The Patent Lawyer

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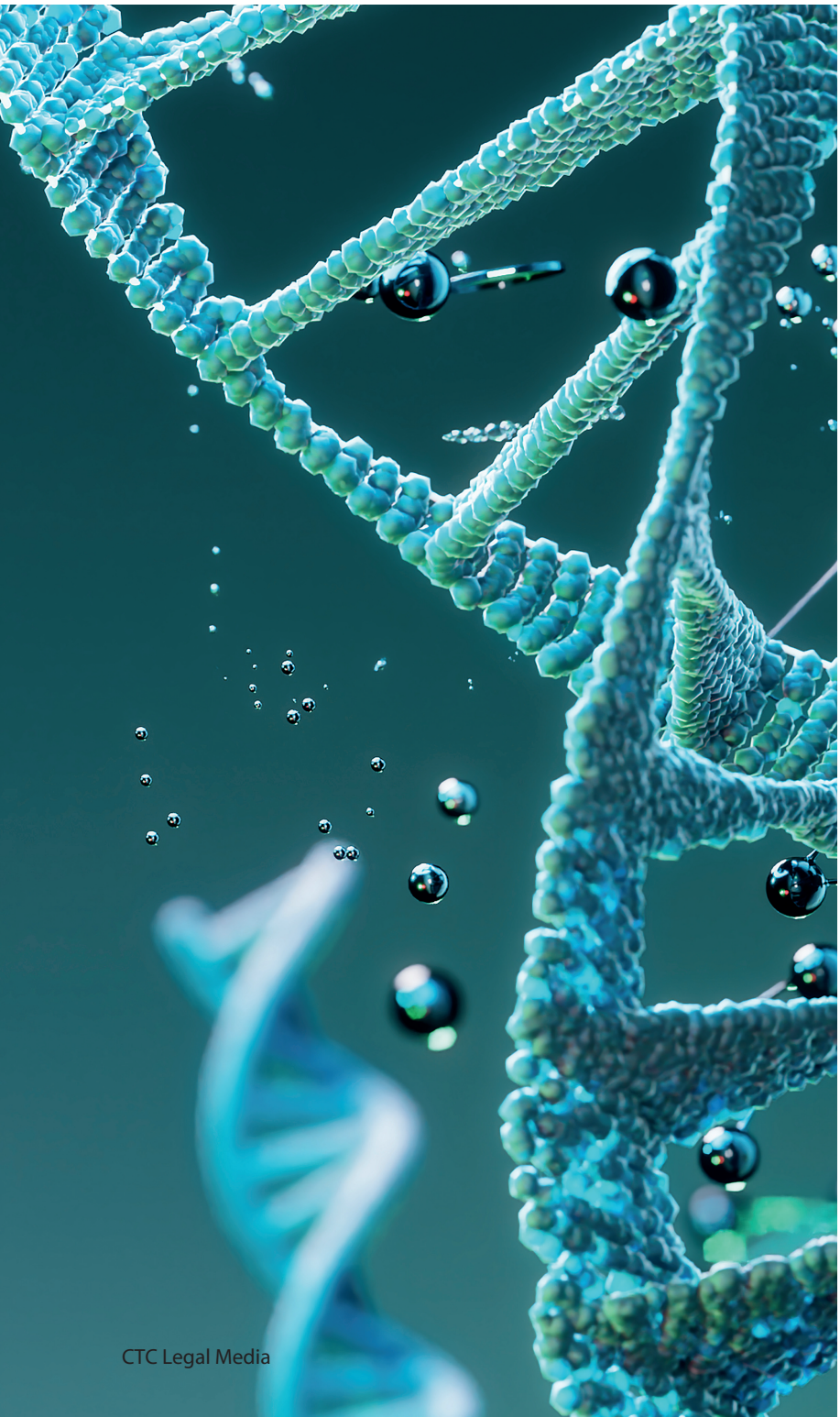

CTC Legal Media

Rommy Morales, Sergio Olivares, Daniel Sánchez, and Jorge Juarez of OLIVARES introduce the changes set out in WIPO Standard ST.26, including new rules for representing amino acids and nucleotides and the need for applicants to adjust in preparing and submitting patent applications.

Biotechnology has transformed several fields like medicine, agriculture, and environmental sciences by promoting advancements at the molecular level. Many of these developments rely on DNA, RNA, or amino acid sequences, which are key components of new biotechnological drugs, genetically modified organisms, and diagnostic tools. To protect these biotechnological inventions, sequence listings must be included in patent applications as they are an essential component thereof.

The sequence listings provide a standardized way to disclose biological sequences, which is important for patent examination, public disclosure, and the future development of related technologies.

On July 1, 2022, the World Intellectual Property Organization (WIPO) introduced Standard ST.26, a new standard for sequence listings that replaced the previous ST.25. This new standard brings significant changes to how sequence

Résumés

Rommy Morales boasts over 16 years of experience in intellectual property, with a specialization in patent prosecution, IP litigation, and plant variety protection. She is renowned for accurately identifying clients' needs and subsequently developing and implementing strategies tailored to the protection of their industrial property rights. Rommy provides technical and legal advice to national and international clients in the pharmaceutical, biotechnology, and chemical industries. Her advice covers the preparation, filing, prosecution, granting, and enforcement of patents, including patentability and validity opinions, as well as freedom-to-operate analyses. In her role, Rommy supervises the team responsible for filing and prosecuting patent applications. Owing to her distinguished reputation as a biologist and her extensive experience in the field, she also leads the department dedicated to plant variety protection in Mexico.

Sergio Olivares joined OLIVARES in 1987 and has been practicing IP law for more than three decades. He has been a partner since 1994 and Chairman of the firm's Management Committee since 2009. He is proficient across all areas of IP law, working very closely with the firm's Patent Group. Sergio is highly recommended by leading industry publications and directories as a leader in IP. He has been integral to OLIVARES' expansion into new and innovative practice areas; has been at the helm of cases that are helping to shape the standard for evaluating inventive step and novelty for pharmaceutical patents; and was involved in a landmark Supreme Court case that changed the landscape for unfair competition enforcement in Mexico. Sergio received his J.D. from the Universidad Intercontinental in 1991 and graduated from the Franklin Pierce Center for Intellectual Property in 1993.

Daniel Sanchez joined OLIVARES in 2000, became a partner in 2011, and co-chairs the firm's Litigation and Patent Teams. He is one of the leading intellectual property and administrative litigators in Mexico and is recognized by industry rankings and publications including Chambers Latin America, IAM Patent 1000, and WTR 1000. As one of the few regulatory and administrative litigation experts in Mexico, Daniel guided the development and implementation of a revolutionary and proprietary software system that replicates the drug naming and labeling approval process within COFEPRIS, Mexico's health ministry. This drastically improves the accuracy of advice about whether clients' marketing authorizations can and will be approved. He has also led Olivares' team in obtaining approval for alcoholic beverage advertisements from COFEPRIS, authored various articles on IP and Life Sciences-related matters, and lectured on IP topics in both national and international forums.

Jorge Juárez has been in the IP field since 2006 and works in the patent department of Olivares. His primary area of practice is related to the fields of Industrial Designs, Electronics, Electricity, Software, Mechanical, and Information Technologies (IT), wherein he provides specialized advice related to patent prosecution including technical and legal consultancy in substantive examination matters, patent searching, and patent drafting. He also supports the patent litigation team providing technical options. He co-chairs the Patent Subcommittee of Industrial Designs and Mechanical and Electronic Inventions of the Mexican Association for the Protection of Intellectual Property (AMPPI).

listings are formatted and submitted in patent applications.

The role of sequence listings in biotechnology patents

In biotechnology patent applications, the inclusion of nucleotide or amino acid sequences is often crucial to the invention. These sequences must be clearly disclosed, and sequence listings provide a structured and standardized format for presenting them. This ensures that the invention is disclosed in a sufficiently clear and complete manner, allowing a person skilled in the art to replicate it – an essential requirement of the patent system. Additionally, sequence listings help clarify the scope of the claims in a patent by defining the subject matter for which protection is sought. They also facilitate the search and examination process, enabling patent offices to more efficiently assess the patentability of the invention.

The transition to WIPO Standard ST.26

In accordance with WIPO guidelines, ST.26 applies to all patent applications filed on or after July 1, 2022, regardless of the priority date.

The introduction of WIPO Standard ST.26 on July 1, 2022, marked a significant change in how sequence listings are presented in patent applications. Under ST.26, sequence listings must be filed in Extensible Mark-up Language (XML) format, replacing the text or PDF formats used under ST.25. This change addresses the limitations of the text-based format of ST.25, which was not fully compliant with the requirements of public sequence databases and often resulted in data loss during the transfer of sequence listings. The adoption of the XML format under ST.26 allows for automated validation and improved search features, benefiting both patent offices and applicants.

This transition was motivated by the need to harmonize sequence listing practices across different jurisdictions, reflect advances in biotechnology, and meet the requirements of current public sequence databases.

Key differences between ST.25 and ST.26 standards

WIPO Standard ST.25 has become less effective and is no longer sufficient to include the increasing variety of sequences that have emerged in the field of biotechnology. For example, ST.25 did not properly address the representation of linear portions of branched sequences, D-amino acids, or nucleotide analogs. The adoption of ST.26 solves these problems by introducing these additional sequence types, making ST.26 more complete and better adapted to modern biotechnology developments.

ST.26 also introduces new rules for representing amino acids and nucleotides. For example, amino acids are now represented by a single capital letter rather than the codes used under ST.25, which included three letters. Additionally, RNA sequences are now repre-sented using "t" instead of "u" for uracil, aligning with current standards in public sequence databases.

Likewise, ST.26 excludes sequences with fewer than 10 defined nucleotides or four defined amino acids from the sequence listing.

Consequently, the transition to ST.26 requires applicants and patent offices to make some adjustments in how they prepare, submit, and receive patent applications containing sequence listings, considering these differences.

To support this transition, WIPO developed the WIPO Sequence Validator software, which allows patent offices to verify that sequence listings comply with ST.26.

For applicants, WIPO also developed the WIPO Sequence software, which is compatible with Windows, Mac OS, and Linux operating systems. This software helps applicants generate ST.26-compliant sequence listings and automatically validates them to ensure they meet the new standard. It also facilitates the transformation of ST.25 sequence listings into ST.26 format, although applicants must be careful to avoid introducing new matter during this process, as it could affect the validity of the patent application. While the use of WIPO Sequence is not mandatory, it is recommended to minimize errors in sequence listings.

On the other hand, for applicants, WIPO has also developed software called WIPO Sequence. This software can be used on three operating systems: Windows, Mac OS, and Linux. It helps applicants generate amino acid or nucleotide sequence listings that meet the requirements of Standard ST.26 by checking it and highlighting any issues that need to be addressed through automated validation. Additionally, it allows the transformation of ST.25 sequence listings into ST.26 format if an applicant has previously submitted a sequence listing under ST.25. The transformation process involves converting the listing into XML format and adding any additional information required under ST.26; however, care should be taken to avoid introducing new matter as it could affect the validity of the patent application. WIPO has provided guidelines for applicants on converting sequence listings to ST.26 while preserving the content and scope of the original application.

Filing PCT applications with sequence listings

The introduction of ST.26 also impacts the filing of Patent Cooperation Treaty (PCT) applications with sequence listings. In this regard, the ePCT system now includes real-time validation features that help prevent errors and ensure compliance with ST.26. In addition, it is no longer possible to submit ST.25 sequence listing for a PCT application filed after July 1, 2022. All such applications must comply with the new format. This requirement ensures that sequence listings in PCT applications are consistent with those filed in national patent offices, promoting global harmonization in biotechnological patent applications.

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Mexican legislation on sequence listings

In Mexico, the presentation of sequence listings in patent applications is regulated by specific provisions set forth in the Federal Law for the Protection of Industrial Property, Regulations of the IP law, and "Agreement on the Rules for the Filing of Patent Applications in Mexico."

The main consideration regarding sequence listings, as outlined in the Mexican legislation, is that sequence listing must be presented as a separate part of the patent application and titled "Sequence Listing." If a sequence listing is included within the descriptive chapter of the patent application, the Mexican Institute of Industrial Property (IMPI) will require the applicant to amend the specification and present the sequence listing as an independent section of the application. It is important to note that there is no requirement to submit a Spanish translation of the sequence listing presented under the ST.26 format.

According to Mexican Law, to get a filing date for a patent application, the sequence listing must be submitted from the beginning. If a sequence listing is required but not presented, IMPI will recognize the filing date as the date and time when the sequence listing is submitted.

Although WIPO Standard ST.26 should apply to all patent applications filed on or after July 1, 2022, regardless of the priority date, IMPI stipulated that the ST.26 format must be used for non-PCT applications, if the claimed priority under the Paris Convention is on or after July 1, 2022. For national applications (those not processed under the PCT or Paris Convention) filed on or after July 1, 2022, the sequence listing must comply with ST.26.

Currently, the IMPI's patent online filing system, known as PASE (Portal for Access to Electronic Services), still allows the submission of sequence listings in PDF format (ST.25 standard) at the time of filing the application. However, it is anticipated that this option will eventually be disabled to promote compliance with the new standard for applications containing sequence listings.

Sequence listings in divisional applications

WIPO recommends that sequence listings for divisional applications filed from July 1, 2022, are submitted in the ST.26 format even if the parent application includes a sequence listing under ST.25 standard.

WIPO leaves it to the discretion of patent offices whether to allow applicants to use the sequence listing from the parent application and incorporate it into the divisional application. In the case of Mexico, for divisional applications containing sequence listings, the filing date of the initial application will determine whether the sequence listing to be submitted must comply with Standard ST.25 or ST.26, that is to say, they should use the same format as the parent application.

Conclusion

The transition to WIPO Standard ST.26 represents an important step in the development of biotechnology inventions containing sequence listings. By adopting the XML format and including additional sequence types, ST.26 enhances the quality, consistency, and accessibility of sequence data in biotechnology patents.

For applicants, the transition to ST.26 requires the use of specialized tools and resources provided by WIPO, such as the WIPO Sequence software and the ePCT system. As the field of biotechnology continues to evolve, the adoption of ST.26 is essential for the harmonization of sequence listing practices.

With ST.26 now in effect, applicants must adapt to the new requirements and take advantage of the opportunities it presents. By doing so, they can ensure that their inventions are properly protected and that their sequence listings are accessible for the assessment of patentability. This accessibility also contributes to advancing biotechnology and related fields on a global scale.

“The transition to ST.26 requires applicants and patent offices to make some adjustments in how they prepare, submit, and receive patent applications containing sequence listings.”

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