New guidelines published by the President of the Polish Patent Office

In October 2020 the Polish Patent Office (PPO) published the latest version of the President's guidelines regarding inventions and utility models. The guidelines elaborate quite often on certain matters that are not expressly addressed in relevant statuary and executive provisions, they suggest possible directions for interpretation of binding law, and specify numerous formal and technical issues. They offer a valuable resource to persons filing patent application, as well as they are capable of shaping, to a significant extent, the judicial practice of the organizational units of the PPO consisting of experts.

We would like to dedicate this issue of the WTS Legal Report **to identifying and presenting to you the rules of interpretation, included in this document, that we consider the most important**. They are related to the following fields: the inventive step; methods for treatment and diagnostic methods; transplants, implants, and tissues; new medical uses; disclosure and corroboration of inventions in the area of pharmacy; as well as disclosure of microorganisms. Let us begin, however, with a few words regarding the characteristics of the Guidelines.

The character and legal effects of the Guidelines

First of all, let us refer to the commentary to Act of 30 June 2000 - Industrial Property Law (hereinafter: IPL) edited by professor Sieńczyło-Chlabicz where the Guidelines are defined as **"interpretative legal principles that are established *a priori*"**. The Supreme Administrative Court in its judgment of 23 November 2004 invoked writings of Z. Miklasinski who considered the Guidelines as belonging to the "category of instructions regarding the application of law" (GSK 899/04).

The prerogative of the President of the PPO to publish general guidelines is based on the IPL legislation: according to Article 269 Section 3, **when adjudicating a case, expert is obliged to take into account the interpretative rules provided in the general guidelines of the President of the PPO.** Subsequent sections of this provision prescribe how the guidelines are issued: this process requires either to carry out the consultations with the College of Experts, or it can be initiated upon their request, which permits the experts to maintain significant influence on the final shape of those principles (Section 4); furthermore, the public announcement of the guidelines is mandatory (Section 5).

The IPL unequivocally states that the experts are bound by the guidelines — however, only when adjudicating a case, and they cannot be invoked as grounds for a particular decision or order. Thus, **while the experts are expected to take the guidelines into the account, they are not binding on the courts** — the courts cannot effectively declare that a given decision of the PPO fails to comply with the guidelines (which has been confirmed by the Provincial Administrative Court in Warsaw in judgment of 7 September 2006; VI SA/Wa 557/06).

Inventive step

Moving on to precise rules formulated in the guidelines, we should note that at the very beginning they address the question of determining the existence of an inventive step as one of the patentability criteria. As it is underscored in the introduction, neither the statute, nor executive provisions, do not clarify how this condition of patentability shall be assessed in practice.

The guidelines leave **a choice between two alternative methods, making a reservation that such a choice should always be based on the circumstances of a parti-**

cular case, taking into account characteristics of a given technical domain and of an invention for which the protection is being sought. It is remarked that the relevant perspective to adopt for such an assessment is the point of view of a person skilled in the art who is familiar with the similar inventions known on the date for which the priority is granted, and possesses general technical knowledge.

The first of the methods proposed consists of five steps: (i) first, we need to identify the essence of the claimed invention; (ii) then, the essence of other solutions known from the state of the art; (iii) later on, we have to designate the person skilled in the art relevant in the light of the particular field. Afterwards, we proceed to the juxtaposition: (iv) **we determine similarities and differences between the essence of the invention and other closest solutions known from the state of the art.** The final step (v) requires us to **examine, on the basis of that comparison, whether on the priority date the solution was obvious to the person skilled in the art** (with regard to the available state of the art and general technical knowledge in a given field).

The alternative method relies on the application of the so-called **problem-solution approach.** It is also described in the Guidelines for Examination published by the EPO (G-VIII, 5); it consists of three steps: (i) determining the closest prior art, (ii) establishing the objective technical problem to be solved; (iii) considering whether the claimed invention, starting from the closest prior art and the objective technical problem, would have been obvious to the skilled person. The new guidelines of the PPO do not mention how the closest state of the art shall be determined.

Moreover, the guidelines provide a slightly different definitions of **obviousness** in the context of the specific methods.

In case of the former, the five-step process, the obviousness would be possible to demonstrate, if "**the closest solutions and general technical knowledge would motivate or prompt the skilled person, to develop,** with the reasonable probability of success, a solution identical to the invention through replacing, combining or modifying the solutions known from the state of the art". Such a situation, as guidelines explain, would occur especially when the state of the art or general technical knowledge would offer some hints as to how the new solution should be developed.

Obviousness with regard to the problem-solution approach could be proved **"if a person skilled in art, having to solve a given technical problem, would arrive at the claimed invention through the modification of solutions known from the state of the art, without any innovative contribution, applying in a professional and routine manner known technical means and general technical knowledge"**. A further reservation is made that it is not about ruling out the permissibility of patenting an invention obtained through the modification of other previously known solutions, but about finding out

whether such a modification was possible without any innovative input. Those explanations echo the EPO Guidelines for Examination where there is a strong emphasis placed on a difference between *could* and *would*: the point not being whether the skilled person could have arrived at the invention by adapting or modifying the closest prior art, but whether he or she **would have** done so because the prior art incited them to do so and they would be expecting certain improvement or advantage.

Moreover, the guidelines provide tha**t it is possible to submit new evidence and materials by an applicant after a filing date with the purpose of providing additional support of the inventive step.** It is stipulated that it is not possible, though, to disclose the essence of the given invention only in that evidence and materials which are submitted at a later date; they are required to concern the application directly and must supplement and corroborate it. It is once again a rule bearing strong resemblance to its counterpart in the EPO Guidelines of Examination — new evidence and materials invoked with regard to the inventive step must be implied by or at least related to the technical problem initially suggested in the originally filed application (G VIII, 11).

Talking about the limits of permissible revisions to the original application, it is also worth adding that this matter has also been covered quite broadly by the guidelines. Clarifying the regulation of Article 37 of the IPL which prohibits additions and revisions to an application reaching beyond the scope of what has been disclosed in the application on the filing date as a subject matter of a claimed invention, **the guidelines provide examples of changes that are forbidden.** Let us name a few of them:

- Introduction of a new subject matter of a solution, which has not been disclosed in an original application or has not constituted the essence of the invention originally claimed;
- Supplementing the patent description with an information that an average skilled person would not be able to objectively deduce from the original application;
- Addition of other examples, technical or biological data, especially in the area of chemistry that have not been featured in the original description of the invention (unless those are supplementary materials or evidence not serving for the disclosure of the invention, but supporting the demonstration of meeting the inventive step criterium).

On the other hand, the permissible changes encompass:

- Supplementing the state of the art in the application;
- Rephrasing of the description of the technical problem that the invention is supposed to solve, as long as it can be deduced from the whole content of the previous application;
- Revising the title, the patent description and the patent claims for the sake of a greater uniformity of the content;
- Removal of ambiguities and contradictions;
- Amending and standardizing the technical vocabulary;

• Revising the editorial and linguistic errors.

Methods for treatment and diagnostic methods

Under Article 29 Section 1(3) of the IPL, the patents shall not be granted for methods for treatment of the human or animal body by surgery or therapy and diagnostic methods practiced on the human or animal body; this provision shall not apply to products, in particular substances or compositions, for use in any of these methods.

The first aspect of this regulation that the guidelines refer to is how the potential patentability of a method for treatment, is affected by **the matter of who is performing a given procedure: a human or a machine, such as, for instance, an autonomous surgical robot.** In fact, even the methods so significantly automated remain covered by the Article 29 exception.

The application of this exception to patentability of diagnostic methods depends on whether given methods involve a step that is not of a technical nature or a step which is a surgical or a therapeutical procedure. Whenever there is a need for knowledge, skills and experience that surpass what is available to the average skilled person, whenever there is a need for carrying out a cognitive process, for example, occurring when interpreting the clinical picture — this kind of a diagnostic method would not be patentable (the guidelines refer to colonoscopy and endoscopy to illustrate this point). Such an approach is driven by the goal of the protection of life and health of humans and animals; exception would not cover the diagnostic methods and methods of treatments that are performed on anatomical models, as well as deceased persons and animals.

The guidelines point to the potential permissibility of individualizing specific steps of the process for the purpose of filing a patent application. If a therapeutical or surgical (non-technical) step is not imperative for a given diagnostic method and it can be individualized, it is possible to remove it from the patent claims.

Subsequently, the guidelines indicate **in which situations the diagnostic method would not fall within the scope of the application of Article 29**: it would be possible to obtain the patent protection for **a diagnostic method in which the role of the aforementioned cognitive processes is insignificant or which is carried out routinely or automatically** (for example, drawing blood and testing its sample).

There is also a reference to **the special category of diagnostic methods which are based on the *in vitro* analysis of biological markers**, such as miRNA expression or gene mutations. A patent claim regarding *in vitro* diagnostics, can be considered to belong

to the category of uses or category of methods. It is highlighted that the requirement of the sufficient disclosure in the context of *in vitro* diagnostics, can be met upon a submission of "credible, statistically significant results of proper research and analyses, confirming the correlation between the presence of a specific biomarker and a disease detected or a level of risk of contracting that disease".

Transplants, implants, and tissues

Starting with the general principle provided by Article 93^3 Section 1 of the IPL, according to which the human body, at the various stages of its formation and development, cannot be considered an invention (the same applies to the simple discovery of one of its elements, including a sequence or a partial sequence of a gene), **the guidelines offer a rather comprehensive, casuistic overview of borderline cases in which that provision will not apply and the grant of a patent would be possible:**

- Products defined by the method used for their manufacturing — unless the method itself or one of the steps that it consists of is excluded from patentability, for instance, on the basis of the public order or morality clause formulated in Article 29 Section 1(1) of the IPL;
- Products obtained from human tissues and organs which are technically processed (for example blood plasma fractionation) — the grant of the patent, however, would not be possible if the manufacturing of such a product requires to carry out a surgical or therapeutical treatment, and the product obtained in this way is introduced into the same organism.
- Products obtained through the cell multiplication taking place outside of a human or animal organism (for example an artificial bone produced with use of an *in vitro* culture) — as it is indicated, the possibility of the grant of the patent would not be excluded even if a fragment of the tissue employed to set up an *in vitro* culture is extracted from the same organism;
- Animal organs destined for transplants characterized by at least one technical quality developed during the preparation of the organ for the transplant;
- Implants containing both an element produced artificially and an element extracted from a human or animal organism — unless the fragments of a tissue are not introduced into the same organism;
- Artificial implants — under the condition that their technical qualities do not involve elements of therapeutic or surgical procedures.

Second medical uses

The guidelines contain also some specific tips when it comes to patenting of second medical uses. The provision of Article 25 Section 4 of the IPL, which concerns novelty as one of the patentability criteria, states that it is possible to grant a patent for an invention related to a substance or composition belonging to the state of art for use or for use in a strictly specified manner in treatment and diagnostic methods, provided that such a use is not within the state of the art. It is emphasized that **the treatment and diagnostic methods that the rule refers to delineate the scope of the patent protection: the claims cannot be extended with regard to a substance or a composition applied for other purposes.**

Above all, the guidelines demand that a patent claim, right after naming a substance or composition, should indicate its use ("for use in/as"). Below we would like to show you an example, derived from the guidelines, illustrating how such a claim shall be phrased.

For the first use: **"Substance X for use in the treatment of/as a medicament";**
For the second use: **"Substance X for use in the treatment of disease Y" / "Substance X for use by the intravenous injection in the treatment of disease Y".**

We must remember that a claim for the second use shall directly indicate the substance for which we are trying to secure the patent protection; a phrasing such as "The use of substance/composition X for the treatment of disease Y" exposes us to a certain risk: an objection might be raised that we are actually trying to obtain a patent for a method of treatment, which — as we know well — is prohibited by Article 29 Section 1(3).

When it comes to the wording of dependent claims, it is necessary to clearly highlight how are they related to the independent claim ("Substance X for the use according to claim (…)").

Under Article 25 Section 4, a new use cannot be comprised within the state of the art. The guidelines list **several factors that might be decisive for declaring that a particular second use differs from the existing state of the art:**

• New medical indications;

- A new, non-obvious group of patients of a distinguishable physiological and pathological status, and at the same time not having anything in common with the group that the therapy was applied to in the past;
- A new way of administering a previously known medication;
- A new dosage regimen.

After proving that a new medical use fulfills the novelty requirement, one must proceed to the assessment of the inventive step. In that case, the guidelines recommend adopting the problem-solution approach. The following criterium of patentability is met if **the invention solves a particular problem in the entirety of the scope claimed**; therefore the applicant is expected to demonstrate it properly.

Disclosure and corroboration of pharmaceutical inventions

An applicant is obliged to sufficiently disclose an invention — meaning, that they should disclose its essence in such a way that a person skilled in the art could carry out the invention. Failing to meet this requirement constitutes a ground for the PPO's decision to refuse the grant of a patent (Article 49 Section 1(2) fo the IPL). The guidelines specify what shall be included in an application concerning pharmaceutical invention, so that an applicant can discharge of this duty.

An application regarding pharmaceutical products and their uses shall contain **data corroborating their efficiency in the treatment of particular diseases** (it can be data of any kind, for instance, pharmacological or biological, that "demonstrate an evident correlation between an activity of a given substance and a disease being treated, or prove its direct effect on an underlying mechanism of a disease indicated"). **It is imperative to demonstrate on the filing date that a particular therapeutic effect has been achieved in the entirety of the scope claimed.** It is permissible to submit results from *in vivo* tests (submission of the results is not mandatory), as well as those obtained in *in vitro* tests ("only if it is possible to directly extrapolate [those results] to *in vivo* systems").

Revising patent claims has already been discussed in the context of the demonstration of the inventive step. In case of pharmaceutical inventions it is acceptable to submit supplementary materials and evidence as long as they refer to what has already been disclosed on the filing date; it is however not a way of remedying for an insufficient disclosure.

Disclosure of microorganisms

Furthermore, the guidelines contain certain hints regarding disclosure of microorganisms. According to Article 93^6, if carrying out of an invention requires use of a biological material which is not available to the public and which cannot be presented in the patent description in such a manner as to enable the invention to be carried out by a person skilled in the art, its disclosure might be realized by invoking a deposit made at the latest on the date of filing of an application, of a material in a collection recognized by an international agreement or in a national collection, designated by the President of the Polish Patent Office through a promulgation in the Official Journal of the Republic of Poland "Monitor Polski".

The guidelines list three collections entitled to receive deposits of microorganisms for patent purposes which are located in the territory of Poland:

1) Instytut Biotechnologii Przemysłu Rolno-Spożywczego im. prof. Wacława Dąbrowskiego (Prof. Wacław Dąbrowski Institute of Agriculture and Food Biotechnology) in Warsaw (international depositary authority);
2) Instytut Immunologii i Terapii Doświadczalnej im. Ludwika Hirszfelda, Polska Akademia Nauk (Ludwik Hirszfeld Institute of Immunology and Experimental Therapy, the Polish Academy of Sciences) in Wrocław (international depositary authority);
3) Narodowy Instytut Leków (National Medicines Institute) in Warsaw (national collection).

Invoking in patent claims any collections that do not have a status of international depositary authorities or national collections has no legal effect. The guidelines suggests also a course of action available to applicants who for certain reasons cannot invoke a legitimate deposit: an invention shall be deemed sufficiently disclosed if the patent description is clear and unambiguous enough so that it is possible to reproduce that invention in a repetitive manner.

