The New EPO Guidelines: An Overview of the Key Changes

Since March 1, 2021 new Guidelines of the European Patent Office (EPO) are in force. Until now, such an update tended to take place annually in November; this shift in calendar is consistent with a broader plan of reforms related to the Strategic Plan 2023 being currently implemented by EPO, which among its key initiatives lists fostering social dialogue and engaging stakeholders. The new guidelines were developed on the basis of public consultations that had been held in March and April of 2020.

In this issue of WTS Legal Report we have prepared for you **an overview of the most important changes introduced in the new Guidelines**: above all, those are amendments related to descriptions of inventions and oral proceedings by videoconference. We pay also attention to some matters specific to biotechnological inventions, such as addition of special instructions related to patenting of antibodies, and directions regarding how to determine the degree of identity or similarity of amino acid or nucleic acid sequences. We also attempt to summarise succinctly other notable changes. Let us, however, begin with some basic information regarding the legal grounds for issuing of Guidelines and functions that they are supposed to serve.

The EPO Guidelines: basic information

The Guidelines for Examination are adopted by the President of the EPO pursuant to Article 10(2)(a) of the European Patent Convention signed in Monachium on 5 October 1973 (hereinafter: EPC), according to which one of the powers of the President is taking all necessary steps to ensure the functioning of the EPO, including the adoption of internal administrative instructions and information to the public. The Guidelines are a set of instructions that are addressed to examining divisions as well as to parties to proceedings before the EPO that deal with various aspects of the procedure regarding European patent applications.

As for the normative effect of the guidelines, it must be remarked that even though they are not legally binding (for instance in the case T 647/93, a Board of Appeal stated that even though it is desirable for examining divisions to act in accordance with the Guidelines, they are not in themselves rules of law, thus a failure to follow them cannot be considered a substantial procedural violation), the parties in proceedings before the EPO are entitled to expect that they will be conducted in accordance with the Guidelines (see: *General Part, point 3 General remarks*). The expectations of parties cannot, naturally, create law, yet they are not entirely irrelevant from the legal point of view: it is worthwhile to summon a thesis from the decision of a Technical Board of Appeal of 13 June 2012 in the case T 1607/08: “The principle of the protection of legitimate expectations, also referred to as the principle of good faith, generally recognised among the Contracting States, is also a well established principle in proceedings pursuant to the EPC”.

The description of an invention

One of the areas in which the updated guidelines offer important changes, is the matter of permissible modifications introduced into the description of an invention.

According to F-IV, 4.3, **any inconsistency between the description and the claims must be avoided** if it may throw doubt on the extent of protection and therefore render the claim unclear or unsupported (in the meaning established by Article 84, second sentence of the EPC) or, alternatively, render the claim objectionable (Article 84, second sentence). The Guidelines specify that such inconsistencies might occur in 4 possible scenarios:

- simple verbal inconsistency;
- inconsistency regarding apparently essential features;

- **part of the subject-matter of the description and/or drawings is not covered by the claims;**
- claim-like clauses used in the description;

The third of these scenarios is the one most impacted by the changes provided in the updated Guidelines. **It is remarked that embodiments in the description which are no longer covered by the independent claims must be deleted unless these embodiments can reasonably be considered to be useful for highlighting specific aspects of the amended claims.** This instruction is followed by a requirement that in such a case the fact that an embodiment is not covered by the claims must be prominently stated (e.g., "embodiment not covered by the claimed invention"). Prominently, so — as we can further read — the common hitherto practice of substituting the wording "invention" with "disclosure" or the wording "embodiment" with "example", "aspect" and the like, is no longer accepted; such a way of rephrasing of the description is not considered sufficient to demonstrate that a given part of the description does not describe part of the invention for which protection is being sought. Likewise, it is not permissible to use broad, generic statements like, for instance, "embodiments not falling under the scope of the appended claims are to be considered merely as examples suitable for understanding the invention," as long as it is not indicated which parts of the description exactly are no longer covered by the claims.

Next, it is mentioned that if the description features **a part that is excluded from patentability**, it must be either excised or reworded such that it does not fall under the exceptions to patentability, or prominently marked as not being according to the claimed invention.

Furthermore, when features required by the independent claims are invoked, it is not permissible to describe them using the terminology that implies that they are "optional" — employing such expressions as "preferably," "may," etc.

Antibodies

For the first time in the part of the Guidelines dedicated to patentability (Part G), in the division concerning exclusions and exceptions for biotechnological inventions, **a section specifically dealing with antibodies has been included.** It clarifies how antibodies should be defined (G-II, 5.6.1), and subsequently offers an explanation how the inventive step as a condition of patentability should be understood in their context (G-II, 5.6.2.)

As for **the definition**, in the Guidelines it is spelled out that conventional antibodies are large, Y-shaped proteins naturally produced by plasma B-cells and composed of two identical light chains and two identical heavy chains, both containing variable and con-

stant domains. It is further pointed out that they bind specifically to antigen targets via the antigen binding region, containing complementarity-determining regions. In the Guidelines we can read that antibodies can be defined by such features as: their own structure (amino acid sequences); nucleic acid sequences encoding the antibody; reference to the target antigen; target antigen and further functional features; functional and structural features; the production process; the epitope; the hybridoma producing the antibody. Each of those features is accompanied by a detailed description; a reservation is also made that this catalogue cannot be considered exhaustive.

When it comes to **the inventive step of a new antibody, the Guidelines provide that an application should demonstrate a surprising technical effect.** How the requirement of "a surprising technical effect" shall be construed? Some examples of such an effect are further listed: among them are an improved affinity, an improved therapeutic activity, a reduced toxicity or immunogenicity. What is particularly important, if a novel antigen binds to the same antigen as other, previously known antibodies, it is not sufficient to show that it is structurally different from the latter — it is presumed that if an application for such an alternative antibody is filed, we are actually faced with something that is obvious to the skilled person. It will be different in case of **those applications that demonstrate that an invention involves overcoming technical difficulties in producing or manufacturing the claimed antibodies.**

Amino acid sequences

Moving back to the Part F of the Guidelines, and, more precisely, to chapter IV concerning claims, it is worthwhile to notice an addition of the subsection F-IV, 4.24: "Interpretation of terms such as identity and similarity in relation to amino or nucleic acid sequences". It is remarked that **such sequences can be defined by a percentage of identity understood as a measure indicating the number of identical residues over a defined length in a given alignment.** In case of amino acid sequences, it is also mentioned that they can be additionally defined by **the degree of similarity (expressed as a percentage of similarity) — similarity would constitute a broader concept, allowing for conservative substitutions of amino acid residues having similar physicochemical properties over a defined length of a given alignmen**t (defining a similitary-scoring matrix is a prerequisite).

In the Guidelines we can also find a reference to **applications demonstrating a percentage of homology of a sequence**. In case of amino acids an applicant is not allowed to invoke a percentage of homology as the only feature distinguishing the subject-matter from the prior art, unless they clearly define in the application the determination or calculation of the percentage of homology. As far as nucleic acid sequences are concer-

ned, it is presumed that homology percentage and identity percentage are usually the same thing.

Oral proceedings by videoconference

The Guidelines include some notable changes when it comes to matters of a procedural nature: they address the practice of holding the oral part of patent proceedings as a videoconference, which owes its increased popularity to the recent circumstances of the global pandemic. Pursuant to C-VII.5 and E-III, 8.2.2., **as a rule, oral proceedings in examination proceedings are held by videoconference unless the direct taking of evidence is required or if there are other serious reasons for not doing so.** An essential clarification regarding as to what will not qualify as serious reasons is also provided: namely, sweeping objections against the reliability of videoconferencing technology or the non-availability of the required equipment will not be considered sufficient for justifying the arrangement of proceedings in a different form.

It is worthwhile to mention an amendment to E-III, 8.2 — *Conduct of oral proceedings*, where it is now provided that the person conducting proceedings must ascertain that no technical problems have prevented the oral proceedings from being conducted **in accordance with the right to be heard and the right to oral proceedings.**

Another novelty is an instruction in E-III, 8.5.2, according to which written submissions by parties during oral proceedings held as a videoconference, are supposed to be filed by email. Meanwhile, in the section E-III, 11, we can find detailed explanations regarding technical aspects: it includes directions related to the required equipment, preparations for the videoconference, solving technical problems, as well as recording of proceedings.

Other changes

- **Fees**

Furthermore, the updated Guidelines contain two noteworthy amendments regarding fees. First, under A-X, 4.2.3 it is provided that if the EPO charges a party for a given amount in a case of a debit order, and later a discrepancy is revealed that the Office corrects of its own motion, the party is duly informed of such a correction and can object to it

in a two-month period. Second, the guideline A-X, 2.2.4 highlights that in the event of the stay of proceedings, renewal fees continue to be due.

- **Revisions related to the decision in the Pepper case (G 3/19)**

The Guidelines offer as well some updates concerning patentability of plant and animal varietes. Those changes are closely linked to the opinion issued by the Enlarged Board of Appeal of the EPO on 14 May 2020 in the case G 3/19 — covered by us in one of our Legal Reports (*Pepper case: exceptions to patentability in the opinion of the Enlarged Board of Appeal of the EPO of May 14, 2020, WTS Legal Report No. 9/2020)*. In the Guidelines a key temporal reservation is introduced: the above-mentioned exclusion does not apply to patents granted before 1 July 2017 nor to pending patent applications with a filing date and/or a priority date before 1 July 2017 (F-IV, 4.12 and G-II, 5.2-5.4).

- **Unity of invention**

Under Article 82 of the EPC, the European patent application shall relate to one invention only or to a group of inventions so linked as to form a single general inventive concept. The update that the Guidelines have undergone in that area should be perceived in the context of the EPO's pursuit of a greater degree of cohesion between its practice and practice of patent offices of its member states. The Guidelines emphasise **the methodology applied in assessment of unity**, providing detailed instructions regarding two distinct stages of that process: (i) determining the common matter; (ii) comparison of the common matter with the prior art at hand; (iii) analysis of the remaining technical features (F-V, 5.3). It is important to point out F-V, 3.3.1 which indicates that **a non-unity objection raised by an examining division must be backed up with a minimum reasoning** that should outline, i.a., the common matter, if any, between the group of inventions (based on the same or corresponding technical features); the reasons why this common matter cannot provide a single general inventive concept based on the same or corresponding technical features; the reasons why there is no technical relationship between the remaining technical features of the different groups of claims; and others.

- **Erroneous elements filed under Rule 20.5bis PCT**

Furthermore, the Guidelines address the question of corrections to applications filed on the grounds of Article 20.5bis of the Patent Cooperation Treaty (PCT). This rule, which permits applicants to correct an erroneously filed element (description or claims) or part of the description, claims or drawings (including all drawings) contained in an international

application, **has been recognised by the EPO as partially incompatible with the EPC** (the Official Notice of January 2020).

The effectivity of such corrections, pursuant to C-III, 1.3, will be therefore limited. The EPO itself will not allow for filing erroneous elements regardless of the international filing date. Meanwhile, if the receiving patent office, other than the EPO, decides that by reference under Rule 20.5bis the correct application documents are to be incorporated into the application without changing the filing date — such an incorporation will not be effective in proceedings before the EPO as a designated/elected office. Once the proceedings enter into the European phase, the EPO will consider the filing date of the application to be date on which the correct applications documents were received — it will inform the applicant about it, setting a time limit of two months for reply (the applicant will be able to choose alternatively to keep the international filing date, while having subsequently filed documents disregarded).

- **Gender-neutral language**

In the available commentaries regarding amendments introduced by the new Guidelines, the aspect of certain adjustments to the language used is also noticed. In order to make the language more gender-neutral, pronoun “he” has been replaced by “they” which in English does not denote any particular gender (see, e.g., H-II, 3.4). We can see it as a consistent continuation of the EPO’s efforts which has already modified appropriately the most recent versions of Rules of procedure of the Boards of Appeal and the European Patent Guide.