Paper Submitted by the epi concerning new WIPO Standard ST.26 on sequence listings

This paper is submitted on behalf of the epi to the EPO.

The Institute of Professional Representatives before the European Patent Office (**epi**) is the professional body representing all representatives entered on the List held by the EPO (European Patent Attorneys). Currently **epi** has about 13,000 European Patent Attorneys as members coming from each of the 38 Contracting States of the European Patent Convention (EPC) who work either in industry or in private practice.

This paper has primarily been written by the Biotechnology committee of the epi. It is being submitted because we have significant concerns with the implementation of WIPO Standard ST.26 on 1st July 2022. The epi has tried to engage with the EPO on several levels, and with different people and different departments, regarding the new ST.26 standard. However, we are becoming increasingly concerned that the EPO is not sharing users' concerns and any issues raised are dismissed by summarily reference to the guidance provided by WIPO . It appears that the EPO has decided that it will implement ST.26 irrespective of the potential consequences for the EPO, practitioners, and applicants alike.

Therefore, we are putting our concerns in writing, so that they are fully documented. This paper is being submitted to DG1, the legal department, and other departments so that they are all well aware, in writing, of potential issues and problems and of the concerns of attorneys.

We thus hope that the EPO will engage with us, although we realise that this is put in writing at a relatively late stage. That is primarily because few, if any, opportunities for users to put forward their concerns to the EPO have arisen. In addition, when concerns have been raised, those have been downplayed by the EPO.

General remarks

ST.26 provides a fundamental and seismic shift in the requirements for sequence listings. Its requirements are considerably different to those of present standard ST.25. One of our concerns is that it is difficult to convert sequence listings from the old ST.25 standard to the new ST.26 standard, particularly for sequence listings with a higher number of entries. This difficult conversion is time consuming and will place a considerable burden on users, applicants and attorneys alike. This will drive up the cost of filing and prosecution of EPO patent applications with sequence listings, both for industry and other users. It will place an additional and disproportionate burden on applicants in one particular technological sector and has the potential to cause legal problems and uncertainty for many years to come.

A fundamental issue with ST.26 is that it requires additional information above and beyond ST.25. In theory, this is perhaps not a bad thing. More information, rather than less information, is better. How this is implemented, however, is key.

Priority-claiming applications

There is no transitional period. The new ST.26 comes into force on 1st July 2022. This applies to all EP applications with an International or European filing date after then, even where an earlier related application has been filed using ST.25. For example, a National patent application could have been validly filed using ST.25, and then a European patent application, filed after 1st July and claiming priority, would require a ST.26 version. Likewise, a priority-

setting European patent application filed before 1st July would have a sequence listing in ST.25 format while the subsequent priority-claiming European patent application filed after 1st July would require an ST.26-compliant sequence listing. This places an added burden on applicants, particularly in order to avoid affecting the validity of the claim to priority (notably under the EPO's strict interpretation of priority).

However, we understand that the EPO is now bound by international agreements on how WIPO Standard ST.26 will be implemented with respect to new International and European patent applications.

Divisional applications – legal considerations

In contrast, the EPO is not bound to the same extent by international agreements in respect of *divisional* applications. In question 31 of its Frequently Asked Questions on the implementation of ST.26[1], WIPO confirms that divisional applications are "*a matter of national law*" and that "*As this is a decision for the Office, some may decide applicants to be allowed to "carry over" the sequence listing from the parent application to the divisional*".

The Decision of the President of the European Patent Office dated 9 December 2021 on the filing of sequence listings (OJ EPO 2021, A96) is silent on divisional applications. Only the subsequent Notice from the European Patent Office dated 9 December 2021 concerning the filing of sequence listings (OJ EPO 2021, A97) expressly sets out the EPO's position with respect to divisional applications.

It appears from this Notice, contrary to pleadings from epi and other user organisations, that the EPO will insist on ST.26 as the standard for all divisional applications submitted on or after 1st July 2022. The Notice alleges that

> "*As an **independent** European patent application, a divisional application must also satisfy the requirements of Rule 30 EPC in conjunction with the decision of the President. Consequently, a sequence listing forming part of the description of a divisional application filed on or after 1 July 2022 must comply with WIPO Standard ST.26*" (point 16; emphasis added).

However, a divisional application is not entirely independent from its parent application. In particular, it is given the **same filing date** as its parent application. Art. 76(1) EPC states "*in so far as [the requirement not to add matter] is complied with, the divisional application **shall be deemed to have been filed on the date of filing of the earlier application** and shall enjoy any right of priority*" (emphasis added). The date on which the divisional application is physically or digitally 'filed' at the EPO is merely the date on which the application is lodged. Hence, for example, the EPO Register indicates the "filing date" for a divisional application to be same as the filing date of the parent application, not the date on which the divisional application was submitted to the EPO.

For at least this reason, we submit that the relevant sequence listing standard for divisional applications should be the standard that is required as of its true filing date (i.e. the filing date of its parent application), such that divisional applications of applications filed before 1st July 2022 should remain under standard ST.25. The EPO has the authority (and, indeed, the obligation under Art. 76(1) EPC) to do so, and can do this without affecting agreements with WIPO.

[1] https://www.wipo.int/standards/en/sequence/faq.html

Divisional applications – added matter concerns

In addition to the general aim of reducing burden on applicants, we have serious concerns about the potential for ST.26 sequence listings filed for divisional applications (when the parent case had been filed before 1st July 2022) to add matter. Such added matter problems will be impossible to remedy. This is because ST.26, by definition, requires more information than ST.25. By requiring more information, the danger is that filing an ST.26 listing will, inherently, add matter. That is an immediate and obvious consequence of ST.26 demanding more information.

The only response we have received from the EPO is to point to Annex VII of Standard ST.26, which purports to provide guidance for how to avoid the pitfalls of added subject matter when preparing an ST.26 sequence listing. However, that Annex itself *acknowledges* that there are a number of situations in which it would *not* be possible to avoid adding matter (e.g. Scenarios 7, 19 and 20). Those situations particularly relate to alleged deficiencies in the earlier ST.25 sequence listings relating to a lack of clarity. Hence, in those situations, a mere lack of clarity in a parent application could give rise to a fundamental problem of *added matter* in a divisional application. This is unacceptable.

Similarly, there are places in Annex VII that refer to an inevitable addition of information that would not be entitled to priority (e.g. Scenarios 7 and 8; see particularly the note at the bottom of page 3.26.vii.5). In the context of a divisional application, this means *added matter*, which cannot be remedied.

Hence, applicants could be caught in an inescapable trap between the potentially conflicting requirements of Rule 30 and Art. 76(1) EPC.

This, therefore, is serious and sufficient evidence that there will be an inherent problem with some divisionals filed after the 1st July.

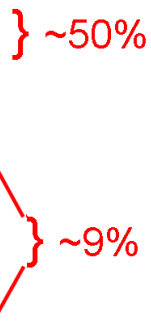
The EPO seems to be either unaware of this problem or would appear to be ignoring it. It is leaving it to applicants to sort out. However, this problem has the potential to create legal uncertainty for years. Divisional applications requiring ST.26 listings filed after 1st July will inevitably be vulnerable to challenge under Article 76(1) EPC, such that we can envisage patents being challenged after grant on the grounds of added matter in sequence listings. This is because it is a relatively easy attack and is worsened by the fact that the EPO's stance on added matter under Articles 123(2)/76(1) EPC is very strict. We fear therefore that granted patents could be opposed on these grounds and that the matter may not be resolved for many years, leading to legal uncertainty.

Divisional applications - burden upon the applicant

The tables below show an analysis of WO 2021 sequence listings published by WIPO, specifically the number of SEQ IDs contained in published sequence listings and the number of pages of these sequence listings if printed using minimal margins.

publication_year	2021

Number of SEQ IDs	Count of SEQ listings	% of total SEQ listings
<=10	3454	29.77%
11-25'	2345	20.21%
26-50	1860	16.03%
51-100	1542	13.29%
101-250	1317	11.35%
251-500	467	4.02%
501-1000	288	2.48%
1001-2500	126	1.09%
2501-5000	62	0.53%
5001-10000	43	0.37%
>10000	54	0.47%
(blank)	46	0.40%
Grand Total	**11604**	**100.00%**



Notably, approximately 50% of published sequence listings contained <=25 SEQ IDs, i.e. would be expected to present a relatively small burden upon applicants to transform from WIPO ST.25 to ST.26, potentially requiring only a few hours' work.

However, approximately 9% of published sequence listings contain >250 SEQ IDs, and almost 2.5% of published sequence listings contain >1000 SEQ IDs. The burden upon applicants of transforming those large sequence listings from WIPO ST.25 to WIPO ST.26 will be very substantial, particularly given the need for manual input and intervention during the transformation process and the need to ensure that any modifications to the sequence listing/sequence information required by ST.26 do not introduce added matter.

The table below shows the number of pages of sequence listing if printed using minimal margins, line spacing and text size[2], together with the corresponding excess page fees that will be due (assuming the application has >=35 pages excluding the sequence listing, which is standard for patent applications incorporating sequence listings).

publication_year	2021			
Number of SEQ IDs	**Count of SEQ listings**	**Average of Pages of SEQ listing**	**Average of Excess page fee**	**% of total SEQ listings**
<=10	3454	15.84	EUR 253.45	29.77%
11-25'	2345	59.77	EUR 956.30	20.21%
26-50	1860	68.74	EUR 1,099.86	16.03%
51-100	1542	87.25	EUR 1,395.94	13.29%
101-250	1317	218.43	EUR 3,494.83	11.35%
251-500	467	361.33	EUR 5,781.31	4.02%
501-1000	288	609.83	EUR 9,757.22	2.48%
1001-2500	126	1351.54	EUR 21,624.63	1.09%
2501-5000	62	2371.16	EUR 37,938.58	0.53%
5001-10000	43	6100.56	EUR 97,608.93	0.37%
>10000	54	24228.00	EUR 387,648.00	0.47%
(blank)	46	14.74	EUR 235.83	0.40%
Grand Total	**11604**	**256.63**	**EUR 4,106.07**	**100.00%**

[2] Margins - Rule 49(5) EPC); 1.5 line spacing and text with 0.21 cm high capital letters (Courier New @ 10.5pt) - Rule 49(8) EPC; 41 lines of text possible on a single A4 page.

Even for applications with <=10 SEQ IDs, the average cost of excess page fees for a sequence listing incorporated into the description of a divisional application is EUR 253. For applications with 251-500 SEQ IDs, the average excess page fee is EUR 5,781, and for applications with 5001-10000 SEQ IDs, the average excess page fee is almost EUR 100,000.

Although it will be possible in some cases with relatively short sequence listings to include the ST.25 formatted sequence listing as part of the description of the divisional application, as illustrated above, the excess page fees required for the larger sequence listings (e.g. the 9% of cases with sequence listings with >250 SEQ IDs) will be very substantial, and for many cases will be an impossible burden.

This burden (and the risk that transformation to ST.26 presents) is entirely disproportionate to the benefits to the EPO and third parties. Ultimately, if the EPO wishes to make procedural changes, the impact upon applicants must be a primary consideration, particularly where there is the potential of causing/forcing the inclusion of added matter which will result in irrecoverable losses. As is stated at Art 4(3) EPC, *"The task of the [European Patent] Organisation shall be to grant European patents."* . In contrast, the current implementation of WIPO ST.26 will actively hinder the granting of European patents for affected applicants.

Divisional applications – solution adopted by the UK IPO

We would like to point out that, in the UK, the Chartered Institute of Patent Attorneys (CIPA) made representations to the UK IPO on precisely this matter. The UK IPO subsequently changed its proposed practice with regard to ST.26 and divisional applications, and now requires that "*For new divisional patent applications filed on or after 1 July 2022, the sequence listing should be supplied in the format required for the parent application*"[3].

The legal basis for this is: (a) Section 15(9)(b) UKPA 1977, which states that *"… the new [divisional] application shall be treated as having, as its date of filing, the date of filing the earlier [parent] application"* and (b) the agreed transition from WIPO ST.25 to WIPO ST.26 being determined based on the international filing date (i.e. WIPO ST.26 is required for PCT applications having an international filing date on or after 1 July 2022) [4] [5].

Proposals from epi

We trust that the EPO will seriously consider the following proposals to be in force as of 1st July 2022.

1. **Establish their true filing date (in accordance with Art. 76(1) EPC) as the determinative date for which sequence listing standard is required for divisional applications, thus enabling them to use the same sequence listing as their parent application (i.e. the same approach as the UK IPO).**
2. **Waive the late furnishing fee under Rule 30(3) EPC for providing ST.26 sequence listings on cases where a pre-existing ST.25 listing is submitted to the EPO for**

[3] https://www.gov.uk/government/publications/changes-for-patent-applications-with-biological-sequence-listings
[4] WIPO CWS/5/22 at paragraph 44 - https://www.wipo.int/edocs/mdocs/cws/en/cws_5/cws_5_22.pdf
[5] Paragraph 183 of document WO/GA/54/15 - https://www.wipo.int/edocs/mdocs/govbody/en/wo_ga_54/wo_ga_54_15.pdf

search purposes only. This would offset the cost of completing the onerous conversion requirements from ST.25 to ST.26.

3. **Waive the requirement for applicants/representatives to file a declaration that the sequence listing does not add subject matter.** This is because this requirement will be impossible to satisfy in some cases. The requirements of ST.26, with the additional information over and above ST.25, may make it impossible for an attorney to declare that the new sequence listing does not add new matter. This would place applicants and representatives in an impossible position in which they would be pressured to declare something that they know is not true.
4. **In the event that proposal 1 is not adopted, waive the requirement for additional page fees that are specifically incurred for the pages of an ST.25 sequence listing that are reproduced as pages of the description of a divisional application to maintain the subject matter of its parent application.**

We realise that these are significant requests. However, they are not disproportionate given the circumstances. The ST.26 standard itself was devised with virtually no applicant, representative or user input. Furthermore, the EPO has decided to implement ST.26 without serious discussion with users and, we feel, without duly taking the impact on applicants into account. We therefore present our concerns and proposed solutions in concrete terms so that the EPO is clearly aware of potential problems, and the issues that will arise for both the EPO and users alike in the future if these concerns are not resolved appropriately.

We would very much appreciate engagement with the EPO on this matter. We believe that this should be seriously considered by legal experts, sequence listing experts and senior management and Examiners before the implementation deadline of 1st July 2022. Serious engagement with users, in order to forestall potential issues which the new ST.26 standard is likely to cause, would be appreciated.

We hope that the EPO will immediately engage with users and applicants alike in order to discuss these issues and to minimise the envisaged problems.

Written by the EPI Biotechnology Committee

21 June 2022