由内容”，而该内容的语言不是由此类基本拉丁字符组成的语言，特别是中文、日文或韩文，则该序列列表就不可能符合 ST. 26。

24. 尽管 ST. 26 允许的“自由内容”和现行的 PCT 序列列表标准十分相似（除了此类自由内容使用的语言必须是以基本拉丁字符组成的之外），产权组织标准 ST. 26 允许使用此类“自由内容”的限定符远多于现行标准。产权组织标准 ST. 26 附件一第 6 节和第 8 节列出了允许使用“自由内容”的限定符。本质上，允许限定符使用的“自由内容”分为以下三类：

(a) 有些“自由内容”是完全与语种无关的，因为尽管其被描述为“自由内容”并且不受文件类型定义（DTD）的控制，但对其格式的预期明确为“数字”或“编号”，在各语言之间并没有区别（例如：产权组织标准 ST. 26，附件一，6.16，限定符“EC-number”；定义：“酶学委员会的酶产物序列编号”；值格式：“自由内容”；例如：“<INSDQualifier\_value>1.1.2.4</INSDQualifier\_value>”）；

(b) 有些“自由内容”可能实际上与语种无关，因为预期值为人名（除非在有些情况下，人名音译为拉丁字符或没有重音）或生物的国际通用术语（例如：产权组织标准 ST. 26，附件一，6.27，限定符“host”；定义：“生物从中获得序列分子的天然（与实验室相对）宿主”；值格式：“自由内容”；例如：“<INSDQualifier\_value>Homo sapiens</INSDQualifier\_value>”）；

(c) 有些“自由内容”总是与语种相关，其形式是真正的“自由内容”说明（例如：产权组织标准 ST. 26，附件一，6.21，限定符“function”；定义：“序列的功能”；值格式：“自由内

容”；例如：“<INSDQualifier\_value>essential for recognition of cofactor</INSDQualifier\_value>”）。

25. 遗憾的是，产权组织标准 ST. 26 目前的形式并未清楚定义，允许用于描述特定限定符的“自由内容”是（完全或实际上）“与语种无关”，还是（总是）“与语种相关”。此外，其并未限制某个限定符使用的“自由内容”只能是上述类别中的一项，所以可以用属于上述三项类别的“混合”“自由内容”作为某个限定符允许的值格式。这使得申请人几乎不可能确定，在说明书的主要部分以撰写说明书所用的语言中纳入哪一部分“自由内容”才能符合 PCT 细则 5.2 (b) 的规定，并保留为国际和国家阶段程序目的仅提交一次序列列表的可能性。理论上，为保险起见，似乎要求申请人在说明书的主要部分重复所有可被视为与语种相关的“自由内容”（包括属于第二项类别“实际上与语种无关”的任何“自由内容”）。

26. 要克服这一难题，似乎有两个选项。其中一个选项是修改产权组织标准 ST. 26，以清楚地确定哪些“自由内容”值格式总是被视为“与语种相关”，并因此需要在说明书的主要部分以撰写说明书所用的语言完整重复。另一方面，限定符使用的任何未确认的“自由内容”则总是被视为“与语种无关”，因此无需在说明书的主要部分以撰写说明书所用的语言进行重复。然而，尽管对产权组织标准 ST. 26 进行修改会有助于继续使用关于“自由内容”的现行 PCT 方法，正如上文第 12 段至第 17 段所述，这似乎有悖于与序列列表工作队商定的不在产权组织标准 ST. 26 中纳入任何程序规定的方法（考虑到对任何自由内容进行翻译的要求似乎是程序性问题）。

27. 另一个选项则是，对于国际申请而言，确认哪些限定符的“自由内容”值格式始终在 PCT 中被视为“与语种相关”（例如，在《PCT 行政规程》附件 C 的附录中）。然而，尽管这一澄清是在 PCT 中作出的，并且如果经专利法条约大会（PLT）决定，也适用于依照 PLT 缔约国国内法提交的国家申请，但不是 PLT 缔约方的国家将必须在其适用的国内法中提供此类澄清，这其中存在不同国家适用不同要求的风险。

28. 无论采用两种方法中的哪一种来帮助申请人编制符合 PCT 细则 5.2 (b) 规定的国际申请说明书的主要部分，国际局目前开发的软件工具（WIPO Sequence）都将包含一项能够自动为（尚未决定的）特定限定符提取相关“自由内容”的功能，以方便申请人将其插入到说明书的主要部分（在“序列列表自由内容”标题下；见《行政规程》第 204 条（viii））。所提取的内容可能以表格形式呈现，包含序列编号、特征关键词、限定符和限定符值等栏，还包括显示相关“自由内容”的两栏，一栏以序列列表所用语言显示，另一栏以说明书主要部分所用语言显示同样的“自由内容”。

29. 需要对上文第 26 段和第 27 段列出的两个选项进行进一步讨论。接下来的工作可能还会包括，允许将译文编制为补充 XML 文件（即不作为申请组成部分的文件），确认序列列表中各个特征的相关位置，以及允许以原文或译文提交带有注释的序列列表的工具。

30. 除了需要明确哪些限定符的“自由内容”值格式始终被视为“与语种相关”之外，似乎还需对与序列列表中所含“自由内容”相关的语种要求的现行方法进行两处改动，下列段落对此进行了概述。

31. 首先，可以看出产权组织标准 ST. 26 的其中一项主要目标是，允许序列数据以电子格式进行交换，并被纳入由序列数据库提供商托管的计算机数据库。然而目前，上传至此类数据库的序列通常不带有任何描述特定序列特征的注释，产权组织标准 ST. 26 旨在使这些注释也能上传到数据库中。然而，这需要任何与语种相关的注释都以英文提供，因为英文似乎是序列数据库提供商为此目的所接受的唯一一种语言。

32. 为了鼓励申请人以英文提交任何与语种相关的“自由内容”，可以对细则进行修改，要求：

- (a) 任何国际检索单位和任何国际初步审查单位，为进行国际检索和初步审查；以及
- (b) 任何指定或选定局，为进行国家阶段处理；

接受以英文（根据产权组织标准 ST. 26，任何与语种相关的“自由内容”最好都用英文）提交的任何与语种相关的“自由内容”，即便英文不被该单位为国际检索和初步审查目的或该局为国家阶段处理目的而接受。此外，可以修改《细则》，规定如果任何与语种相关的“自由内容”是英文的，则申请人无需在说明书的主要部分以撰写说明书所用语言重复任何此类“自由内容”，因为任何以英文提交的此类“自由内容”都是为所有国际阶段和国家阶段处理目的被接受的。这将大大鼓励申请人以保准能够导入检索数据库的文件格式提交序列列表。

33. 其次，为了弥补处理序列列表的现行政程序的差距，似乎最好对《细则》进行修改，澄清以下内容：当要求申请人根据细则 5.2 (b) 提交改正（即，在说明书的主要部分以撰写说明书所用的语言对自由内容进行重复），而所提交的改正中有任何与语种相关的“自由内容”不是以英文提供并且并未在说明书主要部分以撰写说明书所用语言进行重复时，相关国际单位只需在没有改正的情况下，在可以进行检索或初步审查的范围内进行检索或初步审查。

### 检验与改正机会

34. 为编制和检验序列列表而正在开发的软件工具，理想中应意味着申请软件能够检测出序列列表中的任何形式缺陷，并在申请人提交序列列表之前进行更正。然而，实际情况可能是申请程序会报错，申请人需自行检查，并且有机会作出改正：

- (a) 申请人可以使用任何软件编制序列列表，不过强烈建议申请人使用国际局与标准委员会序列列表工作队目前正在共同开发的工具进行编制，该工具将按照产权组织标准中的绝大部分要求提供检验，让申请人能够在提交申请之前改正错误。需要就执行标准中某些要求的严格程度作出决定，例如对“自由内容”限定符允许的字符方面的限制，考虑到产权组织标准 ST. 26 的目标之一就是使数据库提供商接受序列数据。
- (b) 受理局将无需检查序列列表的内容，但在大多数情况下，受理局将已通过在线申请系统收到序列列表，而在线申请系统可能已经检验并报告了本质上能够被申请软件检测出的形式缺陷。这时，在理想情况下，受理局将向申请人发出警告，并为其提供立刻改正此种形式缺陷的机会。此类“参考性”缺陷通知的问题不是序列列表特有的（多数时候，当受理局发现附图转化效果不佳，但又不至于将申请视为应撤回的情况时，就会发出此类“参考性通知”），因此不在本文件中进一步考虑此问题。
- (c) 国际检索单位（以及，在相关情况下，国际初步审查单位）应检验序列列表的格式，并审核其内容。如果在需要提交序列列表的申请中缺少序列列表，或者序列列表不符合要求，相关单位可以请申请人提交改正。如果内容上存在明显错误，相关单位可以请申请人提交更正。
- (d) 申请人可以酌情向国际初步审查单位提交条约第 34 条的修正，例如：删除与权利要求不再相关的某些序列，或添加在说明书主要部分公开的、本应被纳入所提交序列列表中的序列，前提是任何此类删除或添加不会导致公开超出原始申请的公开范围。
- (e) 可能需要在国家阶段提交修正或改正。

35. 正在开发的软件工具将有助于创建和检验经改正和修正的序列列表，并可以帮助各局对序列列表的不同版本进行比较。然而即便如此，编制和比较不同的序列列表版本对申请人和各局来说仍是困难的。因此，附件中的建议力图鼓励采取一些方法，尽可能地减少在申请之后要求提交新序列列表的情况。

#### 预期的生效和过渡性安排

36. 如上文第 3 段所述，标准委员会商定采用“大爆炸式”预设，于 2022 年 1 月 1 日从产权组织标准 ST. 25 过渡至 ST. 26，以适用于在此日或此后提出的任何国家或国际申请。因此，新标准将适用于在此日或此后提出的国家和国际申请（另见文件 CWS/5/7 Rev. 1 和 Rev. 1 Add.）。

37. 在此阶段，如果正在进行中的必要软件工具开发成功完成，预期国际局将提交一份修正《PCT 细则》和修改《行政规程》的正式提案，供 PCT 工作组在其 2020 年会议上审议，并供 PCT 大会在其 2020 年 9 月/10 月的会议上通过，一并提交的拟议生效规定如下：

(a) 《PCT 实施细则》的修正和《PCT 行政规程》的修改将于 2022 年 1 月 1 日生效；

(b) 2022 年 1 月 1 日生效的《细则》和《行政规程》将适用于在 2022 年 1 月 1 日或此后提交的任何国际申请；

(c) 截至 2021 年 12 月 31 日有效的《细则》和《行政规程》将继续适用于在 2022 年 1 月 1 日之前提交的任何国际申请（即便给予的国际申请日晚于 2022 年 1 月 1 日）。

38. 似乎无需为 PCT 目的而进行任何其他过渡性安排，尽管可能需要修改产权组织标准 ST. 25，以明确其所指的是截至 2021 年 12 月 31 日有效的《PCT 行政规程》附件 C 的版本。

39. 请工作组：

(a) 注意本文件附件一中所载的《PCT 实施细则》拟议修正案初稿和本文件附件二及附件三所载的《PCT 行政规程》拟议修改初稿，就本文件第 7 段至第 38 段中所载的问题发表评论意见；并

(b) 就国际局应审议的或可以请标准委员会进一步探讨的事项，向国际局提供指导。

[后接附件]



《PCT 实施细则》拟议修正案初稿<sup>2</sup>

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<sup>2</sup>

建议增加和删除的内容分别通过在有关案文上加下划线和删除线的方式表示。

## 第 5 条

### 说明书

#### 5.1 [无变化]

#### 5.2 核苷酸和/或者氨基酸序列的公开

(a) 如果国际申请包含一个或多个根据行政规程的规定应包括在序列表中的核苷酸和/或氨基酸序列的公开，说明书应包括一个单独的部分（“说明书的序列表部分”），包括其中包括符合行政规程规定的标准的序列表，并根据该标准根据这些规定以单独的 XML 格式电子文件形式将其作为说明书的单独部分提交的序列表（“符合规定的序列表”）。

[说明：根据 PCT 提交和处理序列表的新要求的实质内容主要参照产权组织标准 ST. 26 进行定义（与目前的安排不同，目前的安排是标准完全载于《行政规程》附件 C 中）。但是仍建议参考《行政规程》，而不是直接参考 ST. 26，以便更清楚具体地说明版本控制的细节和 PCT 的具体程序和实施。建议在以后的条款中使用“符合规定的序列表”一词，考虑到一些受理局只会对序列表进行非常有限的检查（如果进行检查的话），但国际单位或指定局和选定局可能要求遵守规定并对其进行检查。]

(a 之二) 据称或看似是序列表的任何电子文件，如果是在受理局确定据称为国际申请的文件满足条约第 11 条 (1) 的所有要求之日或之前收到的，应视为构成说明书的一部分，无论说明书的主要部分或请求书中是否提及该序列表。

[细则 5.2(a 之二), 续]

[说明：拟议增加的新款 (a 之二) 严格来说并不直接与 PCT 序列列表标准向产权组织标准 ST. 26 的过渡相关，但其意图是把因标记不当而导致序列列表未被作为构成所提交国际申请的一部分予以考虑的风险降到最低。如果提交申请的方式是申请主要部分以纸件提交、电子格式的序列列表以物理介质提交，这种风险可能增加。应在《受理局指南》中纳入适当指导，规定受理局应如何处理此类将被视为说明书构成部分的电子文件，同时考虑到申请其余部分的提交格式（纸质或电子）。]

(b) 如果说明书序列列表部分含有行政规程规定的标准定义的任何语种相关自由内容，则该语种相关自由内容，如果不是用英文，也应用撰写说明书所用的语言写入说明书的主要部分内。

[说明：见本文件正文第 26 段和第 27 段。应修改产权组织标准 ST. 26 或《PCT 行政规程》，以清楚地确定“语种相关自由内容”可被用做限定符的有哪些，并由此根据拟议修正的细则 5.2(b)，在说明书的主要部分以撰写说明书所用的语言重复这些自由内容，除非该内容是以英文撰写的。关于序列列表语种相关要求的具体解释，见上文本文件正文第 12 段至第 33 段。]

## 第 12 条

### 国际申请的语言和为国际检索和国际公布目的的译文

#### 12.1 所接受的国际申请的语言

(a) [无变化] 提出国际申请应使用受理局为此目的所接受的任何一种语言。

(b) [无变化] 每一个受理局对国际申请的提出应至少接受一种符合以下两条件的语言：

(i) 是国际检索单位所接受的语言，或在适用的情况下，是对该受理局受理的国际申请有权进行国际检索的至少一个国际检索单位所接受的语言；

(ii) 是公布使用的语言。

(c) [无变化] 尽管有 (a) 的规定，请求书应以受理局为本款目的所接受的任何公布语言提出。

(d) 尽管有 (a) 的规定，本细则 5.2 (a) 所述说明书序列表部分包含的任何文字应符合行政规程的规定制定的标准。

[说明：建议对说明书的整个序列表部分免除细则 12 的语言要求，与现行的细则 20.1 (c)、12.3 (b)、12.4 (b) 和 49.5 类似。关于序列表语种相关要求的具体解释，见上文本文件正文第 12 段至第 33 段。]

12.1 之二至 12.2 [无变化]

12.3 [无变化] 为国际检索目的的译文

(a) [无变化] 如果提出国际申请时所使用的语言不为进行国际检索的国际检索单位所接受，申请人应自受理局收到国际申请之日起 1 个月内，向该局提交一份该国际申请的译文，其使用的语言应符合以下条件：

- (i) 是该检索单位接受的语言；和
  - (ii) 是公布使用的语言；和
  - (iii) 是受理局根据本细则 12.1 (a) 所接受的语言，除非国际申请使用的是公布的语言。
- (b) [无变化] (a) 既不适用于请求书也不适用于说明书的序列表部分。

[说明：未显示出有任何需要修改本细则 12.3 (a) 和 (b) 的必要。]

(c) 至 (e) [无变化]

#### 12.4 [无变化] 为国际公布目的的译文

(a) 如果提出国际申请时所使用的语言不是公布的语言，而且不需要根据本细则 12.3(a) 提交译文，申请人应自优先权日起 14 个月内向受理局提供该国际申请的译文，使用受理局为本款目的所接受的任何公布语言。

(b) (a) 的规定既不适用于请求书，也不适用于说明书的序列表部分。

[说明：未显示出有任何需要修改细则 12.4(a) 和 (b) 的必要。]

(c) 至 (e) [无变化]

### 第 13 条之三

#### 核苷酸和/或者氨基酸序列表

##### 13 之三.1 国际检索单位的程序

(a) 如果国际申请包括了一个或多个根据行政规程规定应包括在序列表中的核苷酸和/或氨基酸序列的公开，但原始提交的国际申请不包括细则 5.2 (a) 所述的符合规定的序列表，为了国际检索的目的，国际检索单位可以要求申请人提交符合行政规程规定标准的电子形式的该符合规定的序列表，除非该电子形式的序列表已经能够由该国际检索单位以一种其能接受的形式和方式所获得，并且在适用的情况下，要求申请人于通知规定的期限内缴纳本款 (c) 所述的后提交费。

[说明：建议修正细则 13 之三.1 (a)，以考虑到产权组织标准 ST.26 更细致地规定了哪些序列需要或无需包括在序列表中，因为按照定义，序列表必须以电子形式提交。]

~~(b) 如果至少国际申请的一部分是以纸件提出的，并且国际检索单位发现说明书不符合本细则 5.2 (a) 的规定，为了国际检索的目的，该国际检索单位可以要求申请人提交符合行政规程规定标准的纸件形式序列表，除非该纸件形式的序列表已经能够由该国际检索单位以一种其接受的形式和方式所获得，无论是否已经根据本款 (a) 要求提交电子形式的序列表，以及在适用的情况下，是否要求申请人于通知规定的期限内缴纳本款 (c) 所述的后提交费。~~

[说明：建议删除 (b) 款，因为已不可能以纸件提交符合规定的序列表。]

[细则 13 之三.1 (a) , 续]

(c) 根据 (a) ~~或 (b)~~ 所述通知而提交序列表的, 国际检索单位为其自身的利益, 可以要求向其缴纳后提交费, 其数额由国际检索单位决定, 但不应超过费用表第 1 项所述的国际申请费的 25%, 不考虑国际申请超过 30 页部分每页的任何费用, ~~但是后提交费只能根据本款 (a) 或 (b) 之一要求缴纳, 而不能同时根据上述两项要求缴纳。~~

[说明: (c) 的拟议修正由于拟议删除 (b) (见上文) 。]

(d) 如果申请人没有在 (a) ~~或 (b)~~ 所述通知规定的期限内提交 本细则 5.2 (a) 所要求的符合规定的 序列表和缴纳任何所要求的后提交费, 国际检索单位只需在没有 符合规定的 序列表的情况下 在 可以进行 的 有意义检索的范围内对国际申请进行检索。

[说明: (d) 的拟议修正由于拟议删除 (b) (见上文) 以及在本细则全文拟议使用细则 5.2 (a) 所述的“符合规定的序列表”一词。]

(e) 任何不包括在 提出时原始提交的 国际申请中的序列表, 无论是否是根据 (a) ~~或 (b)~~ 所述通知提交的, 还是以其他方式提交的, 均不能成为国际申请的一部分;  ~~, 但但是, 根据条约第 34 条 (2) (b) , 本款并不妨碍申请人根据条约第 34 条 (2) (b) 就原始提交的国际申请中包括的任何核苷酸和/或者氨基酸序列的公开修改涉及序列表的说明书, 无论这些序列是否已包括在本细则 5.2 (a) 所述的符合规定的序列表中。~~

[细则 13 之三. 1 (f) , 续]

[说明：建议修正 (e) 款，以明确可以就说明书中所包括的任何序列对说明书进行修改，无论这些序列是否是以符合规定的序列列表形式提交的（当然，只有在不会导致新增任何客体的情况下，才能进行此类修改）。]

(f) 如果国际检索单位发现说明书序列列表部分所包括的任何语种相关自由内容不是以英文撰写，并且也未以撰写说明书所用的语言写入说明书的主要部分，因此说明书不符合本细则 5.2 (b) ，  
应通知申请人于通知规定的期限内提交：

(i) 要求的改正，需使用原始提交的国际申请所用的语言，或者，如果根据本细则 12.3 (a) 或 12.4 (a) 要求提交申请的译文的，则使用译文所用的语言；

(ii) 由申请人或翻译该语种相关自由内容的译者以声明证实，就该申请人或该译者所知，译文完整并忠实地翻译了说明书序列列表部分所包括的语种相关自由内容的原文。

申请人所提出的任何改正应比照适用本细则 26.4 的规定。国际检索单位应将申请人提交的任何改正的副本送交受理局和国际局。



[细则 13 之三.1 (g), 续]

[说明: 建议修正 (f) 款, 以澄清要求申请人根据细则 5.2(b) 提交的任何改正所用的语言 (也就是说, 根据细则 5.2 (b), 序列表中所含任何与语种相关的“自由内容”, 如果不是用英文撰写的, 则应在说明书的主要部分以撰写说明书所用的语言加以重复)。如果提交的改正所用的语言不是英文, 国际检索单位也可以请申请人以英文提交要求的改正, 以使该单位能够将序列表和任何与语种相关的自由内容以英文提供给序列数据库提供商。关于序列表的语种相关要求的具体解释, 见上文本文件正文的第 12 段至第 33 段。]

(g) 如果根据本细则 12.3 (a) 要求提交国际申请的译文, 而申请人并未在 (f) 中的通知所规定的期限内以译文所用语言提交要求的改正, 国际检索单位只需在没有译文的情况下在可以进行有意义检索的范围内对国际申请进行检索, 除非本细则 5.2 (b) 所述的语种相关文字是用英文撰写的。

[说明: 建议增加 (g), 以澄清当为国际检索目的要求提供申请的译文, 而申请人未以译文所用语言提交序列表中所含与语种相关的“自由内容”的译文, 国际检索单位则只需在没有译文的情况下“可以进行的有意义检索的范围内”进行检索, 除非该语种相关“自由内容”用的是英文 (英文是所有单位都应接受的、能够使语种相关的“自由内容”被纳入序列表的语言)。关于序列表语种相关要求的具体解释, 见上文本文件正文第 12 段至第 33 段。]

### 13 之三 2 [无变化] 国际初步审查单位的程序

国际初步审查单位的程序应比照适用本细则 13 之三.1 的规定。

[说明: 似乎无需对本细则 13 之三.2 进行修改。国际初步审查单位的程序应比照适用本细则 13 之三.1 的规定。]

### 13 之三 3 提交给指定局的序列列表

任何指定局都不得要求申请人提交符合行政规程规定标准的本细则 5.2 (a) 所述的符合规定的序列列表之外的序列列表。

[说明: 本细则 13 之三.3 的拟议修正由于拟议在细则全文使用“本细则 5.2 (a) 所述的符合规定的序列列表”一词。见下文关于指定局程序中语种相关要求的细则 49.5 (a 之二)。]

## 第 20 条

### 国际申请日

20.1 [无变化] 根据条约第 11 条 (1) 所作的决定

(a) [无变化] 受理局收到据称是国际申请的文件后，应立即决定该文件是否符合条约第 11 条 (1) 的要求。

(b) [无变化]

(c) [无变化] 为条约第 11 条 (1) (ii) 的目的，看似说明书的部分（除其任何序列表部分外）以及看似权利要求书的部分，是用根据本细则 12.1 (a) 受理局接受的一种语言撰写的，就足够了。

(d) [无变化]

20.2 至 20.5 [无变化]

20.6 确认援引加入的项目和部分

(a) 申请人可以在根据本细则 20.7 适用的期限内向受理局提交一份书面意见通知，确认根据本细则 4.18 援引加入国际申请的项目或者部分，并附具：

[细则 20.6(a), 续]

(i) 涉及包含于在先申请的整个项目或者部分的一页或者多页；如果有关项目是条约第 11 条

(1) (iii) (d) 所述项目且包含电子形式的序列列表，或有关部分是此类电子形式序列列表或其组成部分，书面通知应附具根据行政规程提交的在先申请中所包括的电子形式序列列表的一份或多份副本；

[说明：对 (a) (i) 进行拟议修正的原因是，已不可能以纸件提交序列列表，只能以电子形式提交。当援引加入的项目是说明书并且其中包括电子形式的序列列表，或当援引加入的说明书的部分是序列列表或其组成部分，可能需要提交在先申请中所包括的全部序列列表，如果以物理介质提交，需提供三份副本。还需进一步考虑申请人想以纸件或 pdf 文件援引加入 2022 年 1 月 1 日之前提出的在先申请中所包括的序列列表的情况。]

(ii) 至 (iv) [无变化]

(b) 和 (c) [无变化]

20.7 和 20.8 [无变化]

## 第 49 条

### 根据条约第 22 条的副本、译文和费用

49.1 至 49.4 [无变化]

49.5 [无变化] 译文的内容和形式要求

(a) [无变化] 为条约第 22 条的目的，国际申请的译文应包括说明书（除（a 之二）项规定情况外）、权利要求书、附图中的文字和摘要。如果指定局要求，除（b）、（c 之二）和（e）另有规定外，译文还应：~~—~~

(i) 包括请求书，

(ii) 如果权利要求已经根据条约第 19 条进行过修改，则既应包括原始提交的权利要求，也应包括修改后的权利要求（修改后的权利要求应以根据本细则 46.5（a）规定提交的、替换全部原始权利要求的完整权利要求书的译文形式提交），以及

(iii) 附有附图的副本。

(a 之二) 任何指定局不应要求申请人向其提供：—

(i) 包含说明书序列表部分任何文字的译文，如果序列表部分符合本细则 12.1（d）的规定；  
和

(ii) 行政规程定义的任何语种相关自由内容的译文，如果该自由内容用的是英文；或者，如果不是英文，但说明书符合本细则 5.2（b）的规定。

[细则 49.5(a 之二), 续]

[说明: 建议修订 (a 之二), 以要求指定局接受英文作为序列表中所含任何与语种相关的文字使用的语言。关于序列表语种相关要求的具体解释, 见上文本文件正文第 12 段至第 33 段。]

(b) 至 (1) [无变化]

49.6 [无变化]

## 第 76 条

### 优先权文件的译文；选定局程序中某些细则的适用

76.1、76.2 和 76.3 [仍删除]

76.4 [无变化]

76.5 [无变化] 选定局程序中某些细则的适用

本细则 13 之三.3、20.8 (c)、22.1 (g)、47.1、49、49 之二和 51 之二应予适用，但：

(i) 在上述规定中述及指定局或者指定国之处，应分别理解为述及选定局或者选定国；

(ii) 在上述规定中述及条约第 22 条、第 23 条(2)或者第 24 条(2)之处，应分别理解为述及条约第 39 条(1)、第 40 条(2)或者第 39 条(3)；

(iii) 至 (v) [无变化]

[说明：细则 76.5 似乎无需修改。]

[后接附件二]

PRELIMINARY DRAFT  
PROPOSED MODIFICATIONS TO THE PCT ADMINISTRATIVE INSTRUCTIONS

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## Section 101

### [No change] Abbreviated Expressions and Interpretation

(a) [No change] In these Administrative Instructions:

(i) to (xi) [No change]

(xii) [No change] 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: No change would appear to be needed to Section 101 of the Administrative Instructions.]

(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 is proposed to delete item (vii) of paragraph (a), noting that it will 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) [No change] for matter referred to in Rule 5.2(b), "Sequence Listing Free Text".

[COMMENT: For a detailed explanation of the language related requirements for sequence listings, see paragraphs ~~错误!未找到引用源。~~ to ~~错误!未找到引用源。~~ of the main body of the present document, above.]

(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) [No change] 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) [No change] the claims;

(iv) [No change] the abstract;

(v) if applicable, the drawings;

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

[COMMENT: It is proposed to delete item (vi) of paragraph (a), noting that it will only be possible to submit sequence listings as separate electronic files but not on “sheets” on paper which are to be placed in a particular order within the international application.]

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

(i) [No change] the first series applying to the request only and commencing with the first sheet of the request;

*[Section 207(b), continued]*

(ii) [No change] 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.~~

[COMMENT: It is proposed to delete item (iv) of paragraph (b), noting that it will only be possible to submit sequence listings as separate electronic files but not on “sheets” on paper which are to be numbered with a particular series of numbering.]

## 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.

[COMMENT: The proposed amendment of Section 208 is consequential on the fact that it will no longer be possible to submit a compliant sequence listing on paper.]

## Section 309

### Procedure in the Case of Later Submitted Sheets or Sequence Listing in Electronic Form Furnished for the Purposes of Incorporation by Reference

(a) This Section applies, subject to paragraph (f), to any later submitted sheets and any later submitted sequence listing in electronic form which accompany a notice confirming under Rule 20.6 that an element or part embodied in those sheets or in that sequence listing was incorporated by reference.

(b) Where any later submitted sheets as referred to in paragraph (a) are received, or any later submitted sequence listing in electronic form is received, within the applicable time limit referred to in Rule 20.7 and the receiving Office makes a finding under Rule 20.6(b), the receiving Office shall:

(i) [No change] indelibly mark, in the middle of the bottom margin of each later submitted sheet, the words “INCORPORATED BY REFERENCE (RULE 20.6)”, or their equivalent in the language of publication of the international application;

[COMMENT: The marking of incorporated sequence listings will need to be reviewed in the more general context of improvements to the processing of application bodies and other documents processed in XML format. This should be done by the application of metadata – the sequence listing file itself should not be changed, but its file type and references to it should make clear the status of whether the listing has been incorporated or not. Further thought will have to be given to the case in which the applicant wishes to incorporate by reference a sequence listing on paper or pdf which was contained in an earlier application filed before January 1, 2022.]

(ii) notify the applicant that the element or part contained in the later submitted sheets, or contained in the later submitted sequence listing in electronic form, is considered to have been contained in the international application or purported international application on the date when sheets were first received and that that date has been accorded or retained, as the case may be, as the international filing date;

*[Section 309(b), continued]*

(iii) keep in its files a copy of the later submitted sheets marked under item (i), a copy of the later submitted sequence listing in electronic form and a copy of the notice under Rule 20.6(a);

(iv) where transmittals under Article 12(1) have already been made, notify the International Bureau and the International Searching Authority accordingly, and transmit ~~the~~ any later submitted sheets marked under item (i) to the said Bureau and a copy thereof to the said Authority; in the case of any later submitted sequence listing in electronic form, the receiving Office shall transmit one copy thereof to the International Bureau and one to the said Authority;

(v) where transmittals under Article 12(1) have not yet been made, attach ~~the~~ any later submitted sheets marked under item (i) and the notice under Rule 20.6(a) to the record copy and a copy thereof to the search copy; in the case of any later submitted sequence listing in electronic form, the receiving Office shall attach one copy thereof to the record copy and one copy thereof to the search copy.

(c) Where any later submitted sheets referred to in paragraph (a) are received, or any later submitted sequence listing in electronic form is received, within the applicable time limit referred to in Rule 20.7 and the receiving Office makes a finding under Rule 20.6(c), the receiving Office shall, subject to Section 310*bis*:

(i) effect the required correction of the international filing date or accord as the international filing date the date of receipt of any ~~the~~ later submitted sheets or the date of receipt of any later submitted sequence listing in electronic form or, where both later submitted sheets and a later submitted sequence listing are received on different dates, the date of receipt which is later;

*[Section 309(c), continued]*

(ii) notify the applicant that the content of any~~the~~ later submitted sheets and/or of any later submitted sequence listing in electronic form, is not considered to have been contained in the international application or purported international application on the date when sheets were first received and that the international filing date has been accorded as, or corrected to, as the case may be, the date on which the new sheets were, or the sequence listing in electronic form was, received, as the case may be;

(iii) keep in its files a copy of any~~the~~ later submitted sheets, of any sequence listing in electronic form and of the notice under Rule 20.6(a);

(iv) where transmittals under Article 12(1) have already been made, notify the International Bureau and the International Searching Authority accordingly and transmit a copy of the corrected first and last sheets of the request, any~~the~~ later submitted sheets, any later submitted sequence listing in electronic form and the notice under Rule 20.6(a) to the said Bureau and a copy thereof to the said Authority;

(v) where transmittals under Article 12(1) have not yet been made, attach any~~the~~ later submitted sheets, any later submitted sequence listing in electronic form and the notice under Rule 20.6(a) to the record copy and a copy thereof to the search copy.

(d) Where any later submitted sheets referred to in paragraph (a) are received, or any later submitted sequence listing in electronic form is received, within the applicable time limit referred to in Rule 20.7 but the purported international application still does not fulfill the requirements of Article 11(1), the receiving Office shall proceed as provided in Rule 20.4, but not before the expiration of the time limit under Rule 20.7.

[Section 309, continued]

(e) Where any later submitted sheets referred to in paragraph (a) are received, or any later submitted sequence listing in electronic form is received, after the expiration of the applicable time limit referred to in Rule 20.7, the receiving Office shall proceed as provided in Section 310*ter*.

(f) Where any later submitted sheets referred to in paragraph (a) are received, or any later submitted sequence listing in electronic form is received, but a missing element or part contained in those sheets or in that sequence listing cannot be incorporated by reference in the international application under Rules 4.18 and 20.6 because of the operation of Rule 20.8(a), the receiving Office shall:

(i) inform the applicant that the notice under Rule 20.6(a) confirming the incorporation by reference of the missing element or part has been disregarded;

(ii) proceed in accordance with Section 310(b), which shall apply *mutatis mutandis*, as if the notice under Rule 20.6(a) were a correction furnished under Rule 20.3(b)(i), or a missing part furnished under Rules 20.5(b) or (c), as the case may be; and

(iii) proceed in accordance with Section 310*bis*(b) where the applicant requests, within the time limit under Rule 20.5(e), that the missing part concerned be disregarded.



### Section 313

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

(a) and (b) [No change]

(c) Any sequence listing in electronic form 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 in electronic form 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: Proposed amendments to Section 313(c) are consequential on the fact that it is no longer possible to submit sequence listings in paper form and on the proposed addition of new Rule 5.2(a-bis), according to which any electronic file purporting or appearing to be a sequence listing received on or before the date on which the receiving Office determines that the papers purporting to be an international application fulfill all of the requirements under Article 11(1) is to be considered to form part of the description.]

## Section 513

### Sequence Listings

(a) [No change] 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.]

*[Section 513, continued]*

(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.]

*[Section 513, continued]*

(e) The International Searching Authority shall:

(i) keep in its files one copy of any sequence listing in electronic form, ~~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).]

*[Section 610, continued]*

(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) [No change] 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) Notwithstanding paragraph (a), any receiving Office shall be required to accept a sequence listing in electronic form on a physical medium:

- (i) where the remainder of the international application is filed on paper; or
- (ii) where the international application is filed in electronic form but it is either not possible or not practical to include the sequence listing within the package containing the remainder of the international application;

and shall, in respect of each International Searching Authority which is competent for the searching of international applications filed with it, specify at least one form of physical medium in accordance with Annex F which it accepts for the filing of such sequence listings which is also accepted by such Authority.

[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 alternatively 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) [No change] 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.<sup>3</sup>

(a-bis) Where ~~a sequence listing is contained in an~~ the international application as filed contains an electronic file purporting or appearing to be 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 such an electronic file.

[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) [No change]

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<sup>3</sup> *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) to (vii) [no change]

(b) to (d) [No change]

[后接附件三]

## ANNEX C

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

#### INTRODUCTION

1. The Instructions set out in this Annex apply to international applications filed on or after January 1, 2020.
2. Pursuant to Rule 5.2(a), “[w]here the international application contains disclosure of one or more nucleotide and/or amino acid sequences which, pursuant to the Administrative Instructions, are required to be included in a sequence listing, the description shall include a separate part of the description (“sequence listing part of the description”) containing a sequence listing complying with those Instructions and presented in the form of a single electronic file in accordance with those Instructions (“compliant sequence listing”).” Pursuant to Section 208, “[a]ny sequence listing, whether forming part of the international application or not forming part of the international application, shall comply with Annex C” (this Annex).

This Annex provides the Instructions referred to above in relation to the filing and processing of sequence listings, whether forming part of an international applications or not forming part of an international application.

#### DEFINITIONS

For the purposes of these Instructions:

- (a) the expression “sequence listing” has the same meaning as defined in WIPO Standard ST.26;
- (b) “nucleotide” and “amino acid” have the same meanings as in WIPO Standard ST.26;
- (c) 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;

(d) 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**

WIPO Standard ST.26 shall apply to any nucleotide and amino acid sequence disclosure in an international application, notably with regard to:

- (e) the question as to whether such disclosure is to be included in a sequence listing;
- (f) the manner in which disclosures are to be presented;
- (g) the question as to when the use of “free text” is permitted as a value format for certain qualifiers in sequences and the identification of those qualifiers for which language-dependent “free text” may be used (see Sections 6 and 8 in Annex I to WIPO Standard ST. 26); and

[COMMENT: Paragraph (c) is drafted on the assumption that WIPO Standard ST.26 is further modified to specify those qualifiers for which language-dependent text may be used. See paragraphs 错误!未找到引用源。 and 错误!未找到引用源。 in the main body of the present document. ]

- (h) the Document Type Definition (DTD) for a sequence listing in XML (eXtensible Markup Language);

subject to the specific requirements set out in this Annex.

Following any revision of WIPO Standard ST.26, the Director General shall decide a date from which the revised version of that 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 an international application on the date on which it is filed.

#### **SEQUENCES WHICH MUST BE PRESENTED IN A LISTING**

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:

- (i) 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
- (j) an unbranched sequence or a linear region of a branched sequence containing four or more specifically defined amino acids, wherein the amino acids form a single peptide backbone, that is, adjacent amino acids are joined by peptide bonds.

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.

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(a), the sequence listing part of the description shall be presented separate from the main part of the description. PCT provisions do not require that the sequences themselves be presented in the main part of the description in addition to the sequence listing; however, there may be valid reasons for doing so. Where the sequences are presented within the main part of description, they may be set out in the manner considered most appropriate to present the information for the relevant purpose, rather than strictly adhering to the presentation requirements of WIPO Standard ST.26. . In the description, claims or drawings of the application, the sequences represented in the sequence listing shall be referred to by the sequence identifier and preceded by "SEQ ID NO:", even if the sequence is also embedded in the description, claims, or drawings.

## **SEQUENCE LISTINGS FORMING PART OF THE INTERNATIONAL APPLICATION**

### **ELECTRONIC FILE PURPORTING OR APPEARING TO BE A SEQUENCE LISTING**

In accordance with Rule 5.2(a-bis), any electronic file purporting or appearing to be a sequence listing received on or before the date on which the receiving Office determines that the papers purporting to be an international application fulfill all of the requirements under Article 11(1) shall be considered to form part of the description, whether or not that listing is referred to in the main part of the description or in the request. This is independent of the question whether or not the electronic file purporting or appearing to be a sequence listing is in fact compliant with WIPO Standard ST.26 (which is not required to be checked by the receiving Office but only by the International Searching Authority, see paragraphs 0 to 0, below).

## INTERNATIONAL APPLICATION, INCLUDING SEQUENCE LISTING, FILED IN ELECTRONIC FORM

Where the international application containing a sequence listing is filed in electronic form, whether transmitted by electronic or physical means, the sequence listing shall preferably form part of a package filed in accordance with Annex F, with the sequence listing indexed in accordance with the standards set out in that Annex.

Notwithstanding paragraph 0, any receiving Office may accept an electronic file purporting or appearing to contain a sequence listing submitted separately from the main package on the date of filing and shall accept such a separate electronic file in any case where it is not practical for the applicant to include the sequence 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 remainder of the international application.

## SEQUENCE LISTING IN ELECTRONIC FORM WITH REMAINDER OF INTERNATIONAL APPLICATIONS FILED ON PAPER

In accordance with Section 703(d), any receiving Office shall be required to accept a sequence listing in electronic form filed on a physical medium of a type accepted by that Office where the remainder of the international application is filed on paper.

## SEQUENCE LISTINGS FILED ON PHYSICAL MEDIA

Any physical medium containing a sequence listing, whether the remainder of the international application is filed on paper or in electronic form, shall be clearly labeled "Sequence Listing" or its equivalent in the language of publication, to which the receiving Office shall add the international application number. Preferably, the physical medium used for the transmittal of the sequence listing shall be of a type accepted by both the receiving Office and the International Searching Authority chosen to carry out the international search.

Where a sequence listing is too large to be included on a single physical medium, it shall 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 physical medium, the physical media shall each be numbered, for example "DISK 1/3", "DISK 2/3", "DISK 3/3".

[COMMENT: Some concern has been expressed over the standards used for splitting and rejoining files. This should be considered as a more general issue in the context of Appendix IV of Annex F, rather than having a provision exclusively for sequence listings.]

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.

#### LANGUAGE RELATED REQUIREMENTS

WIPO Standard ST.26 prescribes the use of “controlled vocabulary” that must be used when describing the features of a sequence, that is, annotations of regions or sites of interest as set out in Annex I to the Standard. This “allowed” controlled vocabulary comprises: nucleotide codes (Section 1 of Annex I); abbreviations for modified nucleotides (Section 2 of Annex I); amino acid codes (Section 3 of Annex I); abbreviations for modified amino acids (Section 4 of Annex I); feature keys for nucleotide sequences (Section 5 of Annex I); qualifiers for nucleotide sequences (Section 6 of Annex I); feature keys for amino acid sequences (Section 7 of Annex I); and qualifiers for amino acid sequences (Section 8 of Annex I).

Under the Standard, “qualifiers” are used to supply certain information about features in addition to that conveyed by the feature key and feature location. There are several types of allowed “value formats” to accommodate different types of information conveyed by qualifiers, namely specific terms, enumerated values (for example, a number or date), “free text” and sequences.

Of the controlled vocabulary allowed to be used when describing the features of a sequence (see paragraph 错误!未找到引用源。 , above), the following is, or is considered to be, *language-independent*:

- (k) the nucleotide codes set out in Section 1 of Annex I of the Standard and the amino acid codes set out in Section 3;
- (l) the abbreviations for modified nucleotides set out in Section 2 and the abbreviations for modified amino acids set out in Section 4 as the only permitted values for the certain qualifiers;
- (m) the names of feature keys set out in Sections 5 and 7, and the names of qualifiers set out in Sections 6 and 8, notwithstanding that many of the allowed names of feature keys and qualifiers are in English or are English abbreviations (see, for example, feature keys 5.1 “C-region” and 7.18 “MOD\_RES” (abbreviation of “modification of a residue”); and qualifiers 6.5 “cell\_type” and 8.3 “ORGANISM”);

(n) all “value formats” set out in Sections 5, 6, 7 and 8 allowed to be used to accommodate different types of information conveyed by qualifiers other than “free text” (that is, specific terms, enumerated values like a number or date, and sequences), notwithstanding that many of these allowed “value formats” contain elements in English or English abbreviations or are recognizably derived from English or Latin words (see, for example, qualifier 6.15 “direction”, with the value format: “left, right or both”).

Questions relating to the need for a translation of any such “language-independent controlled vocabulary” for the purposes of international search or preliminary examination, or for national phase purposes, do not arise.

On the other hand, WIPO Standard ST.26 (in Sections 6 and 8 of Annex I) also permits the use of “free text” as a value format for certain qualifiers in sequences. According to paragraph 85 of the Standard, “[f]ree text is a type of value format for certain qualifiers (as indicated in Annex I), presented in the form of a descriptive text phrase that should preferably be in the English language”.

WIPO Standard ST.26 requires the entire information contained in an electronic sequence listing, except for the information given in the elements “applicant’s name”, “inventor name” and “invention title”, to be composed of printable characters from the Unicode Basic Latin code table (excluding certain reserved characters defined in WIPO Standard ST.26; accented Latin characters are also not permitted). Consequently, it is not possible to submit a WIPO Standard ST.26 compliant sequence listing with any language-dependent “free text” in languages not composed of such Basic Latin characters.

The qualifiers for which the use of “free text” is permitted are set out in Sections 6 and 8 of Annex I of WIPO Standard ST.26. In essence, the “free text” permissible for these qualifiers falls into three different categories:

(o) some “free text” is *entirely language-independent* since, while being described as “free text” and not controlled by a DTD, the expected format is specified as a “number” or “code” which does not vary between languages (example: WIPO Standard ST.26, Annex I, 6.16, qualifier “EC-number”; definition: “Enzyme Commission number for enzyme product of sequence”; value format: “free text”; example: “<INSDQualifier\_value>1.1.2.4</INSDQualifier\_value>”);

(p) some “free text” may be *effectively language-independent* because the expected values are personal names (albeit, where relevant, transliterated into Latin characters or lacking accents) or internationally used terms for an organism (example: WIPO Standard

ST.26, Annex I, 6.27, qualifier “host”; definition “natural (as opposed to laboratory) host to the organism from which sequenced molecule was obtained”; value format: “free text”; example: ““<INSDQualifier\_value>Homo sapiens</INSDQualifier\_value>”);

(q) some “free text” is *always language-dependent*, taking the form of genuinely “free text” comments (example: WIPO Standard ST.26, Annex I, 6.21, qualifier “function”; definition: “function attributed to a sequence”; value format: “free text”; example: “<INSDQualifier\_value>essential for recognition of cofactor</INSDQualifier\_value>”).

WIPO Standard ST.26 (in Sections 6 and 8 of Annex I) clearly identifies those qualifiers for which “free text” which is considered to be “*language dependent*” may be used.

[COMMENT: Paragraphs 23 and 24 are drafted on the assumption that WIPO Standard ST.26 is further modified to specify those qualifiers for which language-dependent text may be used. See paragraphs 错误!未找到引用源。 and 错误!未找到引用源。 in the main body of the present document.

So as to ensure that, during the international phase, the International Authorities, and, during the national phase of procedures, the designated and elected Offices can understand any such *language-dependent “free text”* if that “free text” is not in English (which must be accepted by any International Authority for the purposes of the international phase, and by any designated or elected Office for the purposes of the national phase) and not in a language which is accepted by those Authorities or those Offices, PCT Rule 5.2(b) requires any such “language-dependent free text as defined in the Administrative Instructions” (that is, any “free text” identified, in Sections 6 and 8 of Annex I of ST.26, as “language-dependent”), to be repeated in the main part of the description in the language thereof.

Such inclusion of any *language-dependent “free text”* in the main part of the description in the language thereof ensures that the International Authority concerned and any designated or elected Office will always have such non-English “free text” available to it in a language accepted by it for international search or international preliminary examination and for national phase processing, respectively, be that as part of the international application as filed (or as corrected in accordance with Rule 13~~ter~~.1(f)), or as part of a translation of the international application (including any “free text” repeated in the main part of the description, in the language thereof) into a language accepted by the International Authority furnished by the applicant under Rule 12.3(a) or Rule 55.2, into a language of publication furnished by the applicant under Rule 12.4(a), or into a language accepted by the designated or elected Office furnished by the applicant under Articles 22 or 39.



On the other hand, any “free text” not identified in Sections 6 and 8 of Annex I to WIPO Standard ST.26 as “*language dependent*” will always be considered to be “language-independent” and does thus not have to be repeated in the main part of the description in the language thereof.

Where any *language-dependent “free text”* is not in English and not repeated in the main part of the description in the language thereof, the International Authority concerned is required to invite the applicant to furnish a correction to include such “free text” in the main part of the description, in the language thereof (see current Rules 13~~ter~~.1(f) and 13~~ter~~.2). This is a requirement not so much for the benefit of the International Authority (it applies even if the language-dependent “free text” is already in a language which is accepted by it for the purposes of international search or international preliminary examination) but mainly for the benefit of the applicant; it is only in case any language-dependent “free text” is indeed repeated in the main part of the description, and thus in any translation thereof, that it is guaranteed that the applicant will not be required to furnish a new sequence listing for national phase processing purposes. If such a correction has not been submitted, the applicant would be required to provide a new sequence listing, including any “free text” set out in the language accepted by the designated or elected Office for the purposes of national phase processing.

## CHECKING BY THE RECEIVING OFFICE

### Checking for Compliance with WIPO Standard ST.26

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.

### Calculation of International Filing Fee

In accordance with Section 707(a-bis), where the international application as filed contains an electronic file purporting or appearing to be a sequence listing, the calculation of the international filing fee shall, in the calculation of the number of sheets, not take into account any material contained in such an electronic file. However, where the receiving Office determines that the electronic file in fact contains material which is clearly not a sequence listing, such as PDF pages of the main part of the description or drawings mislabeled as a sequence listing, such pages should be taken into account in the calculation of the number of sheets.

### Language Related Requirements

See paragraphs 0 to 0, above. As noted in paragraph 0, above, the receiving Office will, when checking whether the international application complies with the filing date related language requirements under Article 11(1)(ii), only check the main part of the description for compliance with Article 11(1)(ii) but not any sequence listing part of the description (see Rule 20.1(c)).

### **CORRECTION, RECTIFICATION AND AMENDMENT OF SEQUENCE LISTINGS**

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 forming part of 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 submitting 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.

In compliance with WIPO Standard ST.26, any sequence listing referred to in paragraph 0 shall, where possible, maintain the original numbering of the sequences in the application as filed, representing any “intentionally skipped sequence” as prescribed by WIPO Standard ST.26, where necessary. Otherwise, the sequences shall be numbered in compliance with that Standard in the order in which they appear in the international application.

Where the sequence listing referred to in paragraph 0 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.

### **SEQUENCE LISTINGS NOT FORMING PART OF THE INTERNATIONAL APPLICATION**

Any sequence listing furnished under Rule 13*ter*.1, 13*ter*.2 and 45*bis*.5(c) to an International Authority for the purposes of international search or preliminary examination shall not, pursuant to Rule 13*ter*.1(e) (where applicable, by virtue of Rules 13*ter*.2 and 45*bis*.5(c)), form part of the international application. In compliance with WIPO Standard ST.26, such a sequence listing shall, where possible, maintain the original numbering of the sequences in the application as filed, representing any “intentionally skipped sequence” as prescribed by WIPO Standard ST.26, where necessary. Otherwise, the sequences shall be numbered in compliance with that Standard in the order in which they appear in the international application.

Paragraphs 0, 0 to 0 and 0 of this Annex shall apply *mutatis mutandis* to any sequence listing furnished under Rule 13ter.1, 13ter.2 and 45bis.5(c) to an International Authority for the purposes of international search or preliminary examination. Such sequence listing shall contain all sequences disclosed in the international application as filed, which meet the criteria referred to in paragraph 0, above, shall not go beyond the disclosure of the international application as filed and shall be accompanied by a statement to that effect.

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.

### **PROCEDURE BEFORE DESIGNATED AND ELECTED OFFICES**

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 13ter.3):

- (r) any reference to the receiving Office or the International Searching Authority or the International Preliminary Examining Authority shall be construed as a reference to the designated or elected Office concerned;
- (s) 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;
- (t) 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;
- (u) 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.