LEGAL ELEMENTS FOR PATENT CLAIMS DRAFTING

Legal amendments in the field of patents during the last sixteen years have considerably contributed to the compliance of the practical work of the Intellectual Property Office of Serbia and the European Patent Office (EPO).

The Patent Law in effect from 1990, replaced the restrictive law from 1981, and allowed the protection for the product and the process. Significant changes of the regulations took place in the field of chemistry, pharmacology and biotechnology. Medicinal product is excluded from the protection.

According to the Patent Law from 1995, the subject of the protection is open for a product, process and application. In the above mentioned period, the practical work of the IP Office was for the most of its practical work in compliance with the European Patent Office.

The Patent Law (‘Official Gazette of SM’, no. 32/04), further referred as the Law, harmonizes our patent law with the provisions of international treaties and conventions (Agreement on Trade-Related Aspects of Intellectual Property Rights, European Patent Convention, Patent Cooperation Treaty, European Union Biotechnology Directive).

The Patent Law allows possibility of protection of products, in the field of chemistry and pharmacology, substance, composition, (Article 5, Line 1 of the Law) if its is new, inventive and applicable, and the procedure for obtaining thereof.

Introducing the European Union Biotechnological Directive in the legal text establishes the legal frame to set up distinctive differences between the inventions and discoveries in the field of biotechnological inventions.

Insofar as the subject matter of protection is a substance that naturally emerges, which should be isolated and develop a procedure for obtaining thereof, it is possible to protect the procedure wherefrom the biological meterial is produced, product that consists of biological material and the biological material that is isolated from its natural environment (Article 5, item 2).

Article 6, of the Law, excludes from the protection human body, at any stage of its formation or development, improvement and discovery of some of its elements, including the sequences or partial sequences of the genes.

Element isolated from the human body or produced in a technical procedure, including sequences or partial sequences of genes can be patentable, even if the structure of its elements is identical to the structure of the natural element.

Article 7 of the Patent Law defines the exceptions from patentibility:

1) inventions the commercial application of which would be contrary to *ordre public* and morality ;
- processes for cloning human beings;
- processes for modifying of the germ line genetic identity of human beings;
- uses of human embryos for industrial or commercial purposes;
- processes for modifying the genetic identity of animals which are likely to cause them suffering without any substantial medical benefit to man or animal, and also animals resulting from such processes;
2) inventions concerning methods for treatment by surgery or diagnostic methods or therapy practiced directly on the human or animal body, except products or substances and compositions for use in any of these methods;
3) a plant or animal variety or an essentially biological process for the production of a plant or animal, except:
- a biotechnological process concerning a plant or animal, if the technical feasibility of the invention is not confined to a particular plant or animal variety;
- a microbiological or other technical process, or a product obtained by means of such process.
Protection shall not exclude the patentability of substances or compositions included in the state-of-art, which are used for treatment by surgical or diagnostic or therapeutic methods, provided their use for these methods is not comprised in the state-of-art (Article 8, item 3 of the Patent Law).
Mentioned exceptions along with patentability criteria (novelty, inventive step and industrial applicability) are the main preconditions in defining the scope of protection of the invention that is protected in a patent. The scope of the protection of any

invention is defined in the wording of patent claims, according to the article 58, of the Law

Patent claims shall be clear, concise and fully supported by the description of the invention (Article 26 of the Law). Claims shall define the subject matter for which protection is sought.

Provisions on drafting the patent claims specified as in the Article 7 of the Rules of Procedure on the legal protection of the inventions (''Official gazette of SM'', no. 62/04).

There are two well known categories of patent claims independent and dependent patent claims. Independent claims define the significant characteristics of the invention for which the protection is sought. Dependent claim defines features significant for the invention for which patent protection is sought. Dependent claim defines more precise characteristics of independent claim.

Claims are worded in only one sentence. In the introductory part of the claims the features being in correlation belong to the state-of-art.

New technical features of the invention for which the protection is sought by the invention, are set out in the continuance of the characteristic wording ''is characterized in that''.

The claims are numerated and are set out in the sequence. Moreover, grouping of claims allows determination of the correlation between the dependent claims and hence the meaning thereof may be clearly understood.

Provided that the condition from Article 22 of the Law, which defines a unity of the invention, the application may contain a few independent claims for (a product, process, application).

According to the above mentioned legal provisions in the field of chemistry, biotechnology and pharmacology there may come out the following categories of patent claims, (a patent claim for a product, a patent claim for a procedure as well as a patent claim for application of the invention) for protection:

- products, (substances) a compound for itself
- product defined by the process
- compositions
- formulations
- process

a) new or improved process

b) analogous process

- surgical, diagnostic or therapeutic method
- applicability

At wording patent claim that as the subject matter of protection has a nucleotide sequence, the claim shall include identification number of the sequence that the protection is sought for, as according to the WIPO standard. Provided that the subject matter of the invention is a biotechnological material besides the usual characteristics that define the invention, name of the biological material is worded and should the material be depoted, its depository number.

Example:

Isolated DNA molecule that contains a DNA sequence chosen from a group that includes :

a) SEQ ID No: 1;
b) DNK sequences that code the enzyme that has a sequence of an aminoacid SEQ ID No: 2;
c) DNA sequences that have at least 65 % of homology with isolated DNA from the above (a) or (b) and that code the enzyme quionolate phosphoribozyle transferaze; and
d) DNA sequences that differ from DNA of upper (a), (b) or (c) due to degenetion of gene code and that code the enzyme quinolate phosphoribozyl transferaze.

Applications containing phytopreparations, cosmetic preparations as the subject matter of protection, filed by physical persons, due to unclear description in the application, wherein often there are unclear wording for not even all the features of the invention that the protection is sought for, significantly slow down the examination procedure and often, the scope of eventually granted protection is reduced due to unclear description.

Acceptible claims in the field of chemistry, pharmacology and biotechnology are complementary with the acceptable claims of the EPO that define the mentioned technical fields. With the law from 2004, and introducing the European Union Biotechnological Directive, the provisions in this field are for its most part in compliance with provisions of the European Patent Convention (EPC).

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