



HOFFMANN EITLE

HOFFMANN EITLE *September 2021* QUARTERLY

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Time to Dust off Strategic Plans for the European Patent with Unitary Effect and the Unified Patent Court?

A further roadblock has been removed for the Agreement on a Unified Patent Court (UPCA) and by extension the entire EU Patent Package to come into force, possibly by mid-2022. The three-month sunrise period for patent proprietors to opt out their EP applications, European patents or SPCs from the competence of the Unified Patent Court could commence accordingly in spring of next year. Thus, it may be time to shake off this groundhog-day-feeling and revisit the strategic planning from 2017. Applicants may moreover consider how the European Patent with Unitary Effect (also referred to as Unitary Patent) factors in their filing strategy. And (prospective) plaintiffs and defendants in a patent infringement suits will have to take the Unified Patent Court into account for their litigation strategies

What was the EU Patent Package again?

The European Patent Office (EPO) is a central institution that examines patent applications and grants patents for now up to 38 countries (plus six extension/validation states). After grant, however, European patents must be validated and maintained at the national patent offices, and they can be enforced and nullified in national court proceedings only (except for the right to oppose a European patent within nine months from grant). Since the inception of the EPO in the late 70s, there has been a desire to provide a centralized option also for this later phase of a European patent's lifecycle.

The EU Patent Package is the latest attempt to fill this perceived gap. If it comes into force, it will provide an alternative way – with regard to the participating states – to validate and pay annuities for a granted European patent centrally at the EPO. It will also create a court system with specialized patent judges, the Unified Patent Court, that can grant injunctions and other remedies spanning the entire territory of the participating states. The Unified Patent Court will have several divisions distributed throughout the territory, which will allow for a certain degree of forum shopping and will offer the use of English in the proceedings.

In theory, all 27 European Union member states could implement the EU Patent Package, but not all will. The interest has waxed and waned in some countries, whereas others (e.g. Italy), have been late to convert, but are now staunch supporters. For the EU Patent Package to come into force, at least 13 countries, including Germany, France and Italy must ratify the UPCA. Besides Germany, France, and Italy, the Nether-

lands, Sweden and Belgium are the largest countries that are very likely to participate because they have already ratified the UPCA. These six countries (out of the at least 15 countries likely to join from the beginning) have a combined population of about 250 million people and, together with the USA and China, are within the top three by GDP. The EU Patent Package thus provides a highly attractive territory for patent protection and venue for patent litigation.

What happened, where are we, and what is to happen next?

The EU Patent Package has faced considerable obstacles, *inter alia* a challenge by Italy and Spain before the Court of Justice of the European Union, BREXIT with the UK's unfortunate decision to abstain, and several constitutional complaints to the German Federal Constitutional Court blocking the Germany's ratification.

This past June the German Federal Constitutional Court rejected the two pending applications for preliminary injunctions. In the grounds of the decision, the court also eliminated any realistic hope for the petitioners to prevail in main proceedings. Subsequently, the German president signed the bill permitting ratification and the act was promulgated, clearing the way for Germany to ratify the UPCA. This is crucial because Germany, as mentioned, is one of the three countries which must, together with ten other signatories, ratify the UPCA for it to come into force.

As the other required ratifications have already taken place, Germany's ratification of the UPCA could commence the EU Patent Package. However, for practical reasons it has been decided to preface the start of the EU Patent Package with a provisional application period. During this period, all necessary legal, financial, HR, IT and infrastructure preparations are to be concluded for the court to fully function from day one. This provisional application is based on a further legal instrument, the Protocol on the Provisional Application of the UPCA (PPA), which itself requires the consent by 13 states that have ratified the UPCA as well. Germany is expected to ratify the PPA soon, bringing the number of countries to eleven. The UPC Preparatory Committee stated in a communication of August 18, 2021 that the last two required consents "are expected to take place in a timely manner during autumn of this year". It is unknown which states are expected to consent in the next months; likely candidates are Austria, Greece, Romania, Slovenia, Malta and Portugal. The same committee foresees that it will take about eight months from the start of the PPA to conclude the necessary preparations for the UPC to open its doors. If everything goes to plan, the first European patent could be registered as having unitary effect and the first infringement or revocation action could be filed next summer.

Given the EU Patent Package's failed predecessors and long history of almost-starts (it was agreed in 2013), practitioners are still cautious. It will require a rekindling of political initiative to get the EU Patent Package over its presumably last hurdle.

What are the implications?

Although the start of the EU Patent Package remains uncertain, the time left to prepare will be limited once the provisional application period (PAP) starts. Stakeholders will therefore consider what to do in the approximate eight months of the PAP.

During the PAP: patent proprietors

For most proprietors of European patents or SPCs, and for current applicants, the main consideration will be

whether to opt out and whether to use the EP patent with Unitary Effect (EP-UE / Unitary Patent) in their overall filing strategy. Moreover, some proprietors may be enforcing or contemplating to enforce European patents and will thus have to consider the implications for their litigation strategy.

Should I stay or should I go?

From its start and for a transition period of at least seven years, the Unified Patent Court (UPC) will have shared jurisdiction with the national courts regarding nationally validated European patents and Supplementary Protection Certificates (SPCs). As this includes existing rights, the proprietors are given a right to opt out from the jurisdiction of the UPC, provided such proceedings are not yet pending. Such opt-out remains in place for the entire term of the application, patent or SPC, and an opt-out of an application will extend to the granted patent, as will the opt-out of the patent to the SPCs that are granted based thereon. The proprietor may at any time (irreversibly) withdraw the opt-out, unless a national action is pending.

The main reason to opt out would be to avoid a UPC revocation action. As these revocation actions will be fast, effective over a large commercially valuable territory and have moderate costs compared to the alternative of several national proceedings, the UPC revocation action will share some traits with US *inter partes review* (IPR) proceedings. On this basis, it is possible that the impact of the UPC revocation action in Europe will be similar to that of the IPR proceedings in the US when they were introduced some years ago.

As an opt-out is excluded if an action regarding the patent is pending at the UPC, competitors may pre-empt an opt-out by filing revocation actions. To give proprietors a chance to opt out their applications, patents, and SPCs in an orderly fashion before such action can be filed, a sunrise period will commence three months before the start of the UPC. During this sunrise period, opt-outs can be requested at the EPO and will be registered instantly with the UPC once it becomes operational. Based on the timeline announced by the Preparatory Committee, this sunrise period is anticipated during Q2 of 2022.

Proprietors will need to identify the applications, patents, and SPCs they wish to opt out and make the required practical preparations, possibly together with their representatives, if they want to make use of the relatively short sunrise period. For co-owned applications, patents, and SPCs, the opt-out must be requested by the co-owners. If the application, patent, or SPC is out licensed, the license agreement may require involving the licensee in the decision whether to opt out. Conversely, licensees wishing to have an in-licensed patent opted out may need to contact the proprietor in time.

A smorgasbord of options for one's patent strategy

Applicants will consider whether the upcoming option to register a granted patent as having unitary effect *in lieu* of national validations is attractive. The total costs of maintaining an EP patent with unitary effect are roughly *on par* with validating it in DE, FR, IT and NL, although the EP UE / Unitary Patent provides protection in a significantly larger territory. On the other hand, proprietors will lose their flexibility to prune the portfolio by letting a patent lapse in some countries.

With national patents and utility models, traditionally validated EP patents and EP-UEs/Unitary Patents, applications will have a broad choice on how to suitably protect their inventions in Europe.

If an applicant wishes to use the EP-UE / Unitary Patent, but the application is about to proceed to grant before the end of the provisional application period, the applicant could either request a delay of the grant, which would likely be allowed by the EPO, or file a divisional. In general, for particularly valuable technologies it may be worthwhile having a targeted EP-UE / Unitary Patent for use in an infringement action at the UPC and nationally validated patents with broader protective scope as additional defensive position.

During the PAP: potential defendants in an infringement action?

Conversely, potential defendants in an infringement action may see the UPC as a chance to have a granted European patent revoked in one proceeding for all UPC member states and thus may monitor whether the patent is opted-out.

If protective letters have been filed nationally, they should also be prepared for and filed with the UPC immediately upon its start. Considering the strict time regime of infringement and revocation proceedings at the UPC, preparing one's defence will also become more important.

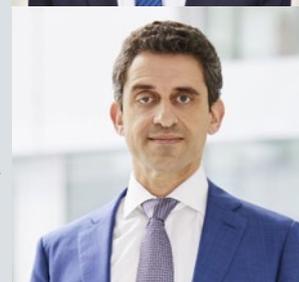
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Difficult Times ahead for Establishing Inventive Step of Medical Use Claims at the EPO

Establishing inventive step of medical use claims at the EPO looks set to become more difficult. T 2443/18 widens the choice of closest prior art documents, opening up more obviousness attacks. T 96/20 reinforces difficulties in establishing inventive step after the publication of planned trials.

The coronavirus pandemic highlighted the importance of inventions based on the discovery of new therapeutic applications of existing medicines. The results of studies reporting various degrees of success in using known agents to treat this novel pathogen frequently made world news over the past year, demonstrating both the importance of this field of research, and also the difficulties faced by inventors. Obtaining patent protection for such inventions may be becoming more difficult in view of the following recent decisions of the EPO Boards of Appeal.

T 2443/18¹ and the closest prior art for assessment of inventive step

It is general EPO practice that in the case of claims directed to medical uses, the closest prior art is usually a document disclosing the same therapeutic indication. This normally benefits the patentee, as obviousness then hinges on whether the known medicine was already taught for the claimed medical use. Absent of any such teaching, inventive step may be acknowledged. T 2443/18 followed another approach, which may make it more difficult to obtain second medical use claims.

Here, tapentadol for use in the treatment of irritable bowel syndrome (IBS) was claimed. The Board started from a document which did not mention IBS but instead disclosed treatment of visceral pain with tapentadol, noting that visceral pain was a known symptom of IBS. The patentee argued that this was an artificial starting point as the skilled person would start from documents relating to IBS in line with the general EPO practice above. The Board did not agree, stating:

...either approach may be taken by a person skilled in the art, depending on the stages reached in the development and life of a drug compound and the rationale for its development. After the initial stage of drug discovery, the suitability of the drug for different therapeutic uses may conceivably be explored. In the case at hand... it was clear that the compound's expected activity was pain relief. The logical next step was to investigate its efficacy against different types of pain (as reported in D1: page 1056, paragraph bridging columns 1 and 2, and D4) to determine the medical indications in which this drug might be useful. The objective technical problem as established starting from the teaching of D4 is thus realistic: It reflects the task the skilled person would have faced after the initial development of tapentadol.

It seems that the Board considers this approach justified where the medicine has already been developed. This is the case for most medical use claims, suggesting that this decision may be applied widely. It weakens the position of the patentee, as they may face more objections from different starting points. Also, the focus for obviousness shifts to whether the medicine that is already known for a particular use might also be applied to the claimed medical use. Based on the rationale applied by the Board, it may be particularly difficult to obtain patent protection where there is some link between the known therapeutic use and the newly discovered one.

¹EPO decision for T 2443/18

T 96/20² and prior art clinical trial data for the assessment of inventive step

It is often necessary to carry out clinical trials to determine whether an existing medicine is actually effective in a new therapeutic application. The details of planned trials are regularly published by clinical trial authorities before the results are available. As a consequence, the applicant has a difficult choice between two strategies. The first strategy is to file the application before the details of the planned trial are published and therefore before the results are available, thus risking the EPO objection that the invention was not plausibly demonstrated at the filing date. The second strategy is to await the results of the trial before filing, but this risks details of the planned trial being cited as prior art. T 96/20 demonstrates the difficulties associated with this second strategy.

In this case, the invention related to Eculizumab for treating myasthenia gravis (MG). Details of planned trials underlying the invention had been published by the US clinical trial authority prior to the filing date. Starting from known treatments of MG, the Board held that the invention was obvious in view of the planned trial:

*Clinical trials are conventionally based on earlier preclinical studies, and the potential therapeutics tested in clinical trials are **duly selected based on experimental data suggesting their success** (see e.g. decision T 239/16, point 6.5 of the Reasons). Thus, the board considers that the **announcement of a detailed safety and efficacy clinical trial protocol** for a particular therapeutic and disease provided the skilled person with a **reasonable expectation of the success** of this particular therapeutic, unless there was **evidence to the contrary in the state of the art**. In the case in hand, the board holds that no such evidence to the contrary has been brought forward by the appellant.*

This decision therefore places the burden on the applicant to demonstrate that the skilled person would not have had a "reasonable expectation" that the

claimed therapeutic use would indeed be attained. In the Board's view, this burden was not shifted by the evidence on file that no therapy for MG had been approved in more than 60 years, and that clinical trials for related diseases based on similar agents had failed. As a result, it follows T 239/16 cited by the Board in making it more difficult to obtain patent protection for medical use claims where details of the planned trial are published before the filing date.

While the choice between the first and second strategy discussed above remains difficult and highly case-specific, this decision rather shifts the balance towards the first strategy of filing early where it is possible to plausibly substantiate the invention using technical explanations in place of data.

Conclusion

Inventions in the field of medical uses require lengthy and costly clinical trials and are undoubtedly of significant benefit to society, as shown by the innovations in response to the pandemic. However, recent decisions T 2443/18 and T 96/20 suggest that it may be becoming more difficult to obtain patent protection for development of such medical uses.

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² EPO decision for T 96/20

„#darferdas?“: The European Court of Justice Expands the Registrability of Trademarks

The European Court of Justice (ECJ) held in its decision C-541/18 (AS vs GPTO) of September 12, 2019 that the distinctive character of a sign applied for as a trademark –a prerequisite of eligibility for trademark protection– must be assessed in the light of all the relevant facts and circumstances. This includes all the likely uses of the trademark applied for. The decision expands the registrability of trademarks in Europe.

In 2015, the applicant filed the word mark „#darferdas?“ (a German phrase that means “can he really do that?”) at the German Patent and Trade Mark Office (GPTO) for goods in Class 25 (clothing, in particular T-shirts; shoes; headgear). The GPTO rejected the trademark application for lack of distinctiveness pursuant to Section 8(2)(1) of the German Trade Mark Act on the grounds that the public would perceive the sequence of words simply as a „fun phrase“.

The applicant filed an appeal against the rejection decision with the German Federal Patent Court (*Bundespatentgericht*) on March 11, 2016 but without success. The Court based its decision on the fact that, when assessing the distinctive character of a sign, the way in which a trade mark is commonly used in relation to the goods and services concerned and, in particular, where it is positioned, must be taken into account. The Court, however, considered only the most likely form of use to be decisive. Other conceivable but less likely uses were not to be considered.

In particular, in the present case, the Court found the most likely use of the sign in question to be on the front or back of a T-shirt, while the use of the sign on a label of a garment was considered relatively less likely. The public would, however, understand the sign –when placed on the front or back of T-shirts– for what it is, namely a simple interrogative phrase composed of common words of the German language inviting the public to discuss the question „darferdas?“. Accordingly, the sign was concluded to lack distinctive character.

Subsequently, the plaintiff appealed to the German Federal Court of Justice (*Bundesgerichtshof*). The Court referred the following question to the ECJ:

‘Does a sign have distinctive character when there are in practice significant and plausible possibilities for it to be used as an indication of origin in respect of goods or services, even if this is not the most likely form of use of the sign?’

The ECJ held that all relevant factors need to be considered when examining distinctiveness, including all likely types of uses of the mark. When it is obvious that several uses of a mark are practically significant or customary, all such uses should be taken into account in order to determine whether the average consumer will perceive that sign as an indication of origin.

In the present case, the referring court found that, in the clothing sector, it is usual to place the mark on both the exterior of the goods and the labels sewn on the inside of them.

In such a situation, the authorities with competence to examine the perception of the average consumer will have to take those uses into consideration and assess whether that consumer, on seeing those two types of placements, or at least one of them on a garment, will perceive the sign at issue as a trade mark. The ECJ referred the case back to the Federal Court of Justice to finally determine whether the sign in question is distinctive and can act as an indication of commercial origin.

The Federal Court of Justice subsequently ruled (German Federal Patent Court, Decision of December 15, 2020 - 29 W (pat) 537/20) that the sign applied-for cannot be denied distinctive character on the basis of the findings to date. In the absence of deviating findings by the Federal Patent Court, it must be assumed in favor of the applicant that, in addition to a decorative use, there are also other practically significant and obvious possibilities of using the sign for the goods at issue here, for example on the label of a garment. Since the Federal Patent Court only considered the most likely type of use as decisive, the decision must be set aside, and the case referred back to the Federal Patent Court.

The Federal Patent Court followed the case law of the ECJ, according to which all practically significant types of use must be taken into account in the examination of distinctiveness, and thereby determined that the use of the trademark on the label must also be taken into account. The Court stated that if signs applied to sewn-in labels of clothing at a place where a trademark is customarily applied in the trade, the public will assume that it is an indication of the origin of the goods. Accordingly, the sign "#darferdas?" was not found to be devoid of distinctive character.

The use of the hashtag ("#") does not change this. At the time of filing the subject application, the use of hashtags on labels on the inside or outside of clothing in a decorative or attention-grabbing way was not (yet) common. The question whether the use of hashtags beyond social media and advertising has now changed this perception of the average consumer can remain open.

Since now all likely positions of use of a sign are to be considered when assessing distinctive character, the ECJ's decision is to be welcomed as it leads to an expansion of the registrability of trademarks.

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Additional Remuneration for Employees' Inventions Made in France

An additional remuneration is due each time employee-inventors make a patentable invention within their duties in France. This article presents the results of a jurisprudential and doctrinal review¹ of this essential requirement for the development of inventions in France.

Around 12,000 French patent applications are filed each year by French entities, whether independent entities or subsidiaries of international groups. Most of these patent applications originate from "mission inventions", i.e. inventions made within employees' duties, either pursuant to an employment contract setting out an inventive mission corresponding to their effective functions, or in the framework of studies or research expressly entrusted to the employees by the employer. Pursuant to Article L.611-7, paragraph 1, of the Intellectual Property Code (IPC), such mission inventions automatically belong to the employer, but the inventors are entitled to an additional remuneration beyond their normal salary.

Art. L.611-7, paragraph 1, IPC also provides that the terms of the additional remuneration shall be determined by the (sector-level) collective bargaining agreements, ("conventions collectives" in French), the (company-level) agreements with the works council ("accords d'entreprise"), and the individual employment contracts. If several of these coexist, the most favourable to the employee prevails. In addition, it derives from Art. L.611-7, paragraph 1, IPC that these agreements shall be of bilateral nature, i.e. not unilaterally set by the employer but explicitly agreed to by the employees instead. Also, the imperative nature of the provisions of Art. L.611-7 IPC prohibits making the grant of the additional remuneration conditional on achieving particular goals. These requirements have been confirmed on numerous occasions by case law.

In the absence of valid agreements for the determination of the additional remuneration, the employer runs the risk of letting this determination out of its control in the event of a dispute. Indeed, the competent

deciding bodies are normally required to set the additional remuneration in accordance with the agreed terms between the employer and the employees, unless those terms are inexistent, invalid and/or insufficient. In such cases, the competent deciding bodies are entitled to decide at their discretion how to close the legal loophole in the contractual relationship between the employer and the employees.

These deciding bodies include the National Commission for Employee Inventions ("Commission Nationale pour les Inventions de Salariés" in French, better known under the abbreviation "CNIS") and the competent French courts. The CNIS is a joint conciliation board made of employers and employees, before which any of the parties may bring a dispute regarding employee inventions, in an attempt to settle the dispute out of court. This possibility is enshrined by Art. L.611-7, paragraph 1, and Art. L.615-21 IPC.

We observe that the courts granted around €10,000 on average per plaintiff-inventor and patented invention over the period 2001-2018, while the CNIS granted around €14,000 on average over the period 2011-2015. However, both the courts and the CNIS do not hesitate to significantly exceed these average values when exercising their discretion in the absence of valid rules agreed between the employer and the employees. Over the period 2010-2019, the judges granted amounts in the range €30,000-€75,000 ten times, and in the range €100,000-€300,000 three times. For their part, the CNIS granted amounts in the range €35,000-€50,000 four times.

¹Sources :

- INPI survey, La Rémunération des Inventions de Salariés, October 2016
- INPI survey, Panorama des déposants français de brevets à l'INPI et à l'OEB, Novembre 2020
- Christian Bessy, L'appropriation des inventions de salariés, une analyse à partir des litiges, 2020
- Review of approximately 40 decisions issued by the French courts over the past ten years

The common denominator of these decisions, apart from the fact that they result from the absence of valid rules previously agreed by the employers and plaintiff-employees, is to base the determination of the additional remuneration on the economic significance of the invention. To be more specific, similarities in the most detailed decisions which have been reviewed allow for empirically approximating the value range of the additional remuneration as follows:

1. The net profit directly related to the patented invention and coming from all possible channels (i.e. by sales, cost reductions, licence fees and the like) is determined (for example, €1,000,000);

2. The notional licence rate that the employer should have paid to exploit the invention by acquiring a licence as a third party is estimated, by taking the typical licence rate in the technical field under consideration, i.e. 3.5-5% in most cases;

3. This rate is weighted by other criteria enshrined in the case law (especially the general framework of search underlying the development of the invention; the personal contribution of the inventor; and the difficulty in the development of the invention), which usually gives a global factor in the range of 0.2-0.6;

4. The notional licence rate is multiplied by this global factor in order to derive the effective contribution share of the inventor to the economic significance of the invention. Based on the figures mentioned above, this share appears to be typically in the range of 0.7%-3%, except for technical fields where the usual licence rate is higher than 5%;

5. The additional remuneration is determined by multiplying the net profit directly related to the invention by this inventor share (€1,000,000 x 0.7%-3% = €7,000-€30,000 in our example).

In order to prevent the CNIS and the courts from setting their own rules and to encourage their employees to invent, most industrial actors established in France have adopted remuneration schemes, which have been agreed by their employees (collectively and/or individually). According to an extensive survey published in 2016 by the French IP National Institute (INPI), almost 40% of the surveyed companies have adopted a remuneration scheme including fixed premiums and a variable premium relating to the exploitation of the invention, while the vast majority of the others have opted for fixed premiums only. Based on these schemes, an inventor receives on average, per invention, between €500 and €2,000 when the compensation scheme is exclusively composed of fixed premiums, and between €400 and €15,000 when the compensation scheme includes fixed and variable premiums.

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Biological Sequence Data: XML is the New TXT

When it comes to patentability of biological sequences, the format in which nucleotide or amino acid sequences are disclosed greatly matters for defining their structure and function. In 2022, the World Intellectual Property Organization (WIPO) will transition to a new global standard for disclosing biological sequences in sequence listings. In the following, we provide an overview of the changes brought by the new XML-based Standard ST.26 over the current TXT-based Standard ST.25.

The Committee on WIPO Standards has recently released an updated framework for working with biological sequence data in patents reflecting a standardized, timely and computer-readable format. To generate a single sequence listing acceptable in all 153 PCT contracting states, new WIPO Standard ST.26 provides guidance to intellectual property offices and applicants.¹ Law firms in biotechnology and science entrepreneurs should take note that the updated Standard ST.26 is complex and includes several major changes over the TXT-based Standard ST.25. In addition to the main body of Standard ST.26, seven annexes (150 pages) provide guidance on the controlled vocabulary required for searches inside the individual offices in the different WIPO jurisdictions (e.g., EPO, USPTO, etc.) and in public sequence databases such as INSDC,² document type definition, character subset from the Unicode Basic Latin Code Table, data exchange requirements, XML (Extensible Markup Language) file examples, and recommendations for transformation from Standard ST.25 to ST.26.

When does Standard ST.26 enter into effect?

The WIPO member states had agreed that they would transition simultaneously to Standard ST.26 compliant sequence listings at the PCT, national and regional levels on January 1, 2022. An international filing date on or after January 1, 2022 was agreed to be the reference date that determines if an application containing a disclosure of biological sequence data falls under Standard ST.25 or ST.26 sequence rules, not the priority date.³ However, requests to postpone the transition date until July 1, 2022 are currently under consideration by the Committee on WIPO Standards. A formal decision on these requests will be made at the WIPO Assemblies in October 2021.⁴

What is new in Standard ST.26?

Changes over Standard ST.25 include the annotation of nucleotide and amino acid sequence data as well as the patent application information. In Standard ST.26, sequence data are identified as DNA, RNA or amino acid (AA) sequences along with a mandatory qualifier to further describe the molecule. For example, an RNA molecule must be described as genomic, mRNA, tRNA, rRNA, etc. The sequence listing must also include D-amino acids, which were excluded under Standard ST.25, linear portions of branched sequences and nucleotide analogues, such as peptide or glycol nucleic acids. Furthermore, sequences having less than 10 specifically defined nucleotides or less than 4 specifically defined amino acids are prohibited under Standard ST.26.

Transformation from Standard ST.25 (i.e., TXT) to ST.26 (i.e., XML), by itself, should not result in added or deleted subject matter. However, care should be taken when fine-tuning the information in the sequence listing to meet the requirements of Standard ST.26. Particularly helpful in this regard is Annex VII of Standard ST.26 (see ST.26 – beginning on page 166⁵), which explains several scenarios where special care may be necessary to avoid incorrectly adding or deleting information not in agreement with the application from which priority is claimed. For example, Standard ST.26 explicitly requires inclusion of new mandatory feature keys and sequences which were excluded under Standard ST.25. While the disclosure contained in the application generally should be sufficient to represent sequences in such a scenario, Annex VII provides recommendations as to how to best proceed with the required ST.26 format.

¹Standard ST. 26

²International Nucleotide Sequence Database Collaboration (INSDC)

³Implementation of WIPO ST.26

⁴C. PCT 1626/C. CWS. 150

⁵See footnote 1.

Along with a basic Latin translation or transliteration, Standard ST.26 allows to include applicant name, inventor name and the title of the invention using any Unicode character, for example, Japanese characters. Detailed information on additional changes can be found in several webinars on Standards organized by WIPO.⁶

How is Standard ST.26 implemented?

To support authoring, generation and validation, WIPO offers a standalone desktop tool named WIPO Sequence⁷ which simplifies XML file creation. WIPO Sequence is currently under development and will move to the maintenance phase once the updated 1.1.0 version is available. According to WIPO, the USPTO software tool PatentIn will not be updated to generate sequence listings compliant with Standard ST.26, and its use will be phased out once Standard ST.25 is no longer the valid format. In contrast, the EPO is planning a TXT-to-XML conversion tool for use with their sequence submission tool BiSSAP.⁸

As we move from Standard ST.25 adopted 23 years ago⁹ toward the new Standard ST.26, we expect that the enhanced accuracy and quality of biological sequence data under Standard ST.26 will impact searching for intellectual property of biological sequence data, e.g., for patentability assessment during patent examination, validity challenges and for freedom-to-operate (FTO) searches.

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⁶WIPO Standards Webinars

⁷Software tool WIPO Sequence

⁸Sequence submission tool BiSSAP

⁹Standard ST.25 (May 1998)

G 1/21 – Oral Proceedings by Videoconference at the EPO, a Brief Update

On July 16, 2021, the Enlarged Board of Appeal issued its order in case G 1/21. As a reminder (see Hoffmann Eitle Quarterly June 2021, pp. 11-12), the question referred to the Enlarged Board related to whether the current EPO practice of holding oral proceedings by videoconference (ViCo), even without the consent of all parties, is legal under the European Patent Convention (EPC) in its current form. The Enlarged Board of Appeal answered with a qualified yes, as follows:

“During a general emergency impairing the parties’ possibilities to attend in-person oral proceedings at the EPO premises, the conduct of oral proceedings before the boards of appeal in the form of a videoconference is compatible with the EPC even if not all of the parties to the proceedings have given their consent to the conduct of oral proceedings in the form of a videoconference.”

The answer is qualified in two ways. First, the Enlarged Board held that the EPC authorizes oral proceedings by ViCo without the consent of all parties only during “a general emergency impairing the parties’ possibilities to attend in-person oral proceedings at the EPO premises”. Second, the Enlarged Board answered the question only insofar as oral proceedings before the Boards of Appeal are concerned.

The first qualification means that the Enlarged Board has partially struck down Article 15a of the Rules of Procedure of the Boards of Appeal (RPBA). Article 15a(1) RPBA, which entered into force on April 1, 2021, authorized a Board to hold oral proceedings by ViCo if the Board considered it appropriate, without requiring the consent of the parties and without any other precondition. Now, by requiring the existence of “a general emergency impairing the parties’ possibilities to attend in-person oral proceedings at the EPO premises”, the Enlarged Board has clearly set limits on the Boards’ discretion to hold oral proceedings by ViCo. That is, it appears that once the COVID-19 pandemic will have

ended—or perhaps earlier, once the pandemic will have ceased to impair the ability of the parties concerned to attend oral proceedings in person at the EPO premises—a party will again be able to demand to be heard in person rather than by ViCo, if preferred. Thus, the Enlarged Board appears to have struck a healthy balance between the need for the EPO to continue to function during a general emergency and the preferences of the parties as to how they wish to present their case.

The Enlarged Board’s order is also qualified in that the legality of holding oral proceedings by ViCo without the consent of all parties during first-instance proceedings has been left unanswered. In its order, the Enlarged Board chose to remain silent in that regard. When the reasons for the Enlarged Board’s decision become available,¹ those may (or may not) help gauge what G 1/21 means for the fate of in-person oral proceedings before the Examining and Opposition Divisions in the long term.

For now, many oral proceedings will continue to be held by ViCo before the Boards of Appeal as well as before the first-instance departments. Once the COVID-19 pandemic will be over, in-person oral proceedings can be expected to become much more common again, at least before the Boards of Appeal.

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¹The reasons for the decision were not available at the time of going to press.



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