

*STATE INTELLECTUAL PROPERTY OFFICE (SIPO)  
OF THE REPUBLIC OF CROATIA*

# **SIPO GUIDELINES FOR PATENT SEARCH AND EXAMINATION**

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## **PART A – THE PATENT APPLICATION; PRIORITY**

### **Chapter A-I.**

#### **Content of the application (other than claims)**

##### **1. Documents required for an application**

The content of a patent application is specified in Art. 20 PA.

The different documents needed (1 copy each) for a patent application are – Art. 20(1) PA:

- the request for the grant of a patent (P1 Form),
- the description of the invention,
- the claim(s) specifying the extent of protection claimed,
- the drawings, if any,
- the abstract.

The application as filed can be accompanied by the following documents:

- priority document(s),
- translation of the priority document(s),
- the authorisation of the patent representative,
- foreign examination results,
- sequence listing(s).

The requirements for the filing of a patent application in the Republic of Croatia are set out in the Patent Regulations. These Regulations prescribe the content of, as well as the manner of drafting and filing, a patent application and its enclosures.

The "Patent Regulations" (PR) specify in detail:

- How to file a patent application: Art. 2 PR,
- Content and method of drafting a patent application: Art. 4 PR,
- The description: Art. 5 PR,
- The claims: Art. 6 PR,
- The drawings: Art. 7 PR,
- The abstract: Art. 8 PR,
- Requirements concerning the drafting of particular elements, e.g. sheet size, margins, formulae, physical units, terminology: Art. 9 PR,
- Subject-matter not to be contained in the patent application: Art. 10 PR,

- Later submissions: Art. 11 PR,
- Deposit of biological material: Art. 12-14 PR
- Nucleotide and/or amino acid sequence listings: Art. 15 PR.

## **2. Form for request for grant (P1 Form)**

The request for the grant of a patent should be made by the applicant on a printed P1 Form which is provided free of charge by SIPO at the Receiving Division and via the SIPO website.

The data to be included in the P1 Form are as follows:

- identity of applicant(s), inventors and, where appropriate, of representative;
- the title of the invention;
- the designation of the inventor(s);
- the checklist of enclosures filed;
- the signature;
- the declaration of priority, where appropriate.

With the exception of the title, these items do not normally concern the examiner.

Title – The title should clearly and concisely state the technical designation of the invention. Art. 4 (1)2 PR states that the title "should not contain commercial names, trademarks, names, codes or abbreviations common to particular products and the like". While any obvious failures to meet these requirements are likely to be noted by the Legal Service, the examiner could review the title in the light of his reading of the description and claims and any amendments thereto. However, the need to change the title during the substantive examination, i.e. when preparing the text of the granted patent (HR B publication), does not arise very often.

## **3. Description**

Art. 20(4) PA requires a sufficient disclosure of the invention in the patent application. It states that "the patent application must disclose the invention in a manner sufficiently clear and precise so that a person skilled in the art could carry it out."

This requirement of disclosure should be met by the description with the aid of drawings, if any.

The meaning of "person skilled in the art" is discussed in B-II, 7.3.

Art. 5(2)6 PR states that "The description shall describe in detail at least one mode for carrying out the invention in terms of examples..."

The purpose of these provisions for the description is:

- (a) to ensure that the application contains sufficient technical information to enable a skilled person to put the invention into practice, to carry out the invention; and
- (b) to enable the reader to understand the contribution to the art which the inventor has made, so that it is possible to evaluate the invention.

## Parts of description

Title – The description should start with the title. The title of the invention should be the same as appears in the P1 Form.

Art. 5(2) PR specifies that the description of the invention should be presented under the following appropriate headings and order:

- 1) Technical field
- 2) Technical problem and the solution of the technical problem "as claimed"
- 3) State of the art; citation of patent documents
- 4) Essence of the invention; novelty
- 5) Brief description of the drawings, if any
- 6) Detailed description of at least one mode for carrying out the invention
- 7) Industrial application, if not obvious from the nature of the invention.

The manner and order of presentation of the different parts of the description should be as set out above. In exceptional cases, because of the nature of the invention, a different manner or a different order may be followed if it would afford a better understanding and a more economic presentation. Some departure from the requirements of Art. 5(3) PR is acceptable, provided the description is clear and orderly and all the requisite information is present. Also, certain technically simple inventions may be fully comprehensible with the minimum of description and but slight reference to prior art.

### 3.1 Technical field

Art. 5(2)1 PR says that "The description ... shall specify the technical field to which the invention relates, indicating the classification symbol (Int. Cl.) according to the International Patent Classification, if it is known to the applicant."

### 3.2 State of the art

Art. 5(2)3 PR states that the heading "State of the art" should contain a description and analysis of known technical solutions which were used for solving the technical problem and with which the applicant is acquainted. Also, disadvantages of those solutions may be indicated through an analysis of the observed deficiencies.

Here should be mentioned any state of the art of which the applicant is aware and which can be regarded as useful for understanding the invention and its relationship to the prior art. Identification of documents reflecting such art, especially patent documents, should preferably be included. This applies in particular to the state of the art corresponding to the first or "prior art" portion of the independent claim or claims.

Subsequently identified prior art – The insertion into the statement concerning the state of the art of references to documents identified subsequently, e.g. by the first examiner communication, should be required, where necessary, to put the invention into proper perspective. For instance, while the originally filed description of prior art may give the impression that the inventor has developed the invention from a certain point, the cited documents may show that certain stages in, or aspects of, this alleged development were already known. In such a case the examiner should require a reference to these documents and a brief summary of the relevant contents. The subsequent inclusion of such a summary in the introduction of the description does not contravene Art. 33 PA on the unallowable extension of content. This summary does not constitute what is called "added subject-matter". References to prior art

introduced after filing must be purely factual. Any alleged advantages of the invention must be adjusted in the light of prior art if necessary. New statements of advantages are permissible, provided that they do not introduce into the description matter which could not have been deduced from the application as originally filed.

If the relevant prior art consists of another patent application filed in the Republic of Croatia falling within the terms of Art. 8(3) PA, the fact that this document is a conflicting application filed in the Republic of Croatia should be explicitly acknowledged, thus making clear to the public that the document is not relevant to the question of inventive step.

Since the reader is presumed to be aware of the general state of the technical knowledge appropriate to the art, the examiner should not require the applicant to insert anything in the nature of a treatise or research report or explanatory matter which is obtainable from textbooks or is otherwise well known. Likewise, the examiner should not require a detailed description of the content of cited prior documents. It is sufficient that the reason for the inclusion of the reference is indicated. Lists of several reference documents relating to the same feature or aspect of the prior art are not required. Only the closest prior art document need be referred to. On the other hand, the examiner should not insist upon the excision of any such unnecessary matter, except when it is very extensive.

### 3.3 Technical problem

If it is decided that an independent claim defines a patentable invention, it must be possible to derive a technical problem from the application. The assessment of inventive step will take place according to the "problem-and-solution approach". See further under B-II, 7.7.

Art. 5(2)4 PR requires the applicant to "disclose the essence of the invention in such terms that the technical problem and its solution can be understood". The technical novelty of the invention should be stated with reference to the state of the art.

### 3.4 Solution of the technical problem

The invention as claimed in the independent claims solves the technical problem. In cases where the subject-matter of a dependent claim can be understood either from the wording of the claim itself or from the description of a way of performing the invention, no additional explanation of this subject-matter will be necessary. A mention in the description that a particular embodiment of the invention is set out in the dependent claim will then be sufficient. When there is doubt, however, as to whether certain details are necessary, the examiner should not insist on their excision.

It is not necessary, moreover, that the invention be presented explicitly in problem-and-solution form. Any advantageous effects which the applicant considers the invention to have in relation to the prior art should be stated, but this should not be done in such a way as to disparage any particular prior product or process. Furthermore, neither the prior art nor the applicant's invention should be referred to in a manner likely to mislead. This might be done, e.g. by an ambiguous presentation giving the impression that the prior art had solved less of the problem than was actually the case. Fair comment is, however, permitted.

### 3.5 Listing of the drawings

If drawings are included, their figures should first be briefly mentioned.

Example:

"Figure 1 is a plan view of the transformer housing;

Figure 2 is a side elevation of the housing;

Figure 3 is an end elevation looking in the direction of the arrow 'X' of Figure 2;

Figure 4 is a cross section taken through AA of Figure 1."

### 3.6 Detailed description of the invention

A detailed description of at least one way of carrying out the invention must be given. This will normally be the best mode known to the applicant for carrying out the invention. A detailed description of the drawings, if any, is presented here. The commercial use of the invention seems irrelevant to the disclosure of the invention. Since the application is addressed to the person skilled in the art, it is neither necessary nor desirable that details of well-known ancillary features should be given. However, the description must disclose in sufficient detail any feature essential for carrying out the invention so as to render it obvious to the skilled person how to put the invention successfully into practice. In many cases a single example or single embodiment will suffice. However, where the claims cover a broad field, the description should not usually be regarded as satisfying the requirements of Art. 20(4) PA unless it gives a number of examples or describes alternative embodiments or variations extending over the area protected by the claims. There are, however, some instances where even a very broad field is sufficiently exemplified by a limited number of examples or even one example.

The description and drawings should be consistent with one another, especially in the matter of reference signs, and each number or sign must be explained. However, where as a result of amendments to the description whole passages are deleted, it may be tedious to delete all superfluous references from the drawings. In such a case the examiner should not pursue an objection, as to consistency, too rigorously. All reference numbers or signs used in the description or claims must also appear on the drawings.

When it is necessary to refer in the description to elements of the drawings, the name of the element should be referred to and followed by its reference sign.

The reference should not be in the form:

"3 is connected to 5 via 4",

but it should be: "resistor 3 is connected to capacitor 5 via switch 4".

The following is likewise not suitable:

"resistor (reference sign 3) is connected to capacitor (reference sign 5) via switch (reference sign 4)".

It is the responsibility of the applicant to ensure that he supplies, when he first files his application, a sufficient disclosure, i.e. one that meets the requirements of Art. 20(4) PA in respect of the invention as claimed in all the claims. If the disclosure is seriously insufficient, such a deficiency cannot be cured subsequently by adding further examples or features without offending against Art. 33 PA, which requires that the subject-matter of the application must not be extended after the original filing date: what is called "added subject-matter" is not allowed.

Therefore, in such circumstances, either the application must be refused or, if the deficiency arises only in respect of part of the subject-matter claimed, the claims should be restricted to that part of the invention for which a sufficient description was originally filed.

Insufficiency of disclosure – Occasionally applications are filed in which there is a fundamental insufficiency in the description in the sense that the invention cannot be carried out by a person skilled in the art. There is then a failure to satisfy the requirements of Art. 20(4) PA which is essentially irreparable. Two instances thereof deserve special mention.

(i) The first is where the successful performance of the invention is dependent on chance. That is

to say, the skilled person, in following the instructions for carrying out the invention, finds either that the alleged results of the invention are not repeatable or that success in obtaining these results is achieved in a totally unreliable way.

An example where this may arise is a microbiological process involving mutations. Such a case should be distinguished from one where repeated success is assured even though accompanied by a proportion of failures – as can arise, e.g. in the manufacture of small magnetic cores or electronic components. In this latter case, provided the satisfactory parts can be readily sorted by a non destructive testing procedure, no objection arises under Art. 20(4) PA.

(ii) The second instance is where successful performance of the invention is inherently impossible because it would be contrary to well-established physical laws.

Industrial application – If this is not obvious from the description or from the nature of the invention, the description should indicate explicitly the way in which the invention may be applied in industrial production including agriculture – Art. 5(2)7 PR. It is to be expected that, in most cases, the way in which the invention can be exploited in industry will be self-evident, so that no more explicit description on this point will be required. However, there may be a few instances, e.g. in relation to methods of testing, where the manner of industrial exploitation is not apparent and must be made so.

Terminology – Although the description should be clear and straight-forward with avoidance of unnecessary technical jargon, the use of recognised technical terms is acceptable, and will often be desirable. Little-known or especially formulated technical terms may be allowed, provided that they are adequately defined and that there is no generally recognised equivalent. This discretion may be extended to foreign terms when there is no equivalent in the Croatian language. Terms already having an established meaning should not be allowed to be used to mean something different if this is likely to cause confusion. There may be circumstances where a term may legitimately be borrowed from an analogous art. Terminology, signs and symbols must be consistent throughout the application – Art. 9(11) PR.

When the properties of a material are referred to, the relevant units should be specified if quantitative considerations are involved. If this is done by reference to a published standard (e.g. a standard of sieve sizes), and such standard is referred to by a set of initials or similar abbreviation, it should be adequately identified in the description.

### 3.7 Units of measurement

Physical units of measurement shall be expressed in terms of the International System of Units (SI) – Art. 9(10) PR. If another system is used in an application, the units must also be expressed in this metric system. Similarly, temperature must be expressed at least in degrees Celsius or, in cryogenics, in Kelvin.

Physical values must be expressed in the units recognised in international practice, which is generally in the metric system, using SI units and the other units referred to in Chapter I of the Annex to EEC Directive 80/181/EEC of 20.12.1979, as amended by EEC Directives 85/1/EEC of 18.12.1984, 89/617/EEC of 27.11.1989 and 1999/103/EC of 24.01.2000.

The relevant provisions of these Directives are shown in Annex 2 to this Chapter, "Units of measurement recognised in international practice".

Thus "metric units" should be interpreted to mean "SI units".

If a measurement is expressed in other units, the examiner should allow the expression in other units to remain in parenthesis after the measurement as expressed in SI units, since this facilitates subsequent checking that the conversion from one unit to another has been correctly made.

Chemical and mathematical symbols, atomic weights and molecular formulae should be those in general use, and technical terms, signs and symbols should be those generally accepted and used in the art concerned – Art. 9(10) PR. In particular, if there are any agreed International Standards in the field concerned, these should be adopted wherever practicable.

### 3.8 Proper names, trademarks, trade names

The use of proper names, trademarks and trade names or similar words to refer to materials or articles is undesirable insofar as such words merely denote origin or where they may relate to a range of different products. If such a word is used, then, where it is necessary in order to satisfy the requirements of sufficient disclosure – Art. 20(4) PA, the product must be sufficiently identified, without reliance upon the word, to enable the invention to be carried out by the skilled person.

However, where such words have become internationally accepted as standard descriptive terms and have acquired a precise meaning, they may be allowed without further identification of the product to which they relate.

Examples: "Bowden" cable, "Belleville" washer, "Panhard" rod, "Teflon" layer, "caterpillar" belt.

Registered trademarks – It is the applicant's responsibility to ensure that registered trademarks are acknowledged as such in the description.

### 3.9 Reference documents

References in patent applications filed in the Republic of Croatia to other documents may relate either to the background art or to part of the disclosure of the invention.

Where the reference document relates to the background art, it may be in the application as originally filed or introduced at a later date.

Where the reference document relates directly to the disclosure of the invention (e.g. details of one of the components of a claimed apparatus) and if it is to be taken into account in respect of sufficient disclosure, Art. 20(4) PA, it must be in the application as originally filed. The reference document must be clearly identified in such a manner that the document can be easily retrieved. If subject-matter of the reference document is essential to satisfy the requirements of Art. 20(4) PA, at least a summary of this matter should be incorporated expressis verbis in the description. This is because the patent application should, regarding essential features of the invention, be self-contained, i.e. capable of being understood without reference to any other document.

### 3.10 Prohibited matter

- (i) Morality – There are three categories of specifically prohibited subject-matter, these being defined in Art. 10(1) PR.

It should be noted that the omission of passages or drawings by the Office, from the publication of the application, is mandatory only for the first category, namely statements or other matter contrary to the law or morality ("ordre public").

Examples:

Incitement to riot or to acts of disorder;

Incitement to criminal acts;

Racial, religious or similar discriminatory propaganda; and

Grossly obscene matter.

- (ii) Disparaging statements – It is necessary to discriminate in the second category between libellous or similarly disparaging statements, which are not allowed, and fair comment, e.g. in relation to obvious or generally recognised disadvantages, or disadvantages stated to have been found and substantiated by the applicant, which, if relevant, is permitted – Art. 10(1)2. PR.
- (iii) Irrelevant matter – The third category is irrelevant matter. It should be noted, however, that such matter is specifically prohibited only if it is "obviously irrelevant or unnecessary"; for instance, if it has no bearing on the subject-matter of the invention or its background art – Art. 10(1) 3. PR.
- (iv) Omission of matter from publication – If the Office omits prohibited matter from publication of the application, it should indicate to the applicant the place and the number of words or drawings omitted. The Office shall furnish, upon request, individual copies of the passages omitted – Art. 10(2)(3) PR.

#### 4. Drawings

The requirements relating to the form and content of drawings are set down in Art. 7(1)-(3) PR. Most of these are formal but the examiner may sometimes need to consider the requirements of this Article. The only question likely to cause difficulty is whether the textual matter included on the drawings is absolutely indispensable – Art. 7(2)11 PR.

In the case of circuit diagrams, block schematics and flow sheets, identifying catchwords for functional integers of complex systems (e.g. "magnetic core store", "speed integrator") may be regarded as indispensable from a practical point of view if they are necessary to enable a diagram to be understood rapidly and clearly.

#### 5. Abstract

Purpose of the abstract – The application must contain an abstract – Art. 20(1)5 PA. The purpose of the abstract is to give brief technical information about the disclosure as contained in the description, claims and any drawings. The abstract must be drafted in such a manner as to constitute an efficient instrument for the purpose of searching in the particular technical field. Art. 8 PR specifies the requirements for the abstract.

The abstract is initially supplied by the applicant. An examiner has the task of determining its definitive content, which will normally be published in the Official Gazette and with the application (HR A2 publication). In doing this he should consider the abstract in relation to the application as filed.

In determining the definitive content the examiner should take into consideration that the abstract is merely for use as technical information. In particular the abstract must not be used for the purpose of interpreting the extent of the legal protection sought. The abstract should in particular make it possible to assess whether there is a need for consulting the full text of the patent application filed in the Republic of Croatia itself.

Content of the abstract – The abstract must:

- (a) contain the title of the invention,
- (b) indicate the technical field to which the invention pertains,
- (c) contain a concise summary of the disclosure as contained in the description, claims and drawings. This summary must be so drafted as to allow a clear understanding of the



technical problem, the gist of the solution of that problem and the principal use or uses of the invention. Where appropriate, the abstract should contain the chemical formula which, among all the formulae contained in the application, best characterises the invention,

- (d) not contain statements on the alleged merits or value of the invention or its speculative application,
- (e) not contain more than 150 words, and
- (f) if the application contains any drawing, the applicant shall indicate the figure (or exceptionally more than one figure) of the drawings which should accompany the abstract when published. Each main technical feature mentioned in the abstract and illustrated by that drawing should be followed by a reference sign in parenthesis.

Figure accompanying the abstract – The examiner should consider not only the text of the abstract but also the selection of the figures for publication with it. He should alter the text to the extent that this may be necessary in order to meet the requirements set out above. He will select a different figure (or figures) of the drawings if he considers that they better characterise the invention.

In determining the definitive content of the abstract, the examiner should concentrate on conciseness and clarity, and refrain from introducing alterations merely for the purpose of embellishing the language.

In considering the abstract the applicant and the examiner should check it against the "Checklist for considering the abstract" contained in WIPO Standard ST.12/A, shown hereafter in Annex 1.

**Annex 1****CHECKLIST FOR CONSIDERING THE ABSTRACT**

In the following checklist, the abstractor should, after having studied the disclosure to be abstracted, place a check in the second column after the applicable terms listed in the first column. The requirements listed in the third column corresponding to the checked items of the first column should be borne in mind by the abstractor as he prepares his abstract. Finally, the abstractor may compare his finished abstract with the checked requirements and place a corresponding checkmark in the fourth column if he is satisfied that the requirements have been met.

<b>If the invention is a(n)</b>	<b>Check here</b>	<b>The abstract should deal with:</b>	<b>If so, check here</b>
Article		its identity, use; construction, organization, method of manufacture	
Chemical compound		its identity (structure if appropriate); method of preparation, properties, uses	
Mixture		its nature, properties, use; essential ingredients (identity, function); proportion of ingredients, if significant; preparation	
Machine, apparatus, system		its nature, use; construction, organization; operation	
Process or operation		its nature and characterizing features; material and conditions employed; product, if significant; nature of and relationship between the steps, if more than one	
If the disclosure involves alternatives		the abstract should deal with the preferred alternative and identify the others if this can be done succinctly; if this cannot be done, it should mention that they exist and whether they differ substantially from the preferred alternative	

Total number of words less than 250:.....in range 50-150: .....

Ref: Standards – ST. 12/A, April 1994

Original: Handbook on Industrial Property Information and Documentation, Publication N° 208(E), 1998, WIPO, Geneva (CH).

## **6. Inventions relating to biological material; public availability**

### **6.1 Biological material**

Applications relating to biological material are subject to the special provisions set out in Art. 20(5)-(6) PA and Art. 12-15 PR. In accordance with Art. 5(3) PA, the term "biological material" means any material containing genetic information and capable of reproducing itself or being reproduced in a biological system.

If an invention involves the use of or concerns biological material which is not available to the public and which cannot be described in the patent application filed in the Republic of Croatia in such a manner as to enable the invention to be carried out by a person skilled in the art, the disclosure is not considered to have satisfied the requirements of Art. 20(4) PA, unless the requirements of Art. 12(1) PR and Art. 13(1) PR on the deposit of viable biological material have been met.

### **6.2 Public availability of biological material**

Accordingly, the examiner must form an opinion as to whether or not the biological material is available to the public. There are several possibilities. The biological material may be known to be readily available to those skilled in the art, e.g. baker's yeast or *Bacillus natto*, which are commercially available. It may also be a standard preserved strain, or other biological material which the examiner knows to have been preserved in a recognised depository and to be available to the public.

Alternatively, the applicant may have given in the description sufficient information to satisfy the examiner as to the identifying characteristics of the biological material and as to the prior availability in a depository institution recognised for the purposes of Art. 20(6) PA. In any of these cases no further action is called for. If, however, the applicant has given no or insufficient information on public availability and the biological material is a particular strain not falling within the known categories such as those already mentioned, then the examiner must assume that the biological material is not available to the public.

The examiner must also check whether the biological material could be described in the patent application filed in the Republic of Croatia in such a manner as to enable the invention to be carried out by a person skilled in the art as required by Art. 20(4) PA, i.e. that the invention is sufficiently disclosed. For example, in a microbiological process involving mutations, the successful performance of the invention is dependent on chance; the results of the invention are therefore likely to be unrepeatable and consequently the requirements of Art. 20(4) PA are not fulfilled.

### **6.3 Deposit of biological material**

If the biological material is not available to the public and if it cannot be described in the application in such a manner as to enable the invention to be carried out by a person skilled in the art, the examiner must check:

- (i) whether the application as filed gives such relevant information as is known to the applicant on the characteristics of the biological material in accordance with Art. 12(1) PR. The relevant information under this provision concerns the classification of the biological material and significant differences from known biological material. For this purpose, the applicant must, to the extent available to him, indicate morphological and biochemical characteristics and the proposed taxonomic description. For characterising bacteria, for example, the relevant standard work would be R.E. Buchanan, N.E. Gibbons: *Bergey's Manual of Determinative Bacteriology*. Against this background, information should then be given on every further specific morphological or physiological characteristic relevant for recognition and propagation of the biological material, e.g. suitable nutrient media (mixture of ingredients), in particular where the latter are modified.

If biological material is deposited that cannot replicate itself but must be replicated in a biological system (e.g. viruses, bacteriophages, plasmids, vectors or free DNA or RNA), the above-mentioned information is also required for such a biological system. If, for example, other biological material is required, such as host cells or helper viruses, that cannot be sufficiently described or is not available to the public, this material must also be deposited and characterised accordingly. In addition, the process for producing the biological material within this biological system must be indicated. In many cases the above required information will already have been given to the depositary institution and need only be incorporated into the application (see Rule 6.1(a)(iii) and 6.1(b), Budapest Treaty on the International Recognition of the Deposit of Microorganisms for the Purposes of Patent Procedure; hereinafter referred to as the 'Budapest Treaty');

- (ii) whether the name of the authorised depositary institution and the accession number of the deposit were indicated in the patent application as required by Art. 20(5) PA. If the name of the depositary institution and the accession number of the deposit were submitted later, it should be checked whether they were filed within the relevant time period under Art. 12(2) PR.

In order to provide the evidence for the indications made by the applicant pursuant to Art. 20(5) PA, the examiner, in addition to the checks referred to under (i) and (ii) above, should request the deposit receipt issued by the authorised depositary institution (see Rule 7.1, Budapest Treaty) or for equivalent proof of the deposit of a biological material if such proof has not been filed before. If this deposit receipt has already been filed within the relevant time period according to Art. 12(2) PR, this document on its own is regarded as submission of the information according to Art. 12(1)3 PR.

In addition, the depositary institution named must be one of the recognised institutions according to Art. 20(6) PR.

If any of these requirements is not satisfied, the biological material in question cannot be considered as having been disclosed pursuant to Art. 20(4) PA by way of reference to the deposit.

**Annex 2:****UNITS OF MEASUREMENT RECOGNISED IN INTERNATIONAL PRACTICE****LIST OF CONTENTS**

1. SI units and their decimal multiples and submultiples
  - 1.1 SI base units
    - 1.1.1 Special name and symbol of the SI unit of temperature for expressing Celsius temperature
  - 1.2 Other SI units
    - 1.2.1 Supplementary SI units
    - 1.2.2 Derived SI units
    - 1.2.3 Derived SI units having names and symbols
  - 1.3 Prefixes and their symbols used to designate certain decimal multiples and submultiples
  - 1.4 Special authorised names and symbols of decimal multiples and submultiples of SI units
2. Units which are defined on the basis of SI units but are not decimal multiples or submultiples thereof
3. Units used with the SI, whose values in SI are obtained experimentally
4. Units and names of units permitted in specialised fields only
5. Compound units

**1. SI units and their decimal multiples and submultiples****1.1 SI base units**

Quantity	Unit	
	Name	Symbol
Length	metre	m
Mass	kilogram	kg
Time	second	s
Electric current	ampere	A
Thermodynamic temperature	kelvin	K
Amount of substance	mole	mol
Luminous intensity	candela	cd

Definitions of SI base units:

– Unit of length

The metre is the length of the path travelled in a vacuum by light during 1/299792458 seconds.

– Unit of mass

The kilogram is the unit of mass; it is equal to the mass of the international prototype of the kilogram.

– Unit of time

The second is the duration of 9 192 631 770 periods of the radiation corresponding to the transition between the two hyperfine levels of the ground state of the caesium 133 atom.

– Unit of electric current

The ampere is that constant current which if maintained in two straight parallel conductors of infinite length, of negligible circular cross-section and placed one metre apart in a vacuum, would produce between these conductors a force equal to  $2 \times 10^{-7}$  newton per metre of length.

– Unit of thermodynamic temperature

The kelvin, unit of thermodynamic temperature, is the fraction  $1/273.16$  of the thermodynamic temperature of the triple point of water.

– Unit of amount of substance

The mole is the amount of substance of a system which contains as many elementary entities as there are atoms in 0.012 kg of carbon 12. When the mole is used, the elementary entities must be specified and may be atoms, molecules, ions, electrons, other particles or specified groups of such particles.

– Unit of luminous intensity

The candela is the luminous intensity, in a given direction, of a source that emits monochromatic rays with a frequency of  $540 \times 10^{12}$  hertz and that has a radiant intensity in that direction of  $1/683$  watt per steradian.

### 1.1.1 Special name and symbol of the SI unit of temperature for expressing Celsius temperature

Quantity	Unit	
	Name	Symbol
Celsius temperature	degree Celsius	° C

Celsius temperature  $t$  is defined as the difference  $t = T - T_0$  between the two thermodynamic temperatures  $T$  and  $T_0$  where  $T_0 = 273.15$  K. An interval of or difference in temperature may be expressed either in kelvins or in degrees Celsius. The unit of 'degree Celsius' is equal to the unit 'kelvin'.

## 1.2 Other SI units

### 1.2.1 Supplementary SI units

Quantity	Unit	
	Name	Symbol
Plane angle	radian	rad
Solid angle	steradian	sr

Definitions of supplementary SI units:

– Plane angle unit

The radian is the plane angle between two radii of a circle which cut off on the circumference an arc equal in length to the radius.

– Solid angle unit

The steradian is the solid angle of a cone which, having its vertex in the centre of a sphere, cuts off on the surface of the sphere an area equal to that of a square with sides equal to the radius of the sphere.

### 1.2.2 Derived SI units

Units derived coherently from SI base units and supplementary SI units are given as algebraic expressions in the form of products of powers of the SI base units and/or supplementary SI units with a numerical factor equal to 1.

### 1.2.3 Derived SI units having names and symbols

Quantity	Unit		Expression	
	Name	Symbol	In other SI units	In terms of base or supplementary SI units
Frequency	hertz	Hz		$s^{-1}$
Force	newton	N		$m.kg.s^{-2}$
Pressure, stress	pascal	Pa	$N.m^{-2}$	$m^{-1}.kg.s^{-2}$
Energy, work; quantity of heat	joule	J	$N.m$	$m^2.kg.s^{-2}$
Power <sup>(1)</sup> , radiant flux	watt	W	$J.s^{-1}$	$m^2.kg.s^{-3}$
Quantity of electricity, electric charge	coulomb	C		$s.A$
Electric potential, potential difference, electromotive force	volt	V	$W.A^{-1}$	$m^2.kg.s^{-3}.A^{-1}$
Electric resistance	ohm	$\Omega$	$V.A^{-1}$	$m^2.kg.s^{-3}.A^{-2}$
Conductance	siemens	S		$m^{-2}.kg^{-1}.s^3.A^2$
Capacitance	farad	F	$A.V^{-1}$	$m^{-2}.kg^{-1}.s^4.A^2$
Magnetic flux	weber	Wb	$C.V^{-1}$	$m^2.kg.s^{-2}.A^{-1}$
Magnetic flux density	tesla	T		$kg.s^{-2}.A^{-1}$
Inductance	henry	H	$V.s$	$m^2.kg.s^{-2}.A^{-2}$
Luminous flux	lumen	lm	$Wb.m^{-2}$	$cd.sr$
Illuminance	lux	lx	$Wb.A^{-1}$	$m^{-2}.cd.sr$
Activity (of a radionuclide)	becquerel	Bq	$lm.m^{-2}$	$s^{-1}$
Absorbed dose, specific energy imparted, kerma, absorbed dose index	gray	Gy	$J.kg^{-1}$	$m^2.s^{-2}$
Dose equivalent	sievert	Sv	$J.kg^{-1}$	$m^2.s^{-2}$

<sup>(1)</sup> Special names for the unit of power: the name volt-ampere (symbol 'VA') is used to express the apparent power of alternating electric current, and var (symbol 'var') is used to express reactive electric power.

Units derived from SI base units or supplementary units may be expressed in terms of the units listed in this annex.

In particular, derived SI units may be expressed by the special names and symbols given in the above table. For example, the SI unit of dynamic viscosity may be expressed as  $m^{-1}.kg.s^{-1}$  or  $N.s.m^{-2}$  or  $Pa.s$ .

### 1.3 Prefixes and their symbols used to designate certain decimal multiples and submultiples

Factor	Prefix	Symbol	Factor	Prefix	Symbol
$10^{24}$	yotta	Y	$10^{-1}$	deci	d
$10^{21}$	zetta	Z	$10^{-2}$	centi	c
$10^{18}$	exa	E	$10^{-3}$	milli	m
$10^{15}$	peta	P	$10^{-6}$	micro	$\mu$
$10^{12}$	tera	T	$10^{-9}$	nano	n
$10^9$	giga	G	$10^{-12}$	pico	p
$10^6$	mega	M	$10^{-15}$	femto	f
$10^3$	kilo	k	$10^{-18}$	atto	a
$10^2$	hecto	h	$10^{-21}$	zepto	z
$10^1$	deca	da	$10^{-24}$	yocto	y

The names and symbols of the decimal multiples and submultiples of the unit of mass are formed by attaching prefixes to the word 'gram' and their symbols to the symbol 'g'.

Where a derived unit is expressed as a fraction, its decimal multiples and submultiples may be designated by attaching a prefix to units in the numerator or the denominator, or in both these parts.

Compound prefixes, that is to say prefixes formed by the juxtaposition of several of the above prefixes, may not be used.

### 1.4 Special authorised names and symbols of decimal multiples and submultiples of SI units

Quantity	Unit		
	Name	Symbol	Value
Volume	litre	l or L <sup>(1)</sup>	1 l = 1 dm <sup>3</sup> = 10 <sup>-3</sup> m <sup>3</sup>
Mass	tonne	t	1 t = 1 Mg = 10 <sup>3</sup> kg
Pressure, stress	bar	bar	1 bar = 10 <sup>5</sup> Pa

<sup>(1)</sup> The two symbols 'l' and 'L' may be used for the litre unit.

The prefixes and their symbols listed in 1.3 may be used in conjunction with the units and symbols contained in this table.



## 2. Units which are defined on the basis of SI units but are not decimal multiples or submultiples thereof

Quantity	Unit		
	Name	Symbol	Value
Plane angle	revolution <sup>(a)</sup>		1 revolution = $2\pi$ rad
	grade or gon	gon	1 gon = $\pi / 200$ rad
	degree	°	1° = $\pi / 180$ rad
	minute of angle	'	1' = $\pi / 10\,800$ rad
	second of angle	"	1" = $\pi / 648\,000$ rad
Time	minute	min	1 min = 60 s
	hour	h	1 h = 3 600 s
	day	d	1 d = 86 400 s

(a) No international symbol exists

The prefixes listed in 1.3 may only be used in conjunction with the names 'grade' or 'gon' and the symbols only with the symbol 'gon'.

## 3. Units used with the SI, and whose values in SI are obtained experimentally

The unified atomic mass unit is 1/12 of the mass of an atom of the nuclide  $^{12}\text{C}$ .

The electronvolt is the kinetic energy acquired by an electron passing through a potential difference of 1 volt in a vacuum.

Quantity	Unit		
	Name	Symbol	Value
Mass	unified atomic mass unit	u	1 u $\approx 1,6605655 \times 10^{-27}$ kg
Energy	electronvolt	eV	1 eV $\approx 1,6021892 \times 10^{-19}$ J

The value of these units, expressed in SI units, is not known exactly.

The prefixes and their symbols listed in 1.3 may be used in conjunction with these two units and with their symbols.

#### 4. Units and names of units permitted in specialised fields only

Quantity	Unit		
	Name	Symbol	Value
Vergency of optical systems	Dioptre		1 dioptre = $1 \text{ m}^{-1}$
Mass of precious stones	metric carat		1 metric carat = $2 \times 10^{-4} \text{ kg}$
Area of farmland and building land	are	a	1 a = $10^2 \text{ m}^2$
Mass per unit length of textile yarns and threads	tex	tex	1 tex = $10^{-6} \text{ kg.m}^{-1}$
Blood pressure and pressure of other body fluids	millimetre of mercury	mm Hg	1 mm Hg = 133,322 Pa
Effective cross-sectional area	Barn	b	1b = $10^{-28} \text{ m}^2$

The prefixes and their symbols listed in 1.3 may be used in conjunction with the above units and symbols, with the exception of the millimetre of mercury and its symbol. The multiple of  $10^2$  a is, however, called a "hectare".

#### 5. Compound units

Combinations of the units listed in this annex form compound units.

## Chapter A-II. Claims

### 1. General

Art. 20(1)3 PA stipulates that "The patent application shall contain ... one or more claims for the protection of the invention".

Art. 61(1) PA says that "The scope of the patent owner's exclusive rights shall be determined by the claims which are finally accepted in the patent granting procedure".

The claims are the most important part of the patent application from the legal perspective. They are important throughout the term of the patent since they determine the extent of protection. On the other hand, inasmuch as the patent constitutes a source of technical information, the description and the abstract are generally sufficient.

The essence of a claim, its *raison d'être*, is to define the invention and thereby to set out the extent of protection sought for the patent.

This definition of the invention should seek to strike a balance between the inventor's legitimate wish to obtain the most extensive protection possible and the need to delimit the invention clearly with respect to the prior art.

The ideal claim therefore contains only those features necessary and sufficient for this objective to be achieved.

In general the patent application must contain one or more claims.  
These claims, under Art. 20(7) PA, must:

- (a) define the subject-matter for which protection is sought;
- (b) be clear and concise;
- (c) be supported by the description.

Since the claims determine the extent of the protection conferred by a patent granted in the Republic of Croatia or patent application filed in the Republic of Croatia, the clarity of the claims is of the utmost importance. The claims do not, however, stand in isolation and are not to be interpreted according to their strict literal wording. The description and drawings shall serve to interpret the patent claims. See Art. 61(1) PA.

### 2. Two-part form and content of claims

#### 2.1 Technical features of the invention

Art. 6(1) PR specifies that "the claims shall be drafted in a manner to define the invention exclusively by its technical features". This means that claims should not contain any statements relating, for example, to commercial advantages or other non-technical matters. Statements of purpose should be allowed if they assist in defining the invention.

It is not necessary that every feature should be expressed in terms of a structural limitation. Functional limitations may be included provided that a skilled person would have no difficulty in providing some means of performing this function without exercising inventive skill.

Claims to the use of the invention, in the sense of the technical application thereof, are also allowable.

## 2.2 Two-part form of claims

(i) Prior art portion – Art. 6(3) PR defines the two-part form which a claim should adopt wherever possible. The introductory part of the claim or the "prior art portion" should first state the title of the invention as indicated on the request Form P1. The prior art portion should further state the designation of the subject-matter of the invention, i.e. the general technical class of apparatus, process, etc., to which the invention relates. This is followed by a statement of those technical features which are necessary for the definition of the claimed subject-matter but which, in combination, are part of the closest prior art.

This statement of prior art features is applicable only to independent claims and not to dependent claims.

It is clear from the wording of Art. 6(3) PR that it is necessary only to refer to those prior art features which are relevant to the invention, that is to say those which are necessary for the explanation of the invention.

Example: If the invention relates to a photographic camera but the inventive step relates entirely to the shutter, it would be sufficient for the first part of the claim to read:

"A photographic camera including a focal plane shutter characterised by ...".

There is no need to refer also to other known features of a camera such as the lens and viewfinder.

(ii) Characterising portion – The second part of the claim or the "characterising portion" should state the technical features which the invention adds to the prior art, i.e. the technical features for which, in combination with the features stated in the "prior art portion", protection is sought.

If a single document in the state of the art reveals that one or more features in the second part of the claim were already known in combination with all the features in the first part of the claim and in that combination have the same effect as they have in the full combination according to the invention, the examiner should require that such feature or features be transferred to the first part. Where, however, a claim relates to a novel combination, and where the division of the features of the claim between the prior art portion and the characterising portion could be made in more than one way without inaccuracy, the applicant should not be pressed to adopt a different division of the features from that which he has chosen, if his version is not incorrect.

## 2.3 Two-part form unsuitable

The applicant should be required to follow the two-part form in his independent claim or claims, where, for example, it is clear that his invention resides in a distinct improvement over an old combination of parts or steps. However, this two-part form need be used only in appropriate cases. The nature of the invention may be such that this form of claim is unsuitable, e.g. because it would give a distorted or misleading picture of the invention or of the closest prior art.

Examples of the kind of invention where the two-part form is not appropriate are:

- (a) the combination of known entities of equal status, the inventive step lying solely in the combination;
- (b) the modification of, as distinct from addition to, a known chemical process e.g. by omitting one substance or substituting one substance for another; and
- (c) a complex system of functionally interrelated parts, the inventive step concerning changes in several of these or in their inter-relationships, e.g. complex

combination of electronic circuits.

In examples (a) and (b) the two-part form of claim may be artificial and inappropriate, whilst in example (c) it might lead to an inordinately lengthy and complicated claim.

Another example in which the two-part form of claim may be inappropriate is where the invention is a new chemical compound or group of compounds. It is likely also that other cases will arise in which the applicant is able to adduce convincing reasons for formulating the claim in a different form.

There is a special instance in which the two-part form of claim should be avoided. This is when the only relevant prior art is another patent application filed in the Republic of Croatia falling within the terms of Art. 8(3) PA (Conflicting application). Such prior art should, however, be clearly acknowledged in the description but shall not be taken into consideration in deciding whether an invention involves an inventive step – Art. 10(2) PA.

The claims, as well as the description, may contain chemical or mathematical formulae but not drawings. The claims may contain tables but only if their subject-matter makes the use of tables desirable. The examiner should not object to the use of tables in claims where this form is convenient.

### **3. Kinds of claims**

#### **3.1 Categories of claims**

There exist different "categories" of claims ("product, process, apparatus or use"). For many inventions, claims in more than one category are needed for full protection. In fact there are only two basic kinds of claims, namely claims to a physical object (product, apparatus) and claims to an activity (process, method, use).

The first basic kind of claim ("product claim") includes a substance or compositions (e.g. chemical compound or a mixture of compounds) as well as any physical entity (e.g. object, article, apparatus, machine, system of co-operating apparatus) which is produced by a person's technical skill.

A claim may relate only to one particular category.

A product claim relating to a physical object should specify the structure of that product.

Examples:

- "A steering mechanism incorporating an automatic feedback circuit ..."
- "A woven garment comprising ..."
- "An insecticide consisting of X, Y, Z ..."
- "A communication system comprising a plurality of transmitting and receiving stations ...".

The second basic kind of claim ("process claim") is applicable to all kinds of activities in which the use of some material product for effecting the process is implied. The activity may be exercised upon material products, upon energy, upon other processes (as in control processes) or upon living things.

Example:

"A process for producing a polypeptide according to any of claims 1 to 5, which process comprises:

- (a) preparing a DNA fragment containing a nucleotide sequence which ...
- (b) incorporating said DNA fragment into an expression vector ...
- (c) transforming a host cell ...
- (d) culturing said transformant to allow ...

An application may be refused for lack of clarity if the category of a claim is not clear- Art. 20(7) PA.

### 3.2 Number of claims

Normally the number of independent claims is limited to one independent claim in each category. Art. 6(2) PR stipulates that "The number of claims shall be reasonable in consideration of the nature of the invention claimed. The claims shall be numbered consecutively in Arabic numerals."

Where the requirement concerning unity of invention has been complied with, and where the subject-matter of the invention cannot be covered by one claim, the application may contain several independent claims of the same category – Art. 6(4) PR. This means that the examiner may allow two or more independent claims in the same category in appropriate cases, provided that there is a unifying single inventive concept and that the claims as a whole satisfy the requirement that they should be concise.

The following are examples of typical situations falling within the scope of exceptions from the principle of one independent claim per category:

- (a) Examples of a plurality of interrelated products:
  - an electric plug and socket,
  - transmitter and receiver,
  - intermediate and final chemical products,
  - gene – gene construct – host – protein – medicament.
- (b) Example of a plurality of different inventive uses of a product:
  - claims directed to second or further medical uses when a first medical use is known.
- (c) Examples of alternative solutions to a particular problem:
  - a group of chemical compounds,
  - two or more processes for the manufacture of such compounds.

### 3.3 Independent and dependent claims

All applications contain one or more "independent" claims directed to the essential features of the invention. Any such claim may be followed by one or more dependent claims referring to specific features of that invention. See Art. 6(5) PR. It is evident that any claim relating to a specific feature must effectively include also the essential features of the invention, and hence must include all the features of at least one independent claim.

- (i) Definition of dependent claim – Any claim which includes all the features of any other claim, i.e. all the features of both its prior art portion and its characterising portion, is called a "dependent claim".

According to Art. 6(6) PR, such a claim must contain, at the beginning, a reference to the other claim, all of whose features it includes.

Since a dependent claim does not by itself define all the characterising features of the subject-matter which it claims, expressions such as "characterised in that" or "characterised by" are not necessary in such a claim but are nevertheless permissible. A claim defining further particulars of an invention may include all the features of another dependent claim and should then refer back to that claim. Also, in some cases, a dependent claim may define a particular feature or features which may appropriately be added to more than one previous claim (independent or dependent). It follows that there are several possibilities: a dependent claim may refer back to one or more independent claims, to one or more dependent claims, or to both independent and dependent claims.

Normally a dependent claim refers back to claims of the same category.

Example:

1. Switch machine comprising a thrust rod ... and a coupling device ..., **characterised in that** two counter-rollers are provided which are ....
2. Switch machine according to claim 1, **characterised in that** the retaining pin is constructed as a helical compression spring and is ....
3. Switch machine according to claim 1 or 2, **characterised in that** ....
4. Switch machine according to claim 3, **characterised in that** a single  
....

The formulation of claim dependencies must be clear so that from the wording itself it is unambiguous which combinations are meant.

Normally **not** allowable are "open" enumerations, such as:

"according to one or more of the claims 3 to 8",

"according to at least one of the preceding claims",

"according to claims 4, 6, 8 and/or 7 to 9".

From the definition of "dependent claim", it follows that a claim referring to a claim of a different category is not considered to be a dependent claim.

Example:

"5. Apparatus ... for carrying out a process according to claim 1, characterised by ...".

Similarly, in a situation like the plug and socket example above, a claim to the one part referring to the other co-operating part is not considered to be a dependent claim.

Example:

"3. Plug ... for co-operation with a socket according to claim 1, characterised by ...".

- (ii) Arrangement of claims – All dependent claims referring back to a single previous claim and those referring back to several previous claims must be grouped together to the extent possible and in the most appropriate way possible. The arrangement must therefore be one which enables the association of related claims to be readily determined and their meaning in association to be readily construed. The examiner should object if the

arrangement of claims is such as to create obscurity in the definition of the subject-matter to be protected. See Art. 6(6) PR.

Normally the first claim should be the broadest.

In general, however, when the corresponding independent claim is allowable, the examiner should not concern himself unduly with the subject-matter of dependent claims, provided he is satisfied that they are truly dependent and thus in no way extend the extent of protection of the invention defined in the corresponding independent claim.

If the two-part form is used for the independent claim(s), dependent claims may relate to further details of features not only of the characterising portion, but also of the prior art portion.

### 3.4 Alternatives in a claim

A claim, whether independent or dependent, may refer to alternatives, provided that:

- (a) the number and presentation of alternatives in a single claim does not make the claim obscure or difficult to construe, and
- (b) the claims meet the requirements of unity.

Where alternatives relate to only some of the characterising features of the invention, they may be claimed by providing a first independent claim for one alternative followed by further claims for the other alternatives.

Example:

"2. Machine according to claim 1, modified in that feature X is replaced by feature Y".

It should be noted that such further claims, although dependent in form, are not entirely dependent since they do not include all the features of the first claim but only some of those features.

## 4. Clarity and interpretation of claims

Clarity – The requirement that the claims shall be clear applies to individual claims and also to the claims as a whole. The clarity of the claims is of the utmost importance in view of their function in defining the matter for which protection is sought. In view of the differences in the extent of protection which may be attached to the various categories of claims, the examiner should ensure that the wording of a claim leaves no doubt as to its category.

Interpretation – Each claim should be read giving the words the meaning and scope which they normally have in the relevant art, unless in particular cases the description gives the words a special meaning, by explicit definition or otherwise. Moreover, if such a special meaning applies, the examiner should, so far as possible, require the claim to be amended whereby the meaning is clear from the wording of the claim alone. The claim should also be read with an attempt to make technical sense out of it. Such a reading may involve a departure from the strict literal meaning of the wording of the claims.

### 4.1 Inconsistency between claims and description

Where there is any serious inconsistency between claims and description, amendments to remove this should be required. Such inconsistency can be of the following kinds:

- (i) Simple verbal inconsistency.



**Example:**

There is a statement in the description which suggests that the invention is limited to a particular feature, but the claims are not thus limited.

This inconsistency can be removed either by broadening the description or by limiting the claims.

Similarly, if the claims are more limited than the description, the claims may be broadened or the description may be limited.

(ii) Inconsistency regarding apparently essential features.

The description may state, or may imply from general technical knowledge, that a certain technical feature not mentioned in the independent claim is essential to the performance of the invention. In other words, this feature is necessary for the solution of the problem to which the invention relates.

In such a case, the claim is unclear because an independent claim must not only be comprehensible from a technical point of view but must also define clearly the subject-matter of the invention; this means indicating all essential features thereof. The examiner should require the amendment of the claim to include this feature. If, in response to this objection, the applicant can show convincingly that it would be clear to a person skilled in the art that the description was incorrect in suggesting that the feature in question was essential, amendment of the description should be required instead.

(ii) Part of the subject-matter of the description and/or drawings is not covered by the claims

**Example:**

The claims all specify an electric circuit employing semiconductors, but one of the embodiments in the description and drawings employs electronic tubes instead.

Here again amendment either of the claims or of the description and drawings is required to remove the inconsistency and thus avoid any possible uncertainty which could arise later as to the meaning of the claims.

General statements in the description which imply that the extent of protection may be expanded in some vague and not precisely defined way should be objected to. In particular, objection should be raised to any statement which refers to the "spirit" of the invention.

## 4.2 Relative terms; unclear terms

It is preferable not to use a relative term such as "thin", "wide" or "strong" in a claim. If such terms appear in a claim, it is usually necessary to have them either defined or excised. No objection arises, however, if the relative term has a precise and well-recognised meaning in the art, e.g. "high-frequency amplifier". Where the term has no well-recognised meaning it should, if possible, be replaced by a more precise wording found elsewhere in the original disclosure. Where there is no basis in the disclosure for a clear definition, and where the term is not essential having regard to the invention, it should normally be retained in the claim. Excising it would generally lead to an extension of the subject-matter beyond the content of the application as filed – Art. 33 PA. However, an unclear term cannot be allowed in a claim if the term is essential having regard to the invention. Equally, an unclear term cannot be used by the applicant to distinguish his invention from the prior art.

- (i) "About", "approximately" – Particular attention is required whenever the word "about" or similar terms such as "approximately" are used.

Such a word may be applied, for example, to a particular value (e.g. "about 200°C") or to a range (e.g. "about x to about y"). In each case, the examiner should use his judgement as to whether the meaning is sufficiently clear in the context of the application read as a whole. However, the word can only be permitted if its presence does not prevent the invention from being unambiguously distinguished from the prior art with respect to novelty and inventive step.

- (ii) Trademarks – The use of trademarks and similar expressions in claims is not allowed as it may not be guaranteed that the product or feature referred to is not modified while maintaining its name during the term of the patent. They may be allowed exceptionally if their use is unavoidable and they are generally recognised as having a precise meaning.
- (iii) Optional features – Expressions like "preferably", "for example", "such as" or "more particularly" should be looked at carefully to ensure that they do not introduce ambiguity. Expressions of this kind have no limiting effect on the scope of a claim. That is to say, the feature following any such expression is to be regarded as entirely optional.

#### 4.3 Parameters

Where the invention relates to a chemical compound, it may be characterised in a claim in various ways, namely by its chemical formula, as a product of a process or exceptionally by its parameters. Characterisation of a chemical compound solely by its parameters should, as a general rule, not be allowed. It may, however, be allowable in those cases where the invention cannot be adequately defined in any other way. This can arise e.g. in the case of macromolecular chains, but in such cases only parameters usual in the art should be employed to characterise the compound. The examiner should be aware of the possibility that applicants may attempt to employ unusual parameters to disguise lack of novelty.

#### 4.4 Reference to description/drawings; Reference signs

See Art. 6(7) PR. The claims must not, in respect of the technical features of the invention, rely on references to the description or drawings. In particular the claims must not normally rely on such references as "as described in part ... of the description", or "as illustrated in Figure 2 of the drawings".

An example of an allowable exception would be that in which the invention involved some peculiar shape, illustrated in the drawings, but which could not be readily defined either in words or by a simple mathematical formula. Another special case is that in which the invention relates to chemical products some of whose features can be defined only by means of graphs or diagrams.

Reference signs – See Art. 6(8) PR. If there are drawings, and the technical features of the claims would be rendered more intelligible by relating these features to the corresponding features of the drawings (e.g. where a complete machine has been illustrated), then this should be done by placing the appropriate reference signs in parentheses after the features in the claims. This should be done in both parts of claims having the preferred two-part form. These reference signs are not, however, to be construed as limiting the scope of a claim, but merely as aids to an easier understanding of the subject-matter defined.

#### 4.5 Negative limitations; "disclaimers"

- (i) **Disclaimers disclosed in the application as filed**

A claim's subject-matter is normally defined in terms of positive features indicating that certain technical elements are present. Exceptionally, however, the subject-matter may be restricted using a negative limitation expressly stating that particular features are absent.

This may be done e.g. to remove non-patentable embodiments disclosed in the application as filed, or if the absence of a feature can be deduced from the application as filed. Disclaimers may also be present in the claim on filing, most often in the field of compound chemistry.

Example:

If a claim directed to compounds described by a Markush formula (special chemical structures with many variable fragments) encompasses a compound known from the prior art, albeit for a different use from the claimed compounds, the applicant may choose to exclude it by way of a disclaimer incorporated into the claim as filed.

Negative limitations such as disclaimers should only be allowable if adding positive features to the claim either would not define more clearly and concisely the subject-matter still protectable or would unduly limit the scope of the claim.

**(ii) Disclaimers not disclosed in the application as filed**

Disclaimers may be introduced into the application after filing for various reasons, but most often to overcome a novelty objection with regard to a particular piece of prior art. The examiner must carefully determine whether the introduction of a disclaimer infringes against Art. 33 PA, i.e. whether, by introduction of the disclaimer, subject-matter is added to the application.

Limiting the scope of a claim by using a disclaimer to exclude a technical feature not disclosed in the application as filed does not infringe Art. 33 PA in the following cases:

- (a) restoring novelty over a disclosure under Art. 8(3) PA; conflicting intermediate prior art documents under Art. 8(3) PA are, according to Art. 10(2) PA, not taken into account when assessing inventive step;
- (b) restoring novelty over an accidental anticipation under Art. 8(2) PA. An anticipation is accidental if it is so unrelated to and remote from the claimed invention that the person skilled in the art would never have taken it into consideration when making the invention. An accidental disclosure has nothing to do with the teaching of the claimed invention, since it is not relevant for examining inventive step.

This is the case when the same compounds serve as starting materials in entirely different reactions yielding different end products. Similarly, a chemical compound disclosed in the prior art for an entirely different use to that of the claimed compounds is an accidental disclosure;

- (c) removing subject-matter which, under Art. 5(6) PA to Art. 7 PA, is excluded from patentability for non-technical reasons.

Example: The insertion of "non-human" in order to satisfy the requirements of Art. 7(1) PA is allowable.

However, an undisclosed disclaimer is not allowable if:

- (a) it is made in order to exclude non-working embodiments or remedy insufficient disclosure (Art. 20(4) PA);
- (b) it makes a technical contribution.

An undisclosed disclaimer is, in particular, not allowable if the limitation is relevant for assessing inventive step.

Example: if a compound known from the prior art for the same use as the claimed compounds is disclaimed.

A disclaimer should remove no more than is necessary either to restore novelty or to disclaim subject-matter excluded from patentability for non-technical reasons. A claim containing a disclaimer must meet the clarity and conciseness requirements of Art. 20(7) PA. In the interest of the patent's transparency, the excluded prior art should be indicated in the description, and the relation between the prior art and the disclaimer should be explained.

#### 4.6 Essential features of the invention

An independent claim should specify explicitly all of the essential features needed to define the invention – Art. 6(1) PR. An exception is when such features are implied by the generic terms used, e.g. a claim to a "bicycle" does not need to mention the presence of wheels.

#### 4.7 Functional features in claims

- (i) It is not necessary that every feature in a claim should be expressed in terms of a structural limitation. Functional limitations may be included provided that a skilled person would have no difficulty in providing some means of performing this function without exercising inventive skill.

A claim may broadly define a feature in terms of its function, even where only one example of the feature has been given in the description, if the skilled reader would appreciate that other means could be used for the same function.

Example:

"Terminal position detecting means" in a claim might be supported by a single example comprising a limit switch, it being obvious to the skilled person that e.g. a photoelectric cell or a strain gauge could be used instead.

In general, however, if the entire contents of the application are such as to convey the impression that a function is to be carried out in a particular way, with no intimation that alternative means are envisaged, and a claim is formulated in such a way as to embrace other means, or all means, of performing the function, then objection arises. Furthermore, it may not be sufficient if the description merely states in vague terms that other means may be adopted, if it is not reasonably clear what they might be or how they might be used.

- (ii) Result to be achieved / "desiderata claims" – The extent of protection defined by the claims must be as precise as the invention allows. As a general rule, claims which attempt to define the invention, or a feature thereof, by a result to be achieved should not be allowed. However, they may be allowed if the invention can only be defined in such terms and if the result is one which can be directly and positively verified by tests or procedures adequately specified in the description and involving nothing more than trial and error.

Example:

The invention may relate to an ashtray in which a smouldering cigarette end will be automatically extinguished due to the shape and relative dimensions of the ashtray. The latter may vary considerably in a manner difficult to define whilst still providing the desired effect. So long as the claim specifies the construction and shape of the ashtray as clearly as possible, it may define the relative dimensions by reference to the result to be achieved, provided that the specification includes adequate directions to enable the reader to determine the required dimensions by routine test procedures.

#### 4.8 Product-by-process claim

Normally, product claims define a product in terms of the technical features thereof. For example, a device may be described in terms of its component parts, or a chemical compound may be defined in terms of its molecular structure.

Claims for products defined in terms of a process of manufacture are allowable only if the products as such fulfil the requirements for patentability, i.e. inter alia that they are new and inventive. A product is not rendered novel merely by the fact that it is produced by means of a new process.

A claim defining a product in terms of a process is to be construed as a claim to the product as such.

Example:

A claim directed to acetic acid, defined in terms of a novel and inventive process for its manufacture, cannot be considered novel since the product, acetic acid, is identical to the known compound irrespective of its method of preparation.

The claim may for instance take the form "Product X obtainable by process Y". Irrespective of whether the term "obtainable", "obtained", "directly obtained" or an equivalent wording is used in the product-by-process claim, it is still directed to the product per se and confers absolute protection upon the product.

#### 4.9 Apparatus/Method for ...

If a claim commences with such words as: "Apparatus for carrying out the process ...", this must be construed as meaning merely apparatus "suitable for" carrying out the process. An apparatus which otherwise possessed all of the features specified in the claims, but which would be unsuitable for the stated purpose, or which would require modification to enable it to be so used, should not be considered as anticipating the claim.

Similar considerations apply to a claim for a product for a particular use.

Example:

If a claim refers to a "mould for molten steel", this implies certain limitations for the mould. Therefore, a plastic ice cube tray with a melting point much lower than that of steel would not come within the claim.

Example:

If a claim refers to "A hook for a crane", this implies e.g. particular dimensions of and strength in the hook. Therefore a fish hook could never anticipate the claim, but a hook having the necessary dimensions and strength and possessing all the other features specified in the claim would deprive the claim of novelty whether it was stated to be for use on a crane or not.

Similarly, a claim to a substance or composition for a particular use should be construed as meaning a substance or composition which is in fact "suitable for" the stated use. A known product which is per se the same as the substance or composition defined in the claim, but which is in a form which would render it unsuitable for the stated use, would not deprive the claim of novelty.

An exception to this general principle of interpretation is where the claim is to a known substance or composition for use in a surgical, therapeutic or diagnostic method. See further B-I, 3.8.

#### 4.10 Reference to use; Use claims

Where an apparatus claim seeks to define the invention by specifying features of the use to which the apparatus is to be put, a lack of clarity can result.

Example:

A claim reading "A box for storing magnetic tape cassettes on end, characterised in that the stored cassettes project beyond the upper edges of the box to facilitate removal" is unclear. The claim, though directed to a box, defines not a box per se but its relationship to the cassettes. Such a claim must either make clear the size of the box, if desired by defining the size of the cassettes, or must be directed to a combination of box and cassettes.

Example:

"A storage box containing magnetic tape cassettes on end ...".

Use claims – For the purposes of examination, a "use" claim of a form such as "The use of substance X as an insecticide" should be regarded as equivalent to a "process" claim of the form

"A process of killing insects using substance X".

Thus a claim of the form indicated should not be interpreted as directed to the substance X itself, which could be recognisable (e.g. by further additives) as intended for use as an insecticide. A claim of the form indicated has a different extent of protection from the product claim "Substance X intended for use as an insecticide".

Similarly, a claim for "The use of a transistor in an amplifying circuit" would be equivalent to a process claim for "The process of amplifying using a circuit containing the transistor" and should not be interpreted as being directed to a product claim for "An amplifying circuit in which the transistor is used", nor to a process claim for "The process of using the transistor in building such a circuit".

### 5. Conciseness, number of claims

The requirement that the claims shall be concise refers to the claims in their entirety as well as to the individual claims. The number of claims must be considered in relation to the nature of the invention the applicant seeks to protect. Undue repetition of wording, e.g. between one claim and another, should be avoided by the use of the dependent form of claims. Regarding independent claims in the same category see A-II, 3.

As for dependent claims, while there is no objection to a reasonable number of such claims directed to particular preferred features of the invention, the examiner should object to a multiplicity of claims of a trivial nature.

The proliferation of independent claims and undue repetition of wording is to be avoided. While an examiner should not allow an unnecessary proliferation of independent claims, he should not adopt an overacademic or rigid approach.

Some applications often contain an excessive number of claims of overlapping scope such that the requirements of conciseness and clarity of the claims are not met. In such cases the examiner should require the claims to be redrafted so that there is only the minimum number of independent claims necessary, in each category. In cases where the use of multiple independent claims makes sufficient examination impossible, e.g. when the various presentations

of the invention in the claims make it difficult to determine the matter for which protection is sought, the first examiner communication may be limited to an objection requiring the claims to be redrafted before further examination takes place. An examination of only the first independent claim together with its dependent claims could also be appropriate.

## 6. Support for the claims in description

The claims must be supported by the description. This means that there must be a basis in the description for the subject-matter of every claim. The scope of the claims must not be broader than is justified by the extent of the description and drawings and also by the contribution to the art.

Most claims are generalisations from one or more particular examples. The extent of generalisation permissible is a matter which the examiner must judge in each particular case in the light of the closest prior art. Thus an invention which opens up a whole new field is entitled to more generality in the claims than one which is concerned with advances in a known technology.

A fair statement of claim is one which is not so broad that it goes beyond the invention and not so narrow as to deprive the applicant of a just reward for the disclosure of his invention. The applicant should be allowed to cover all obvious modifications of, equivalents to and uses of that which he has described. In particular, if it is reasonable to predict that all the variants covered by the claims have the properties or uses the applicant ascribes to them in the description, he should be allowed to draw his claims accordingly.

Objection of lack of support – As a general rule, a claim should be regarded as supported by the description unless exceptionally there are well-founded reasons for believing that the skilled person would not be able, on the basis of the information given in the application as filed, to extend the particular teaching of the description to the whole of the field claimed by using routine methods of experimentation or analysis. Support must, however, be of a technical character. Vague statements or assertions which have no technical content provide no basis.

Since the examiner should raise an objection of lack of support only if he has well-founded reasons, it follows that the applicant should be given the benefit of the doubt.

The question of support is illustrated by the following examples:

Example (a):

A claim relates to a process for treating all kinds of "plant seedlings" by subjecting them to a controlled cold shock of such duration and intensity as to produce specified results. The description discloses the process applied to one kind of plant only. Since it is well known that plants vary widely in their properties, there are well-founded reasons for believing that the process is not applicable to all plant seedlings. Unless the applicant can provide convincing evidence that the process is nevertheless generally applicable, he must restrict his claim to the particular kind of plant referred to in the description. A mere assertion that the process is applicable to all plant seedlings is not sufficient.

Example (b):

A claim relates to a specified method of treating "synthetic resin mouldings" to obtain certain changes in physical characteristics. All of the examples described relate to thermoplastic resins and the method is such as to appear inappropriate to thermosetting resins. Unless the applicant can provide evidence that the method is nevertheless applicable to thermosetting resins, he must restrict his claim to thermoplastic resins.

An objection of lack of support can often, as in the examples above, be considered as an objection of insufficient disclosure of the invention, the objection being that the disclosure is insufficient to enable the skilled person to carry out the "invention" over the whole of the broad field claimed.

Support for dependent claims – Where certain subject-matter is clearly disclosed in a claim of the application as filed, but is not mentioned anywhere in the description, it is permissible to amend the description so that it includes this subject-matter.

Where the claim is dependent, it may suffice if it is mentioned in the description that the claim sets out a particular embodiment of the invention.

## **7. Unity of invention**

### **7.1 General remarks**

The basic rule governing unity is found in Art. 18(1) PA which says that "A separate patent application shall be filed for each invention."

Art. 18(2) PA further stipulates alternatively that "One patent application may be used to apply for patent grants for several inventions only if such inventions are so linked as to form a single general inventive concept."

The second of these alternatives, i.e. the single-concept linked group, may give rise to a plurality of independent claims in the same category. However, the more usual case is a plurality of independent claims in different categories.

It may be seen that the application of this Art. 18(2) PA requires an examination comprising a documentary search and the evaluation of novelty and inventive step.

Minor importance – The requirement of unity of invention is not a matter of major importance, because lack of unity is not a ground for invalidating a patent. There remain the fiscal reasons based on the fact that almost all fees are of a fixed amount. In laying down standards for unity, the lawmaker wishes to keep the workload of the Intellectual Property Office within reasonable limits, particularly the workload in respect of search and examination. Otherwise, individual inventors, whose applications are usually not very complex, would be obliged to pay for the large international companies that often group a number of successive inventions in the same field within one application.

### **7.2 Special technical features**

The following reasoning indicates how one determines whether or not the requirement of Art. 18(2) PA is fulfilled when more than one invention appears to be present.

The link between the inventions required by Art. 18(2) PA must be a technical relationship which finds expression in the claims in terms of the same or corresponding special technical features.

The expression "special technical features" means, in any one claim, the particular technical feature or features that define a contribution that the claimed invention considered as a whole makes over the prior art. Once the special technical features of each invention have been identified, one must determine whether or not there is a technical relationship between the inventions and, furthermore, whether or not this relationship involves these special technical features. It is not necessary that the special technical features in each invention be the same.

It should be clear that the required relationship may be found between corresponding technical features. An example of this correspondence is the following: in one claim the special technical feature which provides resilience is a metal spring, whereas in another claim it is a block of rubber.



### 7.3 Claims in different categories

- (i) A plurality of independent claims in different categories may constitute a group of inventions so linked as to form a single general inventive concept. In particular, Art. 18(2) PA should be construed as permitting the inclusion of any one of the following combinations of claims of different categories in the same application:
- (a) in addition to an independent claim for a given product, an independent claim for a process specially adapted for the manufacture of the said product, and an independent claim for a use of the product; or
  - (b) in addition to an independent claim for a given process, an independent claim for an apparatus or means *specifically* designed for carrying out the process; or
  - (c) in addition to an independent claim for a given product, an independent claim for a process specially adapted for the manufacture of the said product, and an independent claim for an apparatus or means *specifically* designed for carrying out the process.

The expression "specifically designed for" does not mean "exclusively designed for".

Other combinations of independent claims are possible without offending against the unity of invention requirement.

A plurality of independent claims in different categories may constitute a group of inventions so linked as to form a single general inventive concept, the link being e.g. that between a product and the process which produces it; or the link between a process and an apparatus for carrying out the process.

For example, where independent claims are allowable for two related articles such as a transmitter and a receiver, it does not follow that an applicant may be allowed to include also, in the one application, four additional independent claims: two claims for a process for the manufacture of the transmitter and the receiver respectively, and two claims for use of the transmitter and receiver respectively.

Moreover, it is essential that a single general inventive concept links the claims in the various categories.

The presence in each claim of expressions such as "specially adapted" or "specifically designed" does not necessarily imply that a single general inventive concept is present.

- (ii) Intermediate and final products – Unity of invention should be considered to be present in the context of intermediate and final products where:
- (a) the intermediate and final products have the same essential structural element, i.e. their basic chemical structures are the same or their chemical structures are technically closely interrelated, the intermediate incorporating an **essential** structural element into the final product, and
  - (b) the intermediate and final products are technically interrelated, i.e. the final product is manufactured directly from the intermediate or is separated from it by a small number of intermediates all containing the same **essential** structural element.
- (iii) Alternatives – Alternative forms of an invention may be claimed either in a plurality of independent claims or in a single claim. In the latter case the presence of the two alternatives as independent forms may not be immediately apparent. In either case, however, the same criteria should be applied in deciding whether or not there is unity of invention, and lack of unity of invention may then also exist within a single claim.

- (iv) Markush grouping – Where a single claim defines (chemical or non-chemical) alternatives, i.e. a so-called "Markush grouping", unity of invention should be considered to be present if the alternatives are of a similar nature.

When the Markush grouping is for alternatives of chemical compounds, they should be regarded as being of a similar nature where:

- (a) all alternatives have a common property or activity, and
- (b) a common structure is present, i.e. a significant structural element is shared by all of the alternatives, or all alternatives belong to a recognised class of chemical compounds in the art to which the invention pertains.

A "significant structural element is shared by all of the alternatives" where the compounds share a common chemical structure which occupies a large portion of their structures, or, in case the compounds have in common only a small portion of their structures, the commonly shared structure constitutes a structurally distinctive portion in view of existing prior art. The structural element may be a single component or a combination of individual components linked together. The alternatives belong to a "recognised class of chemical compounds" if there is an expectation from the knowledge in the art that members of the class will behave in the same way in the context of the claimed invention, i.e. that each member could be substituted one for the other, with the expectation that the same intended result would be achieved. If it can be shown that at least one Markush alternative is not novel, unity of invention should be reconsidered.

- (v) Individual features in a claim – Objection of lack of unity does not arise because of one claim containing a number of individual features, where these features do not present a technical inter-relationship (i.e. a combination), but merely a juxtaposition.

#### 7.4 Lack of unity "a priori", "a posteriori"

Lack of unity may be directly evident "a priori", i.e. before considering the claims in relation to the prior art, or may only become apparent "a posteriori", i.e. after taking the prior art into consideration. The latter happens when a document within the state of the art shows that there is lack of novelty or inventive step in an independent claim, thus leaving two or more dependent claims without a common inventive concept.

Examiner's approach – Although lack of unity may arise "a posteriori" as well as "a priori", it should be remembered that lack of unity is not a ground for revocation in later proceedings. Therefore, although the objection should certainly be made and amendment insisted upon in clear cases, it should neither be raised nor persisted in on the basis of a narrow, literal or academic approach. This is particularly so where the possible lack of unity does not necessitate a further search. There should be a broad, practical consideration of the degree of interdependence of the alternatives presented, in relation to the state of the art as revealed by the search.

If the common subject-matter of the independent claims is well known, and the remaining subject-matter of each claim differs from that of the others without there being any unifying novel concept common to all, then clearly there is lack of unity.

If, on the other hand, there is a common concept or principle which is novel and inventive, then objection of lack of unity does not arise. For determining what is allowable between these two extremes, rigid rules cannot be given and each case should be considered on its merits, the benefit of any doubt being given to the applicant.

## 7.5 Dependent claims

No objection on account of lack of unity is justified in respect of a dependent claim and the claim on which it depends, on the ground that the general concept they have in common is the subject-matter of the independent claim, which is also contained in the dependent claim.

Example: Claim 1 says:

"1. Turbine rotor blade shaped in a specified manner ...",

while claim 2 is for:

"2. Turbine rotor blade as claimed in claim 1 and characterised in that it is produced from alloy Z".

The common general concept linking the dependent with the independent claim is "turbine rotor blade shaped in a specified manner".

If, however, the independent claim appears not to be patentable, then the question whether there is still an inventive link between all the claims dependent on that claim needs to be carefully considered (see Lack of unity "a posteriori"). It may be that the "special technical features" of one claim dependent on this non-patentable independent claim are not present in the same or corresponding form in another claim dependent on that claim.

In most instances lack of unity will have been noted during the search. The examiner will then draw up a "partial" search report and send it to the applicant with the "Result of substantive examination". This "partial search" is based on those parts of the application which relate to the invention, or to the unified linked group of inventions, first mentioned in the claims. The other inventions are listed in the "partial" search report.

If unity is found to be lacking, the applicant should be required to limit his claims in such a way as to avoid the objection in the application under examination. Excision or amendment of parts of the description may also be necessary. One or more divisional patent applications, covering matter removed from the original application to meet this objection, may be filed during the further examination procedure.

## Chapter A-III. Priority

### 1. The right to priority

Art. 23-28 PA define the requirements for the grant of a priority right.

Validly claiming priority – For a valid claim to priority, the following conditions must be satisfied:

- (a) the previous application must have been made in or for a Member State of the Paris Convention or a Member of the World Trade Organization (WTO);
- (b) the previous application whose priority is claimed must have been filed by the applicant of the application filed in the Republic of Croatia or his predecessor in title;
- (c) the previous application must have been filed not more than 12 months before the filing date of the application filed in the Republic of Croatia; and
- (d) the previous application must have been the "first application" filed in respect of the same invention as the one to which the application filed in the Republic of Croatia relates.

First application – The filing date of the "first application" must be claimed as a priority, i.e. the application disclosing for the first time any or all of the subject-matter of the application filed in the Republic of Croatia. If it is found that the application to which the priority claim is directed is in fact not the first application in this sense, but some or all of the subject-matter was disclosed in a still earlier application filed by the same applicant or his predecessor in title, the priority claim is invalid insofar as the subject-matter was already disclosed in the still earlier application.

Multiple priorities – "Multiple priorities may be claimed" – i.e. a Croatian application may claim rights of priority based on more than one previous application. The previous application may have been filed in or for the same or different States or Members of the WTO. However, in all cases the earliest application must have been filed not more than 12 months before the date of filing of the application in the Republic of Croatia. Subject-matter of an application filed in the Republic of Croatia will be accorded the priority date of the earliest priority application which discloses it. If, for instance, the application filed in the Republic of Croatia describes and claims two embodiments (A and B) of an invention, A being disclosed in a French application and B in a German application, both filed within the preceding 12 months, the priority dates of both the French and German applications may be claimed for the appropriate parts of the application filed in the Republic of Croatia. Embodiment A will have the French priority date and embodiment B the German priority date as effective dates.

### 2. Determining priority dates

Examining the validity of a right to priority – As a general rule, the examiner should not make any investigation as to the validity of a right to priority. However, the priority right assumes importance if prior art has to be taken into account which has been made available to the public on or after the priority date claimed and before the date of filing (e.g. an intermediate document). In such cases (i.e. cases where the art in question would be relevant if of earlier date), the examiner must investigate whether the priority date(s) claimed may be accorded to the appropriate parts of the application he is examining and should inform the applicant of the outcome and whether, in consequence, the particular prior art under consideration, e.g. the intermediate document, forms part of the state of the art.

"Same invention" – The basic test to determine whether a claim is entitled to the date of a priority document is, as far as the requirement of "the same invention" is concerned, the same as the test for determining whether or not an amendment to an application satisfies the requirement of

Art. 33 PA. That is to say, for the priority date to be valid in this respect the subject-matter of the claim must be directly and unambiguously derivable from the disclosure of the invention in the priority document, also taking into account any features implicit to a person skilled in the art in what is expressly mentioned in the document.

Example of an implicit disclosure: a claim to an apparatus including "releasable fastening means" would be entitled to the priority date of a disclosure of that apparatus in which the relevant fastening element was, say, a nut and bolt, or a spring catch or a toggle-operated latch, provided the general concept of "releasable" is implicit in the disclosure of such element.

It is not necessary that the subject-matter for which priority is claimed be found among any claims in the previous application. It is sufficient that the documents of the previous application taken as a whole "specifically disclose" such subject-matter. The description and any claims or drawings of the previous application should, therefore, be considered as a whole in deciding this question, except that account should not be taken of subject-matter found solely in that part of the description referring to prior art, or in an explicit disclaimer.

### **3. Claiming priority**

Art. 24 PA says that the applicant intending to take advantage of the right of priority in the Republic of Croatia shall file with the Office:

(1) a priority claim containing essential data concerning the first application (priority country, application number, filing date).

This claim should be filed not later than 2 months from the filing date.

(2) a copy of the first application certified by the foreign patent office. The copy should be filed within the periods defined by Art. 24(2) PA.

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## PART B – PATENTABILITY

### Chapter B-I.

#### Exclusions from patent protection

##### 1. Inventions

###### 1.1 Exclusions

The Patent Act does not define what is meant by "invention", but Art. 5(6) PA contains a non-exhaustive list of things which are not regarded as inventions. It will be noted that the items on this list are all either abstract (e.g. discoveries, scientific theories, etc.) and/or non-technical (e.g. aesthetic creations or presentations of information). In contrast to this, an "invention" must be new, involve an inventive step and be susceptible of industrial application (Art. 5(1) PA).

It must be defined, according to Art. 5(1) PA, exclusively in terms of its technical features. An invention must therefore be of a technical character. It may be in any field of technology.

###### 1.2 Examination practice

In considering whether the subject-matter of an application is an invention within the meaning of Art. 5(1) PA, there are two general points the examiner must bear in mind. Firstly, any exclusion from patentability under Art. 5(6) PA applies only to the extent to which the application relates to the excluded subject-matter as such (Art. 5(7) PA). Secondly, the examiner should concentrate on the content of the claim in order to identify whether the claimed subject-matter, considered as a whole, has a technical character. If it does not, there is no invention within the meaning of Art. 5(1) PA.

The items on the list of exclusions given in Art. 5(6) PA will now be dealt with in turn, and further examples will be given in order to clarify the distinction between what is patentable and what is not.

###### 1.3 Discoveries

If a new *property* of a known material or article is uncovered, it must be considered as a mere discovery and therefore as unpatentable since discovery as such has no technical effect. It is therefore not an invention within the meaning of Art. 5(1) PA. If, however, that property is put to practical use, then this constitutes an invention which may be patentable.

Example: the discovery that a particular known material is able to withstand mechanical shock would not be patentable, but a railway sleeper made from that material could well be patentable.

To find a previously unrecognised substance occurring in nature is also considered as a mere discovery and is therefore unpatentable. However, if that substance found in nature can be shown to produce a technical effect, it may be patentable. An example of such a case is that of a substance occurring in nature which is found to have an antibiotic effect.

In addition, if a microorganism is discovered to exist in nature and to produce an antibiotic, the microorganism itself may also be patentable as one aspect of the invention. Similarly, a gene which is discovered to exist in nature may be patentable if a technical effect is revealed, e.g. its use in making a certain polypeptide or in gene therapy.

## 1.4 Scientific theories

These are a more generalised form of discoveries, and the same principle as set out in 1.3, above, applies.

Example: the physical theory of semiconductivity would not be patentable. However, new semiconductor devices and processes for manufacturing these may be patentable.

## 1.5 Mathematical methods

These are a particular example of the principle that purely abstract or intellectual methods are not patentable.

Example: a shortcut method of division would not be patentable but a calculating machine constructed to operate accordingly may well be patentable.

Example: a mathematical method for designing electrical filters is not patentable; nevertheless filters designed according to this method would not be excluded from patentability by Art. 5(6) PA and Art. 5(7) PA.

## 1.6 Aesthetic creations

An aesthetic creation relates by definition to an article (e.g. a painting or sculpture) having aspects which are other than technical and the appreciation of which is essentially subjective. If, however, the article happens also to have technical features, it might be patentable, a tyre tread being an example of this. The aesthetic effect itself is not patentable, neither in a product nor in a process claim.

Example: a book claimed solely in terms of the aesthetic or artistic effect of its information content, of its layout or of its letter font, would not be patentable, and neither would a painting defined by the aesthetic effect of its subject or by the arrangement of colours, or by the artistic (e.g. Impressionist) style.

Nevertheless, if an aesthetic effect is obtained by a technical structure or other technical means, although the aesthetic effect itself is not patentable, the means of obtaining it may be.

Example: a fabric may be provided with an attractive appearance by means of a layered structure not previously used for this purpose, in which case a fabric incorporating such structure might be patentable.

Example: a book defined by a technical feature of the binding or pasting of the back may be patentable, even though it has an aesthetic effect too, similarly also a painting defined by the kind of cloth, or by the dyes or binders used.

Also a process of producing an aesthetic creation may comprise a technical innovation and thus be patentable.

Example: a diamond may have a particularly beautiful shape (not in itself patentable) produced by a new technical process. In this case, the process may be patentable.

Example: a new printing technique for a book resulting in a particular layout with aesthetic effect may well be patentable, together with the book as a product of that process.

Again, a substance or composition defined by technical features serving to produce a special effect with regard to scent or flavour, e.g. to maintain a scent or flavour for a prolonged period or to accentuate it, may well be patentable.

### 1.7 Rules, instructions or methods for performing mental activities, playing games or doing business

These are further examples of items of an abstract or intellectual character. In particular, a method for learning a language, a method of solving crossword puzzles, a game (as an abstract entity defined by its rules) or instructions for organising a commercial operation would not be patentable.

However, if the claimed subject-matter specifies an apparatus or technical process for carrying out at least some part of the scheme, that scheme and the apparatus or process have to be examined as a whole. In particular, if the claim specifies computers, computer networks or other conventional programmable apparatus, or a program therefor, for carrying out at least some steps of a scheme, it is to be examined as a "computer-implemented invention". (see B-I, 1.9)

### 1.8 Presentation of information

A representation of information defined solely by the content of the information is not patentable. This applies whether the claim is directed to the presentation of the information per se (e.g. by acoustical signals, spoken words, visual displays, books defined by their subject, gramophone records defined by the musical piece recorded, traffic signs defined by the warning thereon) or to processes and apparatus for presenting information (e.g. indicators or recorders defined solely by the information indicated or recorded).

If, however, the presentation of information has new technical features, there could be patentable subject-matter in the information carrier or in the process or apparatus for presenting the information. The arrangement or manner of representation, as distinct from the information content, may well constitute a patentable technical feature.

Examples in which such a technical feature may be present are:

- a telegraph apparatus or communication system using a particular code to represent the characters (e.g. pulse code modulation)
- a measuring instrument designed to produce a particular form of graph for representing the measured information, and
- a gramophone record having a particular groove form to allow stereo recordings.

### 1.9 Computer-implemented inventions

Programs for computers are a form of "computer-implemented invention", an expression intended to cover claims which involve computers, computer networks or other programmable apparatus whereby one or more of the features of the claimed invention are realised by means of a program or programs. Such claims may e.g. take the form of a method of operating said apparatus, the apparatus set up to execute the method, or the program itself. Insofar as examination practice is concerned, no distinctions are made on the basis of the overall purpose of the invention, i.e. whether it is intended to fill a business niche or to provide some new entertainment, etc.

The basic patentability considerations in respect of claims directed to computer programs are in principle the same as for other subject-matter. While "computer programs" are included among the items listed in Art. 5(6) PA as exclusions, if the claimed subject-matter has a technical character it is not excluded from patentability by the provisions of Art. 5(6) PA. If a computer program is capable of bringing about, when running on a computer, a further technical effect going beyond normal physical effects (e.g. electrical currents), it is not excluded from patentability. This further technical effect may be known in the prior art. A further technical effect which lends technical character to a computer program may be found e.g. in the control of an industrial process or in processing data which represent physical entities or in the internal functioning of the computer itself or its interfaces under the influence of the program and could, for example, affect the efficiency or security of a process, the management of computer resources required or the



rate of data transfer in a communication link.

As a consequence, a computer program may be considered as an invention within the meaning of Art. 5(1) PA if the program has the potential to bring about, when running on a computer, a further technical effect which goes beyond the normal physical interactions between the program and the computer. A patent may be granted on such a claim if all other requirements of the law, in particular with regard to novelty and inventive step, are met. Such claims should not contain program listings, but should define all the features which assure patentability of the process which the program is intended to carry out when it is run.

In assessing whether there is an inventive step, the examiner must establish an objective technical problem which has been overcome. The solution of that problem constitutes the invention's technical contribution to the art. The presence of such a technical contribution establishes that the claimed subject-matter has a technical character and therefore is indeed an invention within the meaning of Art. 5(1) PA. If no such objective technical problem is found, the claimed subject-matter does not satisfy at least the requirement for an inventive step because there can be no technical contribution to the art. The claim is then to be rejected on this ground.

## **2. Patentable biotechnological inventions**

### General remarks and definitions

"Biotechnological inventions" are inventions which concern a product consisting of or containing biological material or a process by means of which biological material is produced, processed or used (Art. 5(2)1PA and Art. 5(2)2 PA). "Biological material" means any material containing genetic information and capable of reproducing itself or being reproduced in a biological system (Art. 5(3) PA).

### Patentable biotechnological inventions

In principle, biotechnological inventions are patentable under Art. 5(2) PA and Art. 5(4) PA. For patent applications filed in the Republic of Croatia and patents granted in the Republic of Croatia concerning biotechnological inventions, the relevant provisions of the law are Art. 5(2)-(5) PA, Art. 6 PA and Art. 7(2) PA. European Union Directive 98/44/EC of 6 July 1998 on the legal protection of biotechnological inventions is to be used as a supplementary means of interpretation.

Biotechnological inventions are also patentable if they concern an item on the following non-exhaustive list:

- (i) biological material isolated from its natural environment or produced by means of a technical process even if it previously occurred in nature (Art. 5(2)3 PA).

Hence, biological material may be considered patentable even if it already occurs in nature.

Although the human body, at the various stages of its formation and development, and the simple discovery of one of its elements, including the sequence or partial sequence of a gene, cannot constitute patentable inventions (Art. 6.2 PA), an element isolated from the human body or otherwise produced by means of a technical process, including the sequence or partial sequence of a gene, may constitute a patentable invention, even if the structure of that element is identical to that of a natural element.

The reason such an element is not a priori excluded from patentability is that it is, for example, the result of technical processes used to identify, purify and classify it and to produce it outside the human body, techniques which human beings alone are capable of putting into practice and which nature is incapable of accomplishing itself (EU Dir. 98/44/EC, rec. 21). The industrial application of a sequence or a partial sequence of a gene must be disclosed in the patent application as originally filed (Art. 6.2 PA).

- (ii) plants or animals if the technical feasibility of the invention is not confined to a particular plant or animal variety;

Inventions which concern plants or animals are patentable provided that the technical feasibility of the invention is not confined to a particular plant or animal variety and if the process for carrying out the invention is not essentially biological (Art. 5(4) PA).

Therefore, a claim wherein specific plant varieties are not individually claimed is not excluded from patentability under Art. 6.1 PA even though it may embrace plant varieties. The subject-matter of a claim covering but not identifying plant varieties is not a claim to a variety or varieties. In the absence of the identification of a specific plant variety in a product claim, the subject-matter of the claimed invention is neither limited nor directed to a variety or varieties within the meaning of Art. 6.1 PA; or

- (iii) a microbiological or other technical process, or a product obtained by means of such a process other than a plant or animal variety.

"Microbiological process" means any process involving or performed upon or resulting in microbiological material (Art. 6.1 PA).

### 3. Exceptions to patentability

#### 3.1 Matter contrary to "*ordre public*" or morality

Any invention the commercial exploitation of which would be contrary to "*ordre public*" or morality is specifically excluded from patentability under Art. 7(1) PA. The purpose of this is to deny protection to inventions likely to induce riot or public disorder, or to lead to criminal or other generally offensive behaviour.

Anti-personnel mines are an obvious example.

This provision is likely to be invoked only in rare and extreme cases. A fair test to apply is to consider whether it is probable that the public in general would regard the invention as so abhorrent that the grant of patent rights would be inconceivable. If it is clear that this is the case, objection should be raised under Art. 7(1) PA, otherwise not.

Example: a process for breaking open locked safes may at first sight appear to be contrary to "*ordre public*" as it may be employed by a burglar. However, in an emergency a locksmith may also employ the process. In such a case, no objection arises under Art. 7(1) PA.

Example: if a claimed invention defines a copying machine with features resulting in an improved precision of reproduction and an embodiment of this apparatus could comprise further features (not claimed but apparent to the skilled person) the only purpose of which would be that it should also allow reproduction of security strips in banknotes strikingly similar to those in genuine banknotes, the claimed apparatus would cover an embodiment for producing counterfeit money which could be considered to fall under Art. 7(1) PA. There is, however, no reason to consider the copying machine as claimed to be excluded from patentability, since its improved properties could be used for many acceptable purposes.

However, if the application contains expressions or drawings pertaining to a use which is contrary to "*ordre public*" or morality, deletion of the same should be required under the terms of Art. 10(1)1 PR. Alternatively, the Office may omit said expressions or drawings from its publications, indicating the place and number of words or drawings omitted; Art. 10(2) PR.

#### 3.2 Prohibited matter

Exploitation is not to be deemed to be contrary to "*ordre public*" or morality merely because such exploitation is prohibited by Croatian law or other regulation (Art. 7(1) PA). One reason for this is

that a product could still be manufactured under a patent granted in the Republic of Croatia for export to states in which its use is not prohibited.

### 3.3 Biotechnological inventions

In the area of biotechnological inventions, the following list of exceptions to patentability is laid down in Art. 7(2) PA. The list is illustrative and non-exhaustive and is to be seen as giving concrete form to the concept of "*ordre public*" and "*morality*" in this technical field.

According to Art. 7(2) PA, patents in the Republic of Croatia are not to be granted in respect of biotechnological inventions which concern:

- (i) processes for cloning human beings;

For the purpose of this exception, a process for the cloning of human beings may be defined as any process, including techniques of embryo splitting, designed to create a human being with the same nuclear genetic information as another living or deceased human being (EU Dir. 98/44/EC, rec. 41).

- (ii) processes for modifying the germ line genetic identity of human beings;

- (iii) uses of human embryos for industrial or commercial purposes;

The exclusion of the uses of human embryos for industrial or commercial purposes does not affect inventions for therapeutic or diagnostic purposes which are applied to the human embryo and are useful to it (EU Dir. 98/44/EC, rec. 42).

- (iv) 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.

The substantial medical benefit referred to above includes any benefit in terms of research, prevention, diagnosis or therapy (EU Dir. 98/44/EC, rec. 45).

In addition, the human body, at the various stages of its formation and development, and the simple discovery of one of its elements, including the sequence or partial sequence of a gene, cannot constitute patentable inventions.

Such stages in the formation or development of the human body include germ cells and totipotent cells (EU Dir. 98/44/EC, recs. 16 and 38).

### 3.4 Animal breeds and plant varieties

The list of exceptions to patentability includes "animal breeds, plant varieties and essentially biological processes for the production of plants or animals" – Art. 6.1 PA.

The term "plant variety" may be defined as any plant grouping within a single botanical taxon of the lowest known rank, which grouping, irrespective of whether the conditions for the grant of a plant variety right are fully met, can be:

- (a) defined by expressions of the characteristics that result from a given genotype or combination of genotypes,
- (b) distinguished from any other plant grouping by the expression of at least one of the said characteristics, and
- (c) considered as a unit with regard to its suitability for being propagated unchanged (Plant Variety Protection Act, OG 62/00, N.N. 131(97), Art. 2(1)).

A patent is not to be granted if the claimed subject-matter is directed to a specific plant variety or specific plant varieties (Art. 6.1 PA). However, if the invention concerns plants or animals and if the technical feasibility of the invention is not confined to a particular plant variety or animal breed, the invention is patentable (Art. 5(4) PA).

When a claim to a process for the production of a plant variety is examined, Art. 58(3)3 PA is not to be taken into consideration. Hence, a process claim for the production of a plant variety (or plant varieties) is not a priori excluded from patentability merely because the resulting product constitutes a plant variety.

### 3.5 Processes for the production of plants or animals

A process for the production of plants or animals is essentially biological if it consists entirely of natural processes such as crossing or selection (Art. 5(5) PA).

Example: a method of crossing, inter-breeding, or selectively breeding, say, horses involving merely selecting for breeding and bringing together those animals having certain characteristics would be essentially biological and therefore unpatentable according to Art. 6.1 PA.

On the other hand, a process of treating a plant or animal to improve its properties or yield or to promote or suppress its growth would not be essentially biological since, although a biological process is involved, the essence of the invention is technical.

Example: a method of pruning a tree or the treatment of soil by technical means to suppress or promote the growth of plants would not be excluded from patentability.

### 3.6 Microbiological processes

Art. 6.1 PA states that the exclusion of "animal breeds, plant varieties and essentially biological processes for the production of plants or animals" from patentability does not apply to non-biological processes or to microbiological processes or the products thereof.

A "microbiological process" means any process involving or performed upon or resulting in microbiological material (Art. 6.1 PA). Hence, the term "microbiological process" is to be interpreted as covering not only processes performed upon microbiological material or resulting in such, e.g. by genetic engineering, but also processes which as claimed include both microbiological and non-microbiological steps.

Art. 6.1 PA also states that the products of a microbiological process are not excluded from patentability (product claim). It should be noted, however, that claims for plant or animal varieties cannot be allowed even if the variety is produced by means of a microbiological process (Art. 6.1 PA). The exception to patentability of animal breeds and plant varieties mentioned in Art. 6.1 PA applies to plant varieties irrespective of the way in which they are produced.

Repeatability of the results of microbiological processes is of particular importance. Particular regard should be had to the requirement of repeatability referred to in A-I, 6.1, above: "Inventions relating to biological material; public availability".

As for biological material deposited in a recognised institution under the terms of Art. 20(5) PA, repeatability is assured by the possibility of taking samples (Art. 13 PR), and there is therefore no need to indicate another process for the production of the biological material in the application.

### 3.7 Surgery, therapy and diagnostic methods

Art. 6.3 PA states that "Diagnostic or surgical methods or methods of treatment practised directly on the human or animal body, with the exception of the products, in particular substances or compositions, used in such methods" are to be excluded from patentability.

Hence, patents may be obtained for surgical, therapeutic or diagnostic instruments or apparatuses for use in such methods.

Example: the manufacture of prostheses or artificial limbs could be patentable.

Example: a method of manufacturing insoles in order to correct the posture or a method of manufacturing an artificial limb should be patentable.

In both of the above cases, taking the imprint of the footplate or a moulding of the stump on which an artificial limb is fitted is clearly not of a surgical nature. Furthermore, the insoles as well as the artificial limb are manufactured outside the body.

A method which requires a surgical step may not be considered as patentable. Similarly, a claim directed to a method of treatment of a patient by administering a particular therapeutic substance may not be considered as patentable. Such claims may, for example, be drafted in the form "Use of substance or composition X for the treatment of disease Y ..." and should be regarded as relating to a method for treatment explicitly excluded from patentability under Art. 6.3 PA and therefore should not be accepted.

### 3.8 Products for use in surgery, therapy or diagnostic methods

According to Art. 6.3 PA, products, in particular substances or compositions, used in diagnostic or surgical methods or methods of treatment are not excluded from patentability.

Patents may therefore be obtained for new products, particularly substances or compositions, for use in these methods of treatment or diagnosis. According to Art. 8(4) PA, where the substance or composition is known, it may only be patented for use in these methods if the known substance or composition was not previously disclosed for use in diagnostic or surgical methods, or methods of treatment practised directly on the human or animal body ("first medical use").

Example: a chemical compound known in the prior art as a fungicide for plants may subsequently be patented as a product per se for use in the treatment of diabetes.

Such a claim to a known substance or composition for the first use in surgical, therapeutic and/or diagnostic methods should be in a form such as: "Substance or composition X" followed by the indication of the use, for instance "... for use as a medicament", "... as an antibacterial agent" or "... for curing disease Y".

Art. 8(4) PA thus provides for an exception from the general principle that product claims can only be obtained for (absolutely) novel products. However, this does not mean that product claims for the first and further medical uses need not fulfil all other requirements of patentability, especially that of inventive step.

### 3.9 Second medical indication

- (a) Where a substance or composition is already known to have been used in a "first medical use" (see 3.8, above), it may still be patentable under Art. 8(4) PA for any second or further use in a method according to Art. 6.3 PA, provided that its use in the process mentioned does not form part of the state of the art.
- (b) Alternatively, a claim in the form "Use of a substance or composition X for the manufacture of a medicament for therapeutic application Z" is allowable for either a first or "subsequent" (second or further) such application ("Swiss- type" claim), if this application is new and inventive.

Example: if a particular chemical compound is known from the prior art for the treatment of diabetes, a claim directed to the use of the same compound for the manufacture of a

medicament for the treatment of migraine is also patentable, if such further use is inventive over the originally disclosed use.

In cases where an applicant simultaneously discloses more than one "subsequent" therapeutic use, claims of the above type directed to these different uses are allowable in the one application, but only if they form a single general inventive concept (Art. 18(2) PA).

Regarding use or method claims of the above type, it should also be noted that a mere pharmaceutical effect does not necessarily imply a therapeutic application.

For instance, the selective occupation of a specific receptor by a given substance cannot be considered in itself as a therapeutic application. Indeed, the discovery that a particular substance selectively binds a receptor, even if said discovery represents an important piece of scientific knowledge, still needs to find an application in the form of a defined, real treatment of a pathological condition in order to make a technical contribution to the art and to be considered as an invention eligible for patent protection.

### *Second or further medical use of known pharmaceutical products*

Where a substance or composition is already known to have been used in a "first medical use", it may still be patentable under Article 8(5) for any second or further use in a method according to Article 6.3, provided that said use does not form part of the state of the art.

Article 8(5) thus provides for an exception from the general principle that product claims can only be obtained for (absolutely) novel products. However, this does not mean that product claims for the first and further medical uses need not fulfil all other requirements of patentability, especially that of inventive step.

A claim in the form "Use of substance or composition X for the treatment of disease Y..." will be regarded as relating to a method for treatment explicitly excluded from patentability under Article 6.3 and therefore will not be accepted. A claim in the form "Substance X for use as a medicament" is acceptable, even if X is a known substance, but its use in medicine is not known. Likewise, it is acceptable to have a claim in the form "Substance X for use in the treatment of disease Y", provided that such claim involves an inventive step over any prior art disclosing the use of X as a medicament.

Treating disease with already known substance or composition where the only difference from known treating is dosage regime, represents an example of specific further medical use according to Article 8(5).

Claimed subject matter is novel if the use of medicament is novel and such an invention cannot be expressed as a "Swiss-type" claim.

"Swiss-type" claim relates to purpose-limited **process** claim (use claim), and claims in the form mention above relates to purpose-limited **product** claim (product claim) and these claims give different scope of protection.

### 3.10 Limitations of exclusion under Art. 6.3 PA

It should be noted that the exclusions under Art. 6.3 PA (see 3.7, above) are confined to methods for treatment of the human or animal body by diagnostic or surgical methods or therapy practised on the human or animal body. It follows that other methods of treatment of live human beings or animals or other methods of measuring or recording characteristics of the human or animal body are patentable, provided that (as would probably be the case) such methods are of a technical and not essentially biological character.

Example: treatment of a sheep in order to promote growth, to improve the quality of mutton or to increase the yield of wool.

Example: an application containing claims directed to the purely cosmetic treatment of a human by administration of a chemical product is considered as being patentable. Cosmetic treatment involving surgery or therapy would, however, not be patentable.

Additionally, to be excluded from patentability, a treatment or diagnostic method must actually be carried out on the living human or animal body. A treatment of or diagnostic method practised on a dead human or animal body would therefore not be excluded from patentability by virtue of Art. 6.3 PA. Treatment of body tissues or fluids after they have been removed from the human or animal body, or diagnostic methods applied thereon, are not excluded from patentability insofar as these tissues or fluids are not returned to the same body. Thus the treatment of blood for storage in a blood bank or diagnostic testing of blood samples is not excluded, whereas a treatment of blood by dialysis with the blood being returned to the same body would be excluded.

A method claim is not allowable under Art. 6.3 PA if it includes at least one step defining a treatment of the human or animal body by surgical means or therapy, or a diagnostic method.

It should be noted that "surgery" need not be therapeutic to be excluded under Art. 6.3 PA; surgery for cosmetic purposes is also excluded from patentability. "Therapy" implies the curing of a disease or malfunction of the body and also covers prophylactic treatment, e.g. immunisation against a certain disease.

## Chapter B-II. Patentability criteria

### 1. Basic requirements for patentability

Art. 5(1) PA states that:

"A patent shall be granted for any invention, in any field of technology, which is new, which involves an inventive step and which is eligible for industrial application."

This means that there are four basic requirements for patentability:

- (a) There must be an "invention".
- (b) The invention must be "new".
- (c) The invention must involve an "inventive step".
- (d) The invention must be susceptible of "industrial application".

Requirement (a) is dealt with in the previous chapter. Requirements (b), (c) and (d) will be dealt with in turn in this chapter.

In addition to these four requirements, the examiner should be aware of the following two requirements that are implicitly contained in the Patent Act and the Patent Regulations.

- (e) The invention must be such that it can be carried out by a person skilled in the art (after proper instruction by the application). This follows from Art. 20(4) PA: sufficient disclosure of the invention.
- (f) The invention must be of "technical character" to the extent that it must relate to a technical field, must be concerned with a technical problem, and must have technical features. The matter for which protection is sought shall be defined in the claims in terms of these technical features.

The Patent Act does not require explicitly or implicitly that an invention, to be patentable, must provide some technical progress or even any useful effect. The usefulness of the invention shall not be examined in the substantive examination as to patentability.

Nevertheless, advantageous effects, if any, with respect to the state of the art should be stated in the description. Any such effects are often important in determining the presence of an "inventive step".

### 2. Industrial application

Art. 11 PA states that:

"An invention shall be industrially applicable if its subject-matter can be manufactured or used in any kind of industry, including agriculture".

"Industry" shall be understood in the broad sense as including any physical activity of "technical character", i.e. an activity which belongs to the useful or practical arts as distinct from the aesthetic arts. It does not necessarily imply the use of a machine or the manufacture of an article and could cover e.g. a process for dispersing fog, or a process for converting energy from one form to another. Thus, Art. 11 PA excludes from patentability very few "inventions" which are not already excluded by the lists of "exclusions" – Art. 5(6) PA and Art. 6 PA.



## 2.1 Method of testing

Methods of testing generally should be regarded as inventions susceptible of industrial application and therefore patentable if the test is applicable to the improvement or control of a product, apparatus or process which is itself susceptible of industrial application. In particular, the utilisation of test animals for test purposes in industry, e.g. for testing industrial products (for example for ascertaining the absence of pyrogenetic or allergic effects) or phenomena (for example for determining water or air pollution) would be patentable.

Industrial application vs. exclusions – It should be noted that "industrial applicability" is not a requirement that overrides the restrictions of Art. 5(6) PA.

Example:

An administrative method of stock control is not patentable, having regard to Art. 5(6) PA – Business methods – even though it could be applied to the store of spare parts of a factory.

On the other hand, although an invention must be "susceptible of industrial application" and the description must indicate, where this is not apparent, the way in which the invention is thus susceptible, the claims need not necessarily be restricted to the industrial application(s).

## 2.2 Sequences and partial sequences of genes

In general it is required that the description of a patent application filed in the Republic of Croatia should, where this is not self-evident, indicate the way in which the invention is capable of exploitation in industry. In relation to sequences and partial sequences of genes, this general requirement is given specific form in that the industrial application of a sequence or a partial sequence of a gene must be disclosed in the patent application.

A mere nucleic acid sequence without indication of a function is not a patentable invention (EU Dir. 98/44/EC, rec. 23). In cases where a sequence or partial sequence of a gene is used to produce a protein or a part of a protein, it is necessary to specify which protein or part of a protein is produced and what function this protein or part of a protein performs. Alternatively, when a nucleotide sequence is not used to produce a protein or part of a protein, the function to be indicated could e.g. be that the sequence exhibits a certain transcription promoter activity.

## 2.3 "Perpetuum mobile" devices

Lack of industrial application – One class of "invention" which would be excluded from patentability for lack of industrial application would be articles or processes alleged to operate in a manner clearly contrary to well-established physical laws, e.g. a perpetual motion machine. Objection could arise under Art. 11 PA (lack of industrial application) only in so far as the claim specifies the intended function or purpose of the invention. However, if a perpetual motion machine is claimed merely as an article having a particular specified construction, then objection should be made under Art. 20(4) PA (sufficient disclosure).

Lack of sufficient disclosure – Occasionally applications are filed in which there is a fundamental insufficiency in the invention in the sense that it cannot be carried out by a person skilled in the art. There is then a failure to satisfy the requirements of Art. 20(4) PA, which is essentially irreparable.

One instance is where successful performance of the invention is inherently impossible because it would be contrary to well-established physical laws. This applies e.g. to a perpetual motion machine.

An objection could indicate that

- the stated problem (to generate perpetual motion without energy input) cannot be solved because it is against well-established physical laws,
- the solution claimed in the claim(s) is technically not feasible.

If the claims for such a machine are directed to its function, and not merely to its structure, an objection arises not only under Art. 20(4) PA, but also under Art. 11 PA, that the invention is not "technically feasible".

## 2.4 Inventions in fields where natural laws are not yet established

If an invention is related to a field where natural laws are yet to be established, then it cannot be carried out by a person skilled in the art. In this case the invention suffers from lack of sufficient disclosure, and an objection should be made under Art. 20(4) PA. This failure to satisfy the requirements of Art. 20(4) PA is essentially irreparable.

This applies to e.g. dowsing-rod, shield against geopathogenic radiation, pyramidal energy plant, etc.

## 3. State of the art

Art. 8(1) PA says that: "An invention shall be new if it does not form part of the state of the art."

The definition of the "state of the art" is derived from Art. 8(2) PA:

"The state of the art shall comprise everything made available to the public at the global level by means of written or oral description, by use or in any other way, prior to the date of filing of the patent application."

The width of this definition should be noted. There are no restrictions whatever as to the geographical location where, or the language or manner in which, the relevant information was made available to the public ("universal novelty"). Also no age limit is stipulated for the documents or other sources of the information. There are, however, certain specific exclusions, namely non-prejudicial disclosures. However, the "state of the art" available to the examiner will normally consist of the documents listed in the search report part of the examiner communication.

A problem likely to arise for the examiner is where:

- (a) a document reproduces an oral description (e.g. a public lecture) or gives an account of a prior use (e.g. display at a public exhibition); and
- (b) only the oral description or the prior use was publicly available before the "date of filing" of the application filed in the Republic of Croatia, the document itself being published on or after this filing date.

Such a document can be used in determining novelty.

For the examination of the novelty of claimed subject-matter, see B- II.5.

## 4. Conflict with other patent rights of earlier date

According to Art. 8(3) PA, the definition of the "state of the art" has been extended:

"The state of the art shall also include the content of all patent applications as filed with effect for the Republic of Croatia, the filing dates of which are earlier than the filing date of the present

application, and which were made available to the public (by publication) only on, or after the date of filing the patent application."

(i) Conflict with national applications filed in the Republic of Croatia

The state of the art thus also comprises the content of other applications filed in the Republic of Croatia (HR A2 documents) filed earlier than, but published on or after, the date of filing of the application under examination.

Such earlier applications filed in the Republic of Croatia are part of the state of the art only when considering novelty. This earlier application filed in the Republic of Croatia is not used when assessing inventive step. Again, the "date of filing" is to be interpreted as meaning the date of priority in appropriate cases.

By the content of an application filed in the Republic of Croatia is meant the whole disclosure, i.e. the description, drawings and claims, including any matter explicitly disclaimed or prior art explicitly described ("whole content approach"). However, the "content" includes neither any priority document nor the abstract. The purpose of the priority document is merely to determine to what extent the priority date applies to the disclosure of the application filed in the Republic of Croatia. It is important to note that it is the content of the earlier application as filed which is to be considered when applying Art. 8(3) PA.

(ii) Conflict with European or international applications

Other earlier rights in the territory of Croatia may relate to European or PCT patent applications where Croatia is a designated or elected state.

Art. 105(1) PA and Art. 108g(1) PA stipulates that "A European patent application and a European patent shall have, with regard to a national patent application and a national patent, the same state of the art effect as a national patent application and a national patent." Thus such European patent applications may be conflicting applications for determining the novelty of applications filed in the Republic of Croatia.

Art. 111(5) PA stipulates that "An international application published under Article 21 of the PCT shall not be considered state of the art under Art. 8(3) PA", as long as the PCT application has not entered into the national phase in the Republic of Croatia as required by Art. 111(1) PA.

This means that after entry into the national Croatian phase, these PCT applications may also be conflicting applications for determining the novelty of applications filed in the Republic of Croatia.

(iii) The decisive point in time for determining whether and to what extent a published Croatian, European or international application is a conflicting application is the date of its publication.

If a priority claim in respect of the application under examination was abandoned or otherwise lost with effect from a date prior to the publication of the conflicting application, the filing date and not the priority date is relevant, irrespective of whether or not the priority claim might have conferred a valid priority right.

If the conflicting application has been withdrawn or otherwise lost before the date of publication, but published because the preparations for publication have been completed, the publication is not to be considered a conflicting application. Art. 8(3) PA must be interpreted as referring to the publication of a "valid" application, i.e. a patent application filed in the Republic of Croatia valid at its publication date. Changes taking effect after the date of publication do not affect the application of Art. 8(3) PA.

## 5. Test for novelty

### 5.1 State of the art

Art. 8(1) PA says that: "An invention shall be new if it does not form part of the state of the art."

It should be emphasised that in considering novelty (as distinct from inventive step), it is not permissible to combine separate items of prior art together. This means that normally an embodiment from only one single document can be used for formulating a novelty objection.

However, if a document (the "primary document") refers explicitly to another document (e.g. as providing more detailed information on certain features), the teaching of that other document (e.g. a "Zusatzpatent") may be regarded as incorporated into the document containing the reference.

Equally, it is permissible to use a dictionary or similar document of reference in order to interpret a special term used in the primary document. The effective date for novelty purposes is always the date of the primary document.

### 5.2 Implicit features or well-known equivalents

A document takes away the novelty of any claimed subject-matter derivable directly and unambiguously from that single document. Included are, however, any features implicit to a person skilled in the art in what is expressly mentioned in the document.

Example: A disclosure of the use of rubber in circumstances where clearly its elastic properties are used even if this is not explicitly stated takes away the novelty of the use of an elastic material.

The limitation to subject-matter "derivable directly and unambiguously" from the document is important. Thus, when considering novelty, it is not correct to interpret the teaching of a document as embracing well-known equivalents which are not disclosed in the documents. This is a matter of inventive step.

### 5.3 Relevant date of prior art document

In determining novelty a prior document should be read as it would have been read by a person skilled in the art on the relevant date of the document. By "relevant" date is meant the publication date in the case of a previously published document and the date of filing (or priority date, where appropriate) in the case of a conflicting Croatian document according to Art. 8(3) PA.

However, it should be noted that a chemical compound, the name or formula of which was mentioned in a document, is not thereby considered as known unless the information in the document, together, where appropriate, with knowledge generally available on the relevant date of the document, enables it to be prepared and separated or, for instance in the case of a product of nature, only to be separated.

### 5.4 Generic disclosure and specific examples

In considering novelty it should be borne in mind that a generic disclosure does not usually take away the novelty of any specific example falling within the terms of that disclosure, but that a specific disclosure does take away the novelty of a generic claim embracing that disclosure.

Examples:

1. A disclosure of copper takes away the novelty of metal as a generic concept, but not the novelty of any metal other than copper.

2. The disclosure of rivets takes away the novelty of fastening means as a generic concept, but not the novelty of any fastening other than rivets.

In the case of a prior document, the lack of novelty may be apparent from what is explicitly stated in the document itself. Alternatively, it may be implicit in the sense that, in carrying out the teaching of the prior document, the skilled person would inevitably arrive at a result falling within the terms of the claim. An objection of lack of novelty of this kind should be raised by the examiner only where there can be no reasonable doubt as to the practical effect of the prior teaching.

## 5.5 Examination of novelty

In determining novelty of the subject-matter of claims the examiner should have regard to the guidance given in A-II, 4 – Clarity and interpretation of claims. In particular, he should remember that non-distinctive characteristics of a particular intended use should be disregarded.

Example: A claim to a substance X for use as a catalyst would not be considered to be novel over the same substance known as a dye, unless the use referred to implies a particular form of the substance (e.g. the presence of certain additives) which distinguishes it from the known form of the substance.

That is to say, characteristics not explicitly stated, but implied by the particular use, should be taken into account.

Example: In deciding the novelty of a hook for a crane over a known fish hook of similar shape, one should take into account the differences of size and strength implied by these uses.

## 5.6 Novelty of selection inventions

Selection inventions deal with the selection of individual elements, sub-sets, or sub-ranges, which have not been explicitly mentioned, within a larger known set or range.

- (i) In determining the novelty of a selection, it has to be decided whether the selected elements are disclosed in an individualised (concrete) form in the prior art. A selection from a single list of specifically disclosed elements does not confer novelty. However, if a selection from two or more lists of a certain length has to be made in order to arrive at a specific combination of features, then the resulting combination of features, not specifically disclosed in the prior art, confers novelty.

Examples of such selections from two or more lists are the selection of:

- (a) individual chemical compounds from a known generic (Markush) formula whereby the compound selected results from the selection of specific substituents from two or more "lists" of substituents given in a known prior art generic formula. The same applies to specific mixtures resulting from the selection of individual components from lists of components making up the prior art mixture;
  - (b) starting materials for the manufacture of a final product;
  - (c) sub-ranges of several parameters from corresponding known ranges.
- (ii) A sub-range selected from a broader numerical range of the prior art may be considered novel, if each of the following three criteria is fulfilled:
    - (a) the selected sub-range is narrow compared to the known range;
    - (b) the selected sub-range is sufficiently far removed from any specific examples disclosed in the prior art and from the end-points of the known range;

- (c) the selected range is not an arbitrary specimen of the prior art, i.e. not a mere embodiment of the prior art, but another invention, i.e. a new technical teaching.

An effect occurring only in the claimed sub-range cannot in itself confer novelty on that sub-range. However, such a technical effect occurring in the selected sub-range, but not in the whole of the known range, can confirm that criterion (c) is met, i.e. that the invention is novel and not merely a specimen of the prior art. The meaning of "narrow" and "sufficiently far removed" has to be decided on a case-by-case basis. The new technical effect occurring within the selected range may also be the same effect as that attained with the broader known range, but to a greater extent.

- (iii) In the case of overlapping ranges (e.g. numerical ranges) of the claimed subject-matter and the prior art, the examiner must decide which subject-matter has been made available to the public by the prior art disclosure and thus forms part of the state of the art. As to overlapping ranges or numerical ranges of physical parameters, novelty is destroyed by an explicitly mentioned end-point of the known range, explicitly mentioned intermediate values or a specific example of the prior art in the overlap. It is not sufficient to exclude specific novelty destroying values known from the prior art range, it must also be considered whether the skilled person, in the light of the technical facts and taking into account the general knowledge in the field to be expected from him, would seriously contemplate applying the technical teaching of the prior art document in the range of overlap. If it can be fairly assumed that he would do so, it must be concluded that no novelty exists.

## 6. Non-prejudicial disclosures

There are two specified instances (and these are the only two) in which the prior disclosure of the invention shall not be taken into consideration as part of the state of the art, namely where the disclosure was due to:

- an evident abuse in relation to the applicant or his legal predecessor, e.g. the invention was derived from the applicant and disclosed against his wish; or
- the display of the invention by the applicant at an official or officially recognised international exhibition.

An essential condition is that the disclosure must have taken place not earlier than six months preceding the date of filing the application.

For these so-called "non-prejudicial disclosures", the "period of grace" is six months. See Art. 9 PA.

- (i) Evident abuse – Regarding evident abuse, the disclosure might be made in a published document or in any other way. As a particular instance, the disclosure might be made in a application filed in the Republic of Croatia of earlier priority date.

Example: A person B who has been told of A's invention in confidence, might himself apply for a patent for this invention. If so, the disclosure resulting from the publication of B's application will not prejudice A's rights provided that A has already made an application, or applies within six months of such publication. In any event, having regard to Art. 9.1 PA, B may not be entitled to proceed with his application.

- (ii) International exhibition – According to Art. 9.2 PA "An invention shall also be considered to be new if, not more than six months prior to the filing date of the patent application, it formed part of the state of the art due to: ... the display at an official or officially recognised international exhibition in compliance with the Convention on International Exhibitions, signed at Paris on 22 November 1928 and last revised on 30 November 1972".

In the instance of a recognised international exhibition, the patent application must be made within 6 months of the disclosure of the invention at the exhibition if the display is not to prejudice the application. Furthermore, the applicant must state, at the time of filing the application, that the invention has been so displayed, and must also file a supporting certificate within 4 months from the date of filing, giving the particulars required in the priority certificate.

Priority can only be derived from one of the very limited number of exhibitions which are official, or officially recognised, international exhibitions.

A list of these international exhibitions is available at <http://www.epo.org/law-practice/legal-texts/official-journal/2014/04/a48.html>

## **7. Inventive step**

### **7.1 Definition**

Art. 10(1) PA defines the patentability criterion of inventive step:

"An invention shall involve an inventive step if, having regard to the state of the art, it is not obvious to a person skilled in the art."

Assessing inventive step consists in ascertaining whether, having regard to the "closest relevant prior art", the invention "would not have been obvious" to a person having ordinary skill in the art. This is one of the cornerstones of any system for the protection of inventions. Protection should not be validly given to what is already known and forms part of the prior art. Nor should protection be given to everything that the person with ordinary skill in the art could deduce as an obvious consequence thereof.

Removal of the requirement of non-obviousness would amount to giving an unjust monopoly to a person whose only merit would be to have been the first to apply for a patent for an innovation that was within the reach of any person with ordinary skill in the art and consequently also within the reach of competitors. Such a policy would retard technological progress rather than advance it.

Novelty and inventive step are different criteria. Novelty exists if there is any difference between the invention and the known Art. The question: "Is there inventive step ?", only arises if there is already novelty.

### **7.2 State of the art**

The "state of the art" for the purposes of considering inventive step is as defined in Art. 8(2) PA:

"The state of the art shall comprise everything made available to the public at the global level by means of written or oral description, by use or in any other way prior to the filing date of the patent application."

However, Art. 10(2) PA indicates that: "In deciding whether an invention involves an inventive step, the content of the applications referred to in Art. 8(3) PA – conflicting applications – shall not be taken into consideration."

### **7.3 Person skilled in the art**

This skilled person should be presumed to be an ordinary practitioner in a field of technology aware of what was common general knowledge in the art at the relevant date. He should also be presumed to have had access to everything in the "state of the art", such as the documents cited in the search report part of the examiner communication. He should further be presumed to have had at his disposal the normal means and capacity for routine work and experimentation.

If the problem prompts the person skilled in the art to seek its solution in another technical field, the specialist in that field is the person qualified to solve the problem. The assessment of whether the solution involves an inventive step must therefore be based on that specialist's knowledge and ability.

There may be instances where it is more appropriate to think in terms of a group of persons, e.g. a research or production team, than a single person. This may apply e.g. in certain advanced technologies such as computers or telephone systems and in highly specialised processes such as the commercial production of integrated circuits or of complex chemical substances.

#### 7.4 Obviousness

Thus the question to consider, in relation to any claim defining the invention, is whether at the priority date of that claim, having regard to the closest prior art known at the time, it would have been obvious to the person skilled in the art to arrive at something falling within the terms of the claim. If so, the claim is not allowable for lack of inventive step.

The term "obvious" means what does not go beyond the normal progress of technology but merely follows plainly or logically from the prior art. "Obvious" is something which does not involve the exercise of any skill or ability beyond that to be expected of the person skilled in the art. In considering inventive step, as distinct from novelty, it is fair to construe any published document in the light of subsequent knowledge and to have regard to all the knowledge generally available to the person skilled in the art at the priority date of the claim.

#### 7.5 Combination vs. juxtaposition or aggregation

The invention claimed in one claim must normally be considered as a whole. When a claim consists of a **"combination of features"**, it is not correct to argue that the separate features of the combination taken by themselves are known or obvious and that "therefore" the whole subject-matter claimed is obvious.

However, where the claim is merely an **"aggregation or juxtaposition of features"** and not a true combination, it is enough to show that the individual features are obvious to prove that the aggregation of features does not involve an inventive step. A set of technical features is regarded as a combination of features if the functional interaction between the features achieves a combined technical effect which is different from, e.g. greater than, the sum of the technical effects of the individual features. In other words, the interactions of the individual features must produce a synergistic effect. If no such synergistic effect exists, there is no more than a mere aggregation of features.

Example:

The technical effect of an individual transistor is essentially that of an electronic switch. However, transistors interconnected to form a microprocessor synergically interact to achieve technical effects, such as data processing, which are over and above the sum of their respective individual technical effects.

#### 7.6 Origin of an invention

While the claim should in each case be directed to technical features (and not, for example, merely to an idea), in order to assess whether an inventive step is present it is important for the examiner to bear in mind that there are various ways in which the skilled person may arrive at an invention.



An invention may, for example, be based on the following:

- (i) The formulation of a new idea or of a yet unrecognised problem to be solved (the solution being obvious once the problem is clearly stated).

Example:

Appropriate tests by the applicant revealed that the effect of a known chemical formulation was no longer satisfactory after prolonged storage, the claimed solution being retrospectively trivial and in itself obvious.

- (ii) The devising of a solution to a known problem.

Example:

The problem of permanently marking farm animals such as cows without causing pain to the animals or damage to the hide has existed since farming began. The solution ("freeze branding") consists in applying the discovery that the hide can be permanently depigmented by freezing.

- (iii) The arrival at an insight into the cause of an observed phenomenon (the practical use of this phenomenon then being obvious).

Example:

The agreeable flavour of butter is found to be caused by minute quantities of a particular compound. As soon as this insight has been arrived at, the technical application comprising adding this compound to margarine is immediately obvious.

Many inventions are of course based on a combination of the above possibilities – e.g. the arrival at an insight and the technical application of that insight may both involve the use of the inventive faculty.

## 7.7 Problem-and-solution approach

In practice, in order to assess inventive step in an objective and predictable manner, the examiner should normally apply the so-called "**problem-and-solution approach**".

In the problem-and-solution approach, there are **three main stages**:

- determining the "closest prior art",
- establishing the "objective technical problem" to be solved, and
- considering whether or not the claimed invention, starting from the closest prior art and the objective technical problem, would have been obvious to the skilled person.

- (i) Determination of the closest prior art

The closest prior art is that combination of features, disclosed in one single reference, which constitutes the most promising starting point for an obvious development leading to the invention. In selecting the closest prior art, the first consideration is that it should be directed to a similar purpose or effect as the invention or at least belong to the same or a closely related technical field as the claimed invention.

In practice, the closest prior art is generally that which corresponds to a similar use and requires the minimum of structural and functional modifications to arrive at the claimed invention.

The closest prior art must be assessed from the skilled person's point of view on the day before the filing or priority date valid for the claimed invention.

In identifying the closest prior art, account should be taken of what the applicant himself acknowledges in his description and claims to be known. Any such acknowledgement of known art should be regarded by the examiner as being correct.

#### (ii) Formulation of the objective technical problem

In the second stage, one establishes in an objective way the **technical problem** to be solved. To do this one has to study the application, the closest prior art and the difference (also called "the **distinguishing feature(s)**" of the invention) in terms of features (either structural or functional) between the invention and the closest prior art and then formulates the technical problem.

Features which cannot be seen to make any contribution, either independently or in combination with other features, to the technical character of an invention are not relevant for assessing inventive step. Such a situation can occur for instance if a feature only contributes to the solution of a non-technical problem, for instance a problem in a field excluded from patentability.

In the context of the problem-and-solution approach, the technical problem means the aim and task of modifying or adapting the closest prior art to provide the technical effects that the invention provides over the closest prior art. The technical problem thus defined is often referred to as the "**objective technical problem**".

The objective technical problem derived in this way may not be what the applicant presented as "the problem" in his application. The latter may require reformulation, since the objective technical problem is based on objectively established facts, in particular facts appearing in the prior art revealed in the course of the search. This may be different from the prior art of which the applicant was actually aware at the time the application was filed.

In particular, the prior art cited in the search report part of the examiner communication may put the invention in an entirely different perspective from that apparent from reading the application only.

The expression "technical problem" should be interpreted broadly; it does not necessarily imply that the technical solution is a technical improvement over the prior art. Thus the problem could be simply to seek an alternative to a known device or process providing the same or similar effects or which is more cost-effective.

#### (iii) Could-would approach

In the third stage the question to be answered is whether there is any teaching in the prior art as a whole that **would** (not simply could, but would) have prompted the skilled person, faced with the objective technical problem, to modify or adapt the closest prior art while taking account of that teaching, thereby arriving at something falling within the terms of the claims, and thus achieving what the invention achieves.

In other words, the point is not whether the skilled person could have arrived at the invention by adapting or modifying the closest prior art, but whether he **would have done** so because the prior art incited him to do so in the hope of solving the objective technical problem or in expectation of some improvement or advantage. This must have been the case for the skilled person before the filing or priority date valid for the claim under examination.

### 7.8 Combining prior-art documents

It is permissible to combine the disclosure of one or more documents, parts of documents or other pieces of prior art (e.g. a public prior use) with the closest prior art. However, the fact that more than one disclosure must be combined with the closest prior art in order to arrive at a combination of features may be the sign of the presence of an inventive step.

In considering whether there is inventive step (as distinct from novelty), it is permissible to combine together the disclosures of two or more documents or parts of documents, different parts of the same document or other pieces of prior art. This combination is, however, only permissible where such combination would have been obvious to the person skilled in the art at the effective priority date of the claim under examination.

In determining whether it would be obvious to combine two or more distinct documents, the examiner should have regard to the following:

- (a) Whether the content of the documents is such as to make it likely or unlikely that the person skilled in the art, when concerned with the problem solved by the invention, would combine them.

For example, if two disclosures considered as a whole could not in practice be readily combined because of inherent incompatibility in disclosed features essential to the invention, the combining of these disclosures should not normally be regarded as obvious.

- (b) Whether the documents come from similar, neighbouring or remote technical fields.

- (c) The number of documents which need to be combined.

Normally only two documents are combined. The combining of two or more parts of the same document would be obvious if it would be natural for the skilled person to associate these parts with one another. It would normally be obvious to combine with other prior documents a well-known textbook or standard dictionary.

This is only a special case of the general proposition that it is obvious to combine the teaching of one or more documents with the **common general knowledge** in the art. It would, generally speaking, also be obvious to combine two documents one of which contains a clear and unmistakable reference to the other. In determining whether it is permissible to combine a document with an item of prior art made public in some other way, e.g. by use, similar considerations apply.

## 7.9 Indicators of inventive step

**"Ex post facto" analysis** – It should be remembered that an invention which at first sight appears obvious might in fact involve an inventive step. Once a new idea has been formulated it can often be shown theoretically how it might be arrived at, starting from something known, by a series of apparently easy steps. The examiner should be wary of ex post facto analysis of this kind. He should always bear in mind that the documents produced in the search have, of necessity, been obtained with foreknowledge of what matter constitutes the alleged invention. In all cases he should attempt to visualise the overall state of the art confronting the skilled man before the applicant's contribution. He should seek to make a "real-life" assessment of this and other relevant factors. He should take into account all that is known concerning the background of the invention and give fair weight to relevant arguments or evidence submitted by the applicant.

**Surprising technical advantage** – If, for example, an invention is shown to be of considerable technical value, and particularly if it provides a technical advantage which is new and surprising, and this can convincingly be related to one or more of the features included in the claim defining the invention, the examiner should be hesitant in pursuing an objection that such a claim lacks inventive step.

**Long-felt need** – Where the invention solves a technical problem which workers in the art have been attempting to solve for a long time, or otherwise fulfils a long-felt need, this may be regarded as an indication of inventive step.

Commercial success – This alone is not to be regarded as indicative of inventive step, but evidence of immediate commercial success when coupled with evidence of a long-felt want is of relevance provided the examiner is satisfied that the success derives from the technical features of the invention and not from other influences (e.g. selling techniques or advertising).

#### 7.10 Arguments and evidence submitted by the applicant

The relevant arguments and evidence to be considered by the examiner for assessing inventive step may be taken either from the originally filed patent application, or be submitted by the applicant during the subsequent examination proceedings, e.g. in a letter of reply.

Care must be taken, however, whenever new effects in support of inventive step are referred to. Such new effects can only be taken into account if they are implied by or at least related to the technical problem initially suggested in the originally filed application.

Example of such a new effect:

The invention as filed relates to a pharmaceutical composition having a specific activity. At first sight, having regard to the relevant prior art, it would appear that there is a lack of inventive step. Subsequently, the applicant submits new evidence which shows that the claimed composition exhibits an unexpected advantage in terms of low toxicity.

In this case, it is allowable to reformulate the technical problem by including the aspect of toxicity, since pharmaceutical activity and toxicity are related in the sense that the skilled person would always contemplate the two aspects together.

The reformulation of the technical problem may or may not give rise to amendment or insertion of the statement of the technical problem in the description. Any such amendment is only allowable if it satisfies the conditions listed in D-IV, 6.2. In the above example of a pharmaceutical composition, neither the reformulated problem nor the information on toxicity could be introduced into the description without infringing Art. 33 PA – unallowable extension.

Burden of proof – With regard to inventive step, the burden of proof lies with the person who challenges its existence, as in the case of novelty. In general, it is not for the patent applicant to show what is original or unexpected in his invention ("An invention is born valid!"), but rather for the person who denies inventive step, such as the examiner, who has to support his objection. To that end the examiner has to establish what was the closest prior art on the priority date by citing facts with supporting evidence, e.g. documents. He also has to show what, having regard to the prior art, would have been obvious to the skilled person and why.

#### 7.11 Inventive step of selection inventions

The subject-matter of selection inventions differs from the closest prior art in that it represents selected sub-sets or sub-ranges. If this selection is connected to a particular technical effect, and if no hints exist leading the skilled person to the selection, then an inventive step is acknowledged.

The technical effect occurring within the selected range may be the same effect as attained with the broader known range, but to an unexpected degree. The criterion of "seriously contemplating" mentioned in connection with the test for novelty of overlapping ranges should not be confused with the assessment of inventive step. For inventive step, it has to be considered whether the skilled person would have made the selection or would have chosen the overlapping range in the hope of solving the underlying technical problem or in expectation of some improvement or advantage. If the answer is negative, then the claimed matter involves an inventive step.

EXAMPLES of non-inventive selections:

- (i) An obvious and consequently non-inventive selection among a number of known

possibilities would be a case in which the invention consists merely in choosing from a number of equally likely alternatives.

Example: The invention relates to a known chemical process in which it is known to supply heat electrically to the reaction mixture. There are a number of well-known alternative ways of so supplying the heat, and the invention resides merely in the choice of one alternative.

- (ii) Similarly if the invention resides in the choice of particular dimensions, temperature ranges or other parameters from a limited range of possibilities, and it is clear that these parameters could be arrived at by routine trial and error or by the application of normal design procedures, the selection is not considered inventive.

Example: If the invention relates to a process for carrying out a known reaction and is characterised by a specified rate of flow of an inert gas and the prescribed rates are merely those which would necessarily be arrived at by the skilled practitioner, the selection is not considered inventive.

- (iii) The invention can be arrived at merely by a simple extrapolation in a straightforward way from the known art.

Example: The invention is characterised by the use of a specified minimum content of a substance X in a preparation Y in order to improve its thermal stability, and this characterising feature can be derived merely by extrapolation on a straight-line graph, obtainable from the known art, relating thermal stability to the content of substance X.

- (iv) The invention consists merely in selecting particular chemical compounds or compositions (including alloys) from a broad field.

Example: The prior art includes disclosure of a chemical compound characterised by a specified structure including a substituent group designated "R". This substituent "R" is defined so as to embrace entire ranges of broadly-defined radical groups such as all alkyl or aryl radicals either unsubstituted or substituted by halogen and/or hydroxy, although for practical reasons only a very small number of specific examples are given. The invention consists in the selection of a particular radical or particular group of radicals from amongst those referred to as the substituent "R" (the selected radical or group of radicals not being specifically disclosed in the prior-art document since the question would then be one of lack of novelty rather than obviousness). The resulting compounds are neither described as having nor shown to possess any advantageous properties not possessed by the prior art examples.

#### EXAMPLES of inventive selections:

- (i) The invention involves special selection in a process of particular operating conditions (e.g. temperature and pressure) within a known range, such selection producing unexpected effects in the operation of the process or the properties of the resulting product.

Example: In a process where substance A and substance B are transformed at high temperature into substance C, it was known that there is in general a constantly increased yield of substance C as the temperature increases in the range between 50 and 130 °C. It is now found that in the temperature range from 63 to 65 °C, which previously had not been explored, the yield of substance C was considerably higher than expected.

- (ii) The invention consists in selecting particular chemical compounds or compositions (including alloys) from a broad field, such compounds or compositions having unexpected advantages.

Example: In the example of a substituted chemical compound given at (iv) above, the invention again resides in the selection of the substituent radical "R" from the total field of possibilities defined in the prior disclosure.

In this case, however, not only does the selection embrace a particular area of the possible field, and result in compounds that can be shown to possess advantageous properties, but there are no indications which would lead the person skilled in the art to this particular selection rather than any other in order to achieve the advantageous properties.

#### 7.12 Dependent claims; claims in different categories

If an independent claim is new and not obvious, there is no need to investigate the obviousness or non-obviousness of any claims dependent thereon. Similarly, if a claim to a product is new and non-obvious there is no need to investigate the obviousness of any claims for a process which inevitably results in the manufacture of that product or any claims for use of that product.

#### 7.13 EXAMPLES for assessing inventive step

The following list gives examples, for guidance, of instances where an invention should be regarded as obvious or where it involves an inventive step. It is to be stressed that these examples are only for illustrative purposes and that the applicable principle in each case is the question: "Was it obvious to a person skilled in the art?".

Examiners should avoid attempts to fit a particular case into one of the examples if it is not clearly applicable. The list is not exhaustive.

##### (A1) Non-inventive application of known measures

Inventions involving the application of known measures in an obvious way and in respect of which an inventive step is to be ruled out:

- (i) The teaching of a prior document is incomplete and at least one of the possible ways of **"filling the gap"** which would naturally or readily occur to the skilled person results in the invention.

Example: The invention relates to a building structure made from aluminium. A prior document discloses the same structure and says that it is of light-weight material but fails to mention the use of aluminium.

- (ii) The invention differs from the known art merely in the use of **well-known equivalents** (mechanical, electrical or chemical).

Example: The invention relates to a pump which differs from a known pump solely in that its motive power is provided by a hydraulic motor instead of an electric motor.

- (iii) The invention consists merely in a new use of a well-known material employing the **known properties** of that material.

Example: Washing composition containing as detergent a known compound having the known property of lowering the surface tension of water, this property being known to be an essential one for detergents.

- (iv) The invention consists in the substitution in a known device of a recently developed material whose properties make it plainly suitable for that use (**"analogous substitution"**).

Example: An electric cable comprises a polyethylene sheath bonded to a metallic shield by an adhesive. The invention lies in the use of a particular newly developed adhesive known to be suitable for polymer-metal bonding.

- (v) The invention consists merely in the use of a known technique in a closely analogous situation ("**analogous use**")

Example: The invention resides in the application of a pulse control technique to the electric motor driving the auxiliary mechanisms of an industrial truck, such as a fork-lift truck, the use of this technique to control the electric propulsion motor of the truck being already known.

#### (A2) Inventive application of known measures

Inventions involving the application of known measures in a non-obvious way and in respect of which an inventive step is therefore to be recognised:

- (i) A known working method or means when used for a different purpose involves a new, **surprising effect**.

Example: It is known that high-frequency power can be used in inductive butt welding. It should therefore be obvious that high-frequency power could also be used in conductive butt welding with similar effect. An inventive step would exist in this case, however, if high-frequency power were used for the continuous conductive butt welding of coiled strip but without removing scale (such scale removal being, on the face of it, necessary in order to avoid arcing between the welding contact and the strip). The unexpected additional effect is that scale removal is found to be unnecessary because at high frequency the current is supplied in a predominantly capacitive manner via the scale which forms a dielectric.

- (ii) A new use of a known device or material involves **overcoming technical difficulties** not resolvable by routine techniques.

Example: The invention relates to a device for supporting and controlling the rise and fall of gas holders, enabling the previously employed external guiding framework to be dispensed with. A similar device was known for supporting floating docks or pontoons but practical difficulties not encountered in the known applications needed to be overcome in applying the device to a gas holder.

#### (B1) Non-inventive combination invention

Obvious and consequently non-inventive combination of features:

The invention consists merely in the **juxtaposition** or association of known devices or processes functioning in their normal way and not producing any non-obvious working inter-relationship.

Example: Machine for producing sausages consists of a known mincing machine and a known filling machine disposed side by side.

#### (B2) Inventive combination invention

Not obvious and consequently inventive combination of features:

The combined features mutually support each other in their effects to such an extent that a new technical result is achieved. It is irrelevant whether each individual feature is fully or partly known by itself.

Example: A mixture of medicines consists of a painkiller (analgesic) and a tranquilliser (sedative). It was found that through the addition of the tranquilliser, which intrinsically appeared to have no painkilling effect, the analgesic effect of the painkiller was intensified in a way which could not have been predicted from the known properties of the active substances.

(C) Overcoming a technical prejudice

As a general rule, there is an inventive step if the prior art leads the person skilled in the art away from the procedure proposed by the invention. This applies in particular when the skilled person would not even consider carrying out experiments to determine whether these were alternatives to the known way of overcoming a real or imagined technical obstacle.

Example: Drinks containing carbon dioxide are, after being sterilised, bottled while hot in sterilised bottles. The general opinion is that immediately after withdrawal of the bottle from the filling device the bottled drink must be automatically shielded from the outside air so as to prevent the bottled drink from spurting out. A process involving the same steps but in which no precautions are taken to shield the drink from the outside air (because none are in fact necessary) would therefore be inventive.

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## PART C – TASKS BEFORE PUBLICATION OF NATIONAL APPLICATIONS

### Chapter C-I.

#### Procedure before publication

##### 1. Receiving Office

A patent application is received at the Receiving Office, which accepts the documents filed purporting to be a patent application.

- Clerical staff assigns the date, hour, internal administrative class (not IPC). They also allot the provisional filing number, e.g. P20060008\_
- Bibliographical data are entered into the Receiving Office's "POST" database.
- To each filed document is assigned a code identifying the kind of document, e.g. Request, description, claims, drawings, power of attorney, evidence of payment of fees, etc.
- All the documents constituting the purported patent application are scanned and stored in pdf format in SIPO databases.
- On filing, the applicant immediately receives the proof of filing the documents purporting to be a patent application; that is to say the request for the grant of a patent with the marked date, hour and internal administrative class.
- A paper file wrapper is created.

Capture of patent procedure data – It is to be noted that, throughout the procedure, data concerning all incoming documents and all outgoing official communications are scanned and stored in SIPO databases. Such data are e.g. the date of receipt of a reply letter, the effective date of an official communication, the kind of official letter or reply letter, the cancellation or the extension of a time limit, and so on.

#### **e-Filing**

The following documents can be filed in electronic form:

- Request for the grant of a patent – P1 form with accompanied enclosures,
- Request for the entry of the extended European patent into the Croatian Register of Patents – PE form with accompanied enclosures,

The data from electronically filed patent application are automatically stored in SIPO databases.

##### 2. Accordance of a filing date; formal examination

The formal examination of a patent application upon its receipt is carried out according to Art. 29 PA. After receiving an application a Officer of the Legal Service shall execute the following tasks:

- (1) Accordance of a filing date. This task is carried out with absolute priority and within the shortest time possible.

The minimum conditions to be satisfied in order that a filing date can be accorded and the filed documents be considered a patent application are stipulated in Art. 21.1-3 PA.

If the documents in the patent file wrapper comply with all the requirements of Art. 21 PA, a filing date is accorded. To the provisional application number there is assigned the suffix "A", e.g. P2006008A, and a decision to that effect is issued. The application for which the filing date has been accorded is entered into the Register of Patent Applications – Art. 30(1) PA.

(2) Check if the administrative fee and procedural charges for filing an application are paid – Art. 16 PA.

(3) Further formalities checks include:

- check for completeness of data on the P1 "Request for grant" form (applicant/inventor name, address, signature, priority data, etc.),
- check of list of enclosures, check for missing documents (description, claims, drawings, abstract),
- presentation of documents (script, format, margins, subheadings in description),
- check for the presence of priority document(s).

(4) Check that the translation of the application into the Croatian language is filed.

(5) Check that the drawings referred to in the description have been filed.

(6) Representation: Authorisation for patent representative

Check if the foreign applicant who is a natural or legal person having his or its domicile or principal place of business outside Croatia is represented by a patent representative or any other persons entitled according to the Law Governing Representation in the Field of Industrial Property Rights.

Officer of the Legal Service sends out:

- a communication inviting the applicant to correct filing deficiencies, within a time limit of 2 months, extendable by a further 3 months.

### **3. Formal examination before publication**

The Legal Service executes all the formal examination work to be carried out before publication of the application (HR A2 publication), with the exception of the final classification of the application.

The examination before publication has two aspects: a formal aspect and a substantive aspect.

### **4. Substantive examination before publication**

This check is carried out by a patent examiner. The examination of the pre-requisites for the publication of a patent application shall establish whether the application complies with the following requirements – Art. 34 PA:

- (1) Does it contain all the elements referred to in Art. 20 PA and the necessary attachments (Content of the patent application) and are they drafted in the prescribed manner,
- (2) Classification of the application according to the IPC,
- (3) Check of the abstract, see A-I, 5 and A-I, Annex 1.,

(4) Does the application relate to a secret invention.

If this examination establishes that the requirements are not complied with, the Office shall invite the applicant to correct the deficiencies expressly indicated in the invitation within a time limit of 2 to 3 months. If the applicant does not correct the deficiencies stated in the invitation in time, the Office shall issue a decision on refusal.

## **5. Secret applications**

The grant of patents for inventions which are of interest for national defence matters ("secret inventions") is regulated by the Law on the Production, Overhaul and Trade of Arms and Military Equipment.

The applicant may file an application for a secret invention with the Office in accordance with the provisions of the Patent Act and the Patent Regulations. However, when examining the patent application for compliance with the formal requirements and some substantive requirements before publication of the application, the Office may establish that the application concerns a secret invention.

The Office shall promptly inform the Ministry of Defence accordingly in writing and shall send it a copy of the patent application as filed, together with the results of the examination before publication of the application. This will be sent out before publication of the patent application in the Intellectual Property Gazette of the Republic of Croatia. This normally takes place within 60 to 180 days from receipt of the application.

The Ministry of Defence shall inform the Office and the applicant of the decision that it has made in accordance with the criteria laid down in the Regulation on the criteria for establishing the secrecy of inventions, and the manner of granting patents for such inventions, no later than 90 days from the date of receipt of the patent application transmitted to it by the Office.

If the Ministry of Defence decides that a secret invention is concerned, it shall issue a decision to that effect and shall enter it in the Register of Patents for Secret Inventions kept by it. If the Ministry considers that the invention is not secret, the procedure shall be carried out by the Office and in accordance with the Patent Act.

If the Ministry of Defence does not inform the Office of its interest in the patent application concerned within a period of 90 days, the invention shall be deemed not to be of interest for defence matters, and the procedure shall be carried out in accordance with the Patent Act.

Patent applications for secret inventions shall not be published in the Official Gazette of the Office and shall be treated by the Office as secret files.

Domestic legal and natural persons may seek protection for secret inventions abroad only with the authorisation of the Ministry of Defence.

## **6. IPC classification**

The complete IPC classification of an application at the advanced level of the IPC is a task for the appropriate examiner of the Patent Examination Section. See C-II.

Most foreign-origin applications are received through the PCT route after entry into the national phase. They are already published and IPC classified by an International Searching Authority.

## **7. Publication of the application**

Preparation for the publication of the patent application (HR A2 document) is carried out by the Legal Service.

This task includes:

- Preparation of the electronic digitised format (WORD document) of the patent application by Optical Character Reading (OCR),
- Monitoring the 18-month time limit after the priority date (or 3 months from the filing date, in the case of submission of a request for early publication of the application),
- Information concerning amendment of the title or abstract,
- sending a communication announcing HR A2 publication to the applicant together with the HR A2 document.

This HR A2 publication takes place within 18 months after the priority date in the Official Gazette, which publishes the bibliographical data, including the abstract and a drawing. The full text and drawings of the patent application are published on paper and via the SIPO website <https://www.dziv.hr/en/e-services/on-line-database-search/patents/> on the day of its publication in the Official Gazette.

## **8. Refusal of application for formal deficiencies**

If a formal deficiency cannot be remedied or has not been remedied in time, a decision on refusal is to be drafted by the Legal Service. The patent application will then not be published.

## **Chapter C-II.**

### **Classification of the application**

#### **1. Importance of correct classification**

It is extremely important that published patent applications filed in the Republic of Croatia (HR A2 documents) be correctly classified. If they are not, it is not possible to execute searches among HR A2 documents in the field of technology concerned, or at least to rely on the results of such searches. Such searches are essential for the extent of protection to be granted by new Croatian patents and also as a source of technical information.

Correct classification should enable a reliable search to be carried out in a systematic collection of applications filed in the Republic of Croatia classified according to "Int. Cl.".

Furthermore, international consistency in classification needs to be guaranteed. A correct and complete classification by the examiners will help them greatly during the search on these applications once a Request for examination has been filed and the search and substantive examination has to start.

#### **2. International Patent Classification (IPC)**

By "classification" is meant the assigning of one or more International Patent Classification (IPC) symbols ("Int. Cl.") to a particular application, whereby the technical subject of the invention of that application is identified.

By "preclassification" is meant a first stage of classification, e.g. up to IPC subclass level. It serves the purpose of internal routing within SIPO, and the subject of the claimed invention (or the invention first claimed, if there is more than one) is broadly identified by means of the appropriate classification symbols.

By "final classification" is meant the assigning of the appropriate classification symbols identifying the technical subject of the claimed invention (or the subjects of each of the claimed inventions, if there is more than one). Such identification should be as precise and comprehensive as the classification permits.

Assistance in the use of the classification is also provided by the Guide to the International Patent Classification.

In addition, non-obligatory classification or indexing symbols may be attributed to any additional information contained in the description of the document to be classified, which should be identified according to the Guide to the International Patent Classification. These procedures are more fully explained in the IPC Guide.

See <https://www.wipo.int/publications/en/series/index.jsp?id=183>

#### **3. Preclassification**

In order that an application may be sent to the appropriate examiner, a provisional classification must be made by a member of the Patent Examination Section. The classification can be effected on the basis of a quick and cursory scrutiny of the document (e.g. title, abstract and independent claims). The most appropriate level will usually be that of the Int. Cl. subclass.

The Int. Cl. symbols attributed by foreign patent offices on priority documents can be used as guidance. For internal routing of PCT applications after entry into the national phase, the IPC printed on them is used.

### First classification

The preclassification should be made on the basis of the independent claims. If this results in classification in more than one subclass, then whichever of these seems to be the most relevant to the claimed invention (or the invention first claimed, if there is lack of unity) should be selected. This is the classification which should be indicated first.

The Head of the Patent Examination Section distributes the incoming applications to the relevant examiners for final classification at a later stage.

### Incorrect preclassification

If, on reaching the examiner, an application has been found to have an incorrect provisional classification, a new correct provisional classification should be indicated by this examiner or the name of the corresponding examiner should be specified. Normally this will be done after consultation with the examiner to whom it is proposed to re-dispatch it. However, cases will arise over which there is disagreement or uncertainty regarding classification boundaries, or where the examiner dealing with the case is uncertain as to its correct classification. In such instances the examiner having the case should not spend time in trying to resolve the matter, but should consult his Head of Section for a decision.

## **4. Final classification**

The final complete classification of the application will be determined by the examiner, who should apply all the classification symbols required by the rules of the International Classification, e.g. the last place rule. It will be necessary for the examiner to study the application sufficiently to determine the classification at this stage.

In order to arrive at a complete classification of an application it may be necessary to consult other examiners for further final classifications.

The terms "obligatory classification" and "non-obligatory classification" are defined in the IPC Guide; see paragraphs 115 to 119. The examiner should first of all identify and classify the technical subject or subjects of the invention in accordance with the guidance given under the heading "Obligatory Classification".

If this results in classification in more than one subclass, or more than one main ("/00") group within a subclass, then all such classifications should be assigned. It is important that the classification of the invention itself should be distinguished from any additional information and/or indexing code. For that reason, the invention information symbols are printed or displayed in bold and italic font style, while the additional information symbols and indexing codes are printed or displayed only in italic font style. The version indicator of each IPC symbol is placed in round brackets after the symbol.

Examples:     ***B28B 5/00*** (2006.01)  
                  ***H04H 20/12*** (2008.01)  
                  ***H01H 33/65*** (2009.01)

Where it is necessary to assign more than one symbol for the invention itself, that which in the examiner's opinion most adequately identifies it should be indicated first. This first final classification serves to facilitate subsequent allotment of the application to the patent examiner once a Request for examination (i.e. search and substantive examination) has been filed.

The classification should be determined without taking into consideration the probable content of the application after any amendment, since this classification should relate to the disclosure in the published application. This means only the application as filed is to be considered.

## **5. Classification in the case of technical obscurity**

When the scope of the invention is not clear, the classification will have to be based on what appears to be the invention in so far as this can be understood. The fact that the subject of the invention cannot be identified at all means that the description of the invention is technically obscure. If the examiner detects technical obscurity, he should send the application back to the Head of the Patent Examination Section.

## **6. Classification when lack of unity**

Where objection of lack of unity of invention could arise, all inventions must be classified, since all will be disclosed in the published application. Each invention claimed is to be classified as set out earlier

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## PART D – SEARCH AND EXAMINATION FOR NATIONAL APPLICATIONS

### Chapter D-I.

#### Alternative examination procedures

##### 1. Request for examination

The combined search and substantive examination of a patent application filed in the Republic of Croatia can only start after the filing of a "Request for examination" by the applicant. This request should be filed within a period of 6 months after the publication of the application. This is normally more than 24 months after first filing or priority date.

Art. 36(1) PA provides for 2 different national patent procedures. The applicant should choose one of these options.

- (1) **AI procedure:** a request for examination of a patent on the basis of a substantive examination of the patent application, or
- (2) **AK-procedure:** a request for examination of a patent not including a substantive examination of the patent application ("Consensual patent").

#### **Important note:**

According to Article 36(1) PA2004, which applies to applications filed up to 30 July 2007 one may also chose:

- (3) **AR-procedure:** a request for examination of a patent on the basis of the submitted foreign results of a substantive examination of the patent application that was performed by a foreign Patent Office.

If, within the 6-month time limit, one of the requests has not been filed, or the administrative fee and the procedural charges have not been paid, the patent application shall be considered to be withdrawn.

The Office shall then issue a decision on the suspension of the procedure for the grant of a patent – Art. 36(2) PA.

Upon request for examination some formal examination work has to be carried out by the Legal Service before the application file wrapper is sent to the Patent Examination Section, e.g. check whether the fees and charges have been paid in the prescribed amount and within the prescribed period.

##### 2. Different search and examination procedures and routes

###### 2.1 AI-SIPO route: full search and examination by SIPO

When the applicant has filed a Request for examination on the basis of a substantive examination of the patent application, there are two possible alternative routes of examination: substantive examination carried out by the Office itself (the AI-SIPO route) and substantive examination carried out by the Office in cooperation with particular offices with which it has concluded a cooperation agreement (the AI- OUTSOURCE route) Art. 37(2)(3) PA.



The decision on the route followed is taken by the Office.

(i) Applications of foreign origin via AI-SIPO route

The AI-SIPO route is generally used for applications filed by foreign applicants which have a patent family member in one of the offices applying the same patentability criteria as those prescribed by the national legislation (e.g. EPO, DE, AT ...).

Therefore the Office searches patent databases such as "epoline", EPO Register and INPADOC and checks the status of the foreign corresponding application.

On the basis of the found search results obtained by any of the mentioned foreign offices, the patent examiner shall prepare a substantive examination result in which he shall explain the reasons for which a patent is intended to be granted or refused.

If the examiner has decided to grant a patent, the Legal Service shall invite the applicant to approve the text of the application in which a patent is intended to be granted.

If the examiner is of the opinion that the application does not meet the requirements for grant, he shall prepare the examination result accordingly, stating in detail the reason for which a patent may not be granted. The Legal Service shall send the examination result to the applicant for comments.

If there is not any family member or in the absence of the examiner specialized in the technical field covered by the application in SIPO, the production of a search and examination report will be outsourced to any Office with which SIPO has concluded a cooperation agreement (e.g. the Austrian or Danish Patent Office).

A negative report on patentability can result in granting if the applicant makes the appropriate amendments; otherwise the result will be a refusal.

(ii) Applications of domestic origin via AI-SIPO route

The search and examination work on applications by Croatian residents can be outsourced, but can also be carried out internally (AI- SIPO route). This is possible due to the fact that the search tools available to the SIPO examiners have largely improved by virtue of the possibility of online access to the EPOQUE databases of the European Patent Office. Most domestic-origin applications are "first filings".

## 2.2 AI-OUTSOURCE route: search and Written Opinion outsourced

The AI-OUTSOURCE route is generally used for domestic applications. These are mostly "first filings" filed by Croatian legal or natural persons having a principle place of business, a domicile or a habitual residence, respectively, in the territory of the Republic of Croatia. These applications will normally have no foreign patent family member.

If the SIPO Office decides to use the AI-OUTSOURCE route, the treatment of the patent file is as follows.

As soon as possible after the filing of the Request for examination, the title, relevant parts of the description, as decided by the examiner, the claims and the abstract are translated into the English language. These translations, together with the bibliographic data, are then sent to the Office with which SIPO has concluded a cooperation agreement. The foreign authority conducts the search and substantive examination work according to the PCT Chapter I procedure. The Office receives from the mentioned office a Search Report and a Written Opinion. The examiner translates the Written Opinion and studies it in relation to the cited documents. The SIPO examiners search for national applications filed in the Republic of Croatia. If the Written Opinion is positive on patentability, the examiner decides on the grant, and the applicant is invited to submit

approval of the text of the application proposed for grant within 30 days from the receipt of the invitation. If the Written Opinion is negative, the examiner writes an examiner communication on the basis of the Written Opinion and invites the applicant to reply with amendments and/or comments within the time limit of 2-4 months.

If the applicant does not reply, the application is refused. If he replies, the examiner carries out a re-examination and decides whether to grant or to send a further communication to the applicant. In some cases the examiner sends the reply from the applicant back to the foreign office for further examination. The second Written Opinion from the foreign office results usually in a final decision.

### 2.3 AR procedure: foreign examination results

This AR procedure can be requested by the applicant according to Art. 36(1)2 PA2004 and Art. 38-40 PA2004, if he filed his patent application up to 30 July 2007.

According to Art. 39 PA2004 the applicant shall, with the Request for examination, enclose a signed statement to the effect that he will furnish evidence concerning the results of the search and substantive examination carried out by one of the relevant foreign patent offices.

These are the following patent offices:

1. AT Austrian Patent Office
2. AU Australian Patent Office
3. CA Canadian Intellectual Property Office – 26.07.2004
4. CN State Intellectual Property Office of the People's Republic of China
5. EP European Patent Office
6. ES Spanish Patent and Trademark Office – 01.04.2006
7. FI National Board of Patents and Registration of Finland – 01.10.2003
8. JP Japanese Patent Office
9. KR Korean Intellectual Property Office
10. RU Federal Service for Intellectual Property, Patents and Trademarks (Russian Federation)
11. SE Swedish Patent and Registration Office
12. US United States Patent and Trademark Office
13. DE German Patent and Trade Mark Office
14. DK Danish Patent and Trademark Office

These results should be submitted within 6 months from the date of the availability thereof, and not later than 5 years as from the date of filing the application at the prescribed office.

On the reasoned request of the applicant and the evidence furnished, the Office may extend the time limit for no more than 3 months after termination of the foreign examination procedure.

According to Art. 21(2) PR2004, the applicant shall furnish to the Office:

- (1) a search report and its translation into the Croatian language,
- (2) a substantive examination report and its translation into the Croatian language,
- (3) a patent specification (B document) with translated claims.

After receiving the above documents, the examiner will conduct further substantive examination of the application. He shall establish whether the invention complies with the requirements for grant as set out in Art. 37 PA2004. The claimed invention should also be new with respect to all possible conflicting applications – Art. 8(3) PA2004.

Most applications with AR status are foreign-origin applications that have entered the "PCT national phase".

If the applicant does not furnish the translation of the results of examination within the prescribed period, the application shall be deemed to be withdrawn. The Office shall then issue a decision on the suspension of the procedure.

## 2.4 AK procedure: Consensual patent

The AK procedure was introduced by the Patent Act 2000.

According to Art. 41 PA a consensual patent shall be granted in respect of the invention the subject-matter of which is patentable and not excluded from patentability.

A request for the grant of a consensual patent shall be published in the Official Gazette within 3 months from the request date. After the publication of the request, any legal or natural person may, within 6 months, file at the Office an opposition to the grant of a consensual patent, or file a Request for examination (substantive examination).

The opposition or the Request for examination shall be accompanied by evidence on payment of the procedural charges for opposition, which shall be one third of the procedural charges for the Request for examination.

If the opposition to the grant of a consensual patent or a Request for examination is filed and the administrative fees and procedural charges are paid, the Office shall immediately notify the applicant thereof. If no fee is paid, the opposition is rejected.

The applicant may, within 6 months from the receipt of the notification of opposition, file a request for the grant of a patent on the basis of substantive examination (AI procedure). He shall be required to pay the difference between the administrative fee for opposition already paid and the fee for substantive examination. If the applicant pays the prescribed fee, the application is either directed to the APO route, or is examined at SIPO, and if he fails to file the request and/or to pay the fee the application is rejected.

Art. 46 PA allows a Request for examination by any person during the whole 10-year term. The consensual patent can be converted into a normal 20-year patent after substantive examination.

The same patentability criteria are applied to the substantive examination of an opposition file as those applied during normal substantive examination of a patent application file.

## Chapter D-II.

### Characteristics of the search

#### 1. Objective of the search

The procedure through which a patent application proceeds from the filing of the application to the granting of a patent (or the refusal thereof) comprises two basic stages, i.e. the search and the substantive examination. The search is a necessary first step in the substantive examination procedure.

The objective of the search is to discover the state of the art (also called "prior art") which is relevant for the purpose of assessing novelty and inventive step. The search is needed for the purpose of determining whether the invention to which the application relates is new and involves an inventive step.

The search is essentially a documentary search in a – mostly electronic – patent document collection that is systematically accessible according to the subject-matter content of the documents. These are primarily patent documents of various countries, supplemented by a number of articles from periodicals and other non-patent literature. The search must be as complete and effective as possible, within the limitations necessarily imposed by economic considerations.

The search report part of the examiner communication will be prepared containing the results of the search, in particular by identifying the documents constituting the relevant state of the art.

#### 2. Scope of the search

- (i) Completeness of the search – The search should be a high-quality search, according to European and international standards. Nevertheless, it must be realised that in a search of this kind, 100% completeness cannot always be obtained, because of such factors as the inevitable imperfections of any classification system and its implementation. Completeness may not be economically justified if the cost is to be kept within reasonable boundaries. The examiner should therefore organise his search effort and utilise his search time in such a manner as to reduce to a minimum the possibility of failing to discover existing highly relevant prior art, such as complete anticipations for any claims. Such an essential document should not be omitted. For less relevant prior art, which often exists with a fair amount of redundancy amongst the documents in the search collection, a lower retrieval ratio can be accepted.
- (ii) Effectiveness and efficiency of the search – The effectiveness and efficiency of any search for relevant documents depend on the degree of order which is available in, or which can be applied to, the collection of documents to be searched, the order allowing the examiner to determine sections of the documentation to be consulted.

The basic components for creating order in a collection of documents are words, classification units, indexing codes or bibliographical links between documents by commonly cited documents. The order may have a permanent character, as with indexing words, classification symbols or indexing codes, or it may be created on demand by a search strategy judiciously using the above-mentioned basic components, the outcome of which is a section of the documentation which is likely to contain material pertinent to the invention.

The examiner should for reasons of economy exercise his judgement, based on his knowledge of the technology in question and of the available information retrieval systems, to omit sections of the documentation in which the likelihood of finding any documents relevant to the search is negligible; for example documents falling within a period preceding the time when the area of technology in question began to develop.

Similarly he need only consult one member of a patent family.

- (iii) Search in analogous fields – The search shall be carried out on the basis of the available search tools which may contain material pertinent to the invention. It should first cover all directly relevant technical fields, and may then have to be extended to analogous fields. However, the need for this must be judged by the examiner in each individual case, taking into account the outcome of the search in the initial fields.

The question of which fields are, in any given case, to be regarded as analogous fields shall be considered in the light of what appears to be the essential function or use of the invention and not only the specific functions expressly indicated in the application.

The decision to extend the search to fields not mentioned in the application must be left to the judgement of the examiner, who should not put himself in the place of the inventor and try to imagine all the kinds of applications of the invention possible. The overriding principle in determining the extension of the search in analogous fields should be whether it is probable that a reasonable objection of lack of inventive step could be established on the basis of what is likely to be found by the search in these fields.

### **3. Subject-matter of the search**

#### **3.1 Basis for the search: the claims**

The search should be directed to the invention as defined by the claims and should be interpreted with due regard to the description and drawings (if any), since this determines the extent of the protection which will be conferred by the patent if granted.

- (i) Interpretation of claims – The search should on the one hand not be restricted to the literal wording of the claims, but on the other hand should not be broadened to include everything that might be derived by a person skilled in the art from a consideration of the description and drawings.

The objective of the search is to discover prior art which is relevant to novelty and/or inventive step. The search should be directed to what appear to be the essential features of the invention and take into account any changes in the (objective) technical problem underlying the invention which may occur during the search as a result of the retrieved prior art.

When interpreting claims for the purpose of the search, the search will also take into consideration prior art incorporating technical features which are well-known equivalents to the technical features of the claimed invention, which may undermine inventive step.

Example: If the claim specified a cable clamp having a certain construction, the search should embrace pipe and similar clamps likely to have the specified construction.

Likewise, if the claim is directed to an article consisting of several parts which are defined by their function and/or structure, and the claim stipulates that certain parts are welded together, the search should also embrace equivalent methods of connecting such as gluing or riveting, unless it is clear that welding possesses particular advantages required for the invention.

- (ii) Anticipation of amendments to claims – In principle, and in so far as possible and reasonable, the search should cover the entire subject-matter to which the claims are directed or to which they might reasonably be expected to be directed after they have been amended.

Example: Where an application relating to an electric circuit contains one or more claims only directed to the function and manner of operation, and the description and drawings include an example with a detailed non-trivial transistor circuit, the search must necessarily include this circuit.

Nevertheless, reasons of economy may make certain restrictions necessary, for example when there is a broad claim and many examples and it is not possible to foresee which will be the subject of amended claims.

### 3.2 Broad claims

No special search effort need be made for searching unduly wide or speculative claims, beyond the extent to which they relate to matter which is sufficiently disclosed in the application and are supported by the description.

Example: If in an application relating to and describing in detail an automatic telephone exchange, the claims are directed to an automatic communication switching centre, the search should not be extended to automatic telegraph exchanges, data switching centres etc. merely because of the broad wording of the claim, but only if it is probable that such an extended search could produce a document on the basis of which a reasonable objection as regards lack of novelty or inventive step could be established.

Likewise, if a claim is directed to a process for manufacturing an "impedance element" but the description and drawings relate only to the manufacture of a resistor element, and give no indication as to how other types of impedance element could be manufactured by the process of the invention, extension of the search to embrace, say, manufacture of capacitors would not normally be justified.

Example: If the independent claim relates to the chemical treatment of a substrate, whereas it appears from the description or all the examples that the problem to be solved is solely dependent on the nature of natural leather, it is clear that the search should not be extended to the fields of plastics, fabrics or glass.

Similarly, if the description and drawings are directed to a lock with a safety cylinder whereas the claims refer to a device allowing the indexation of the angular position of a first element with respect to two other rotating elements, then the search should be limited to locks.

In exceptional cases where the lack of disclosure or support is such as to render a meaningful search over the **whole** of the scope of the claim(s) impossible, an incomplete search or a declaration taking the place of a search report may be appropriate.

### 3.3 Independent and dependent claims

- (i) General – The search carried out in sections of the documentation to be consulted for the independent claim(s) must include all dependent claims. Dependent claims should be interpreted as being restricted by all features of the claim(s) upon which they depend. Therefore, where the subject-matter of the independent claim is novel, that of the dependent claims will also be novel. When the patentability of the independent claim is not questioned as a result of the search, there is no need to make a further search or cite documents in respect of the subject-matter of the dependent claims as such.

Example:

In an application relating to cathode ray oscilloscope tubes, in which the independent claim is directed to specific means along the edge of the front of the tube for illuminating the screen, and a dependent claim is directed to a specific connection between the front and the main part of the tube, the examiner should, in the sections of the documentation he consults for searching the illumination means, also search for the connecting means whether in combination with the illumination means or not. If after this search the patentability of the illuminating means is not questioned, the examiner should not extend his search for the connecting means to further sections of the documentation which are likely to contain material pertinent to or specifically provided for these connections.

### Example:

If in an application dealing with a pharmaceutical composition for treating nail infections the patentability of the subject-matter of the independent claim relating to specific combinations of the active ingredients is not questioned as a result of the search, there is no need to continue the search for dependent claims dealing with the use of a specific volatile organic solvent as a carrier in the composition.

- (ii) Search on dependent claims – However, where the patentability of the subject-matter of the independent claim is questioned, it may be necessary for assessing whether the subject-matter of the dependent claim as such is novel and involves an inventive step to continue the search in other sections of the documentation, e.g. in one or more additional classification units. No such special search should be made for features that are trivial or generally known in the art. However, if a handbook or other document showing that a feature is generally known can be found rapidly, it should be cited. When the dependent claim adds a further feature (rather than providing more detail of an element figuring already in the independent claim), the dependent claim is to be considered in combination with the features in the independent claim and should be dealt with accordingly.
- (iii) Combination of elements in a claim – For claims characterised by a combination of elements (e.g. A, B and C) the search should be directed towards the combination. However, when searching classification units for this purpose, sub-combinations, including the elements individually (e.g. AB, AC, BC and also A, B and C separately), should be searched in those units at the same time. A search in additional classification units either for sub-combinations or for individual elements of the combination should only be performed if this is still necessary for establishing the novelty of the element in order to assess the inventive step of the combination.
- (iv) Different categories – When the application contains claims of different categories, all these must be included in the search. However, if a product claim clearly seems to be both new and obvious, the examiner should make no special effort to search claims for a process which inevitably results in the manufacture of that product or for use of the product.

When the application contains only claims of one category, it may be desirable to include other categories in the search.

Example: Generally one may assume that in a claim directed to a chemical process, the starting products form part of the state of the art and need not be searched; the intermediate products will only be searched when they form the subject of one or more claims; but the final products will always have to be searched, except when they are evidently known.

### 3.4 Subject-matter excluded from search

The examiner may exclude certain subject-matter from his search. These exclusions may result from certain subject-matter not complying with the provisions of the Patent Act relating to exclusions from patentability or to susceptibility to industrial application. They may also arise where the application does not comply with the provisions of the Patent Act to such an extent that a meaningful search is impossible for some or all of the claims, or for a part of a claim, for other reasons.

### 3.5 Lack of unity

Also, when the claims of the application do not relate to one invention only, nor to a group of inventions linked so as to form a single general inventive concept, the search will normally be restricted to the invention or the linked group of inventions first mentioned in the claims. Restriction of the search for the above reasons will be notified to the applicant.

### 3.6 Technological background

In certain circumstances it may be desirable to extend the subject-matter of the search to include the "technological background" of the invention.

This would include:

- the introductory part of the first claim, i.e. the part preceding the expression "characterised by"/"characterised in that";
- the state of the art which is said to be known in the introduction of the description of the application but which is not identified by specific citations;
- the general technological background of the invention (often called "general state of the art").



## Chapter D-III.

### Search tools, procedure and strategy

#### 1. Search tools and patent documentation

##### 1.1 EPOQUE online patent searching

Since March 2007 SIPO examiners have had access to EPOQUEnet. In 2006, the number of electronically searchable documents in the main search database of the European Patent Office (EPO) rose to around 57.1 million documents. This database covers 78 countries.

It is also available to the Croatian public via the World Patent Finder ("esp@cenet").

See [https://worldwide.espacenet.com/advancedSearch?locale=en\\_EP](https://worldwide.espacenet.com/advancedSearch?locale=en_EP)

Cooperative Patent Classification (CPC) – The EPO and USPTO developed joint classification system which is an expanded version of the International Patent Classification (IPC). The CPC system comprises about 250.000 classification groups to allow fast and systematic access to patent search documentation in all areas of technology.

See <https://worldwide.espacenet.com/classification>

##### 1.2 SIPO patent database

The SIPO patent database is maintained by the SIPO IT department. It contains bibliographic data of all the published HR A2 patent applications and granted HR B patents.

In-house searches using various search criteria (e.g. Int. Cl., inventor name, publication date, registration number, title words) can be carried out on abstracts of all the published applications.

The HR A2 documents are available electronically. Photocopies on paper can be ordered. HR B2 documents are available of all HR patents, with the exception of nostrifications (i.e. patents entered into the SIPO Register and granted by the Yugoslav Federal Patent Office up to 8 October 1991). Photocopies on paper can be ordered.

Published HR A2 patent applications consist of a first page containing bibliographic data, the abstract and one drawing. The full description, all claims and all drawings are also available to the public.

See [www.dziv.hr/en/e-services/on-line-database-search/patents/](http://www.dziv.hr/en/e-services/on-line-database-search/patents/)

The data from the Patent Register are accessible online to examiners only.

##### 1.3 Other patent search tools

###### (i) Internet access

"Google Patents", various dictionaries and "Wikipedia" could be useful tools on the Internet.

###### (ii) Classification schemes

- IPC: The International Patent Classification schemes are the most widely used classification system at SIPO. It is obligatory for publication purposes.
- CPC: The Cooperative Patent Classification schemes are normally used for search purposes by SIPO examiners in the EPOQUE databases.

(iii) Patent family service

- The aim of a Patent Family search is mainly the detection of a corresponding patent document already presenting search results.
- Patent Family Service exists in EPOQUE and in esp@cenet.
- The definition of a "patent family" differs in different databases.

(iv) Non-patent literature

- Technical periodicals: It is possible to order a publication from the National Library, from University faculties or from industrial companies.
- Technical books and dictionaries are available at SIPO, e.g. Merck Index.

## 2. Procedure prior to searching

(i) Foreign results – When receiving a new application to be searched and examined, the examiner is strongly recommended to prepare the search and examination work by the following actions:

- identification of patent family members,
- printing copies of corresponding foreign patent documents which contain foreign search results and/or claims granted after substantive examination,
- provision of copies of the documents cited in these foreign search results.

(ii) Analysis of the application – When taking up a new application to be searched, the examiner should first consider the application in order to determine the subject of the claimed invention. For this purpose he should make a critical analysis of the claims in the light of the description and drawings. Although he need not study all the details of the description and drawings, he should consider these sufficiently to identify the problem underlying the invention, the insight leading to its solution, the totality of the means essential to the solution, particularly as reflected in the technical features found in the claims, and the results and effects obtained.

(iii) Documents cited – Documents cited in the application under consideration should be examined if they are cited

- as the starting point of the invention,
- or as showing the state of the art,
- or as alternative solutions to the problem concerned,
- or when they are necessary for a correct understanding of the application.

However, when such citations clearly relate only to details not directly relevant to the claimed invention, they may be disregarded.

## 3. Search strategy

(i) Subject of the search – Having determined the subject of the invention, it may be desirable for the examiner to prepare first a concise search statement, defining the subject of his search as precisely as possible. This search statement (e.g. some keywords, a diagram, a sketch) is preferably written on an internal report on search. In many instances one or more of the claims may themselves serve this purpose, but they may have to be

generalised in order to cover all aspects of the invention.

At this time, the considerations relating to subjects excluded from patentability and lack of unity should be borne in mind. The examiner may also have to restrict the subject of the search because of obscurities. However, he should not do this if it can be avoided, and he should subsequently amend his search if such obscurities are clarified during the search. Any restrictions of the search due to obscurities or subjects excluded from patentability shall be indicated on the internal report on search.

- (ii) Formulating a search strategy – Next the examiner should start the search process by formulating a search strategy, i.e. a plan consisting of a series of search statements expressing the subject of the search, resulting in sections of the documentation to be consulted for the search. In its initial phase, a search strategy will contain one or more combinations of the basic components. The search process should be interactive and iterative in the sense that the examiner should reformulate his initial search statement(s) according to the usefulness of the information retrieved. When using classification units, the examiner should select the classification units to be consulted for the search, both in all directly relevant fields and in analogous fields.

The selection of classification units in related fields should be limited to:

- (a) higher subdivisions allowing searching by abstraction (generalisation) inasmuch as this is justified from a technical viewpoint,
- (b) parallel subdivisions, bearing in mind the fact that the fields in question will become increasingly unrelated.

When the examiner is in doubt about the appropriate fields in which to conduct his search, he may request advice from his colleagues.

Usually various search strategies are possible, and the examiner should exercise his judgment, based on his experience and knowledge of the available search tools, to select the search strategy most appropriate to the case in hand. He should give precedence to search strategies yielding sections of the documentation in which the probability of finding relevant documents is highest. Usually the main technical field of the application will be given precedence, starting with the basic components most relevant to the specific example(s) and preferred embodiments of the claimed invention.

- (iii) Carrying out the search – The examiner should then carry out the search, directing his attention primarily to documents relevant for novelty and inventive step.

He should also note any documents that may be of importance for other reasons, such as:

- (a) conflicting documents which are:
  - published applications filed in the Republic of Croatia under Art. 8(3) PA,
  - published PCT international applications under Art. 111(5) PA,
  - published EP extended patent applications,
  - any document published during the priority interval of the application which may be relevant under Art. 8(3) PA in case of a non-valid priority date;
- (b) documents putting doubt upon the validity of any priority claimed;
- (c) documents contributing to a better or more correct understanding of the claimed invention; or

- (d) documents illustrating the technological background.

However, he should not spend a significant amount of time in searching for these documents, nor in the consideration of such matters.

The examiner should concentrate his search efforts on the use of search strategies yielding sections of the documentation in which the probability of finding highly relevant documents is greatest, and, in considering whether to extend the search to other less relevant sections of the documentation, he should always take account of the search results already obtained.

The examiner should continuously evaluate the results of his search, and if necessary reformulate the subjects of the search accordingly.

Example: The selection of the classification units to be searched or the order of searching them may also require alteration during the search as a consequence of intermediate results obtained. The examiner should also use his judgement, taking into account results obtained, in deciding at any time during or after the systematic search whether he should approach the search documentation in some different manner, e.g. by consulting:

- (a) documents cited in relevant documents produced by the search, e.g. cited in the description or in the search report of a patent document,
- (b) documents citing a relevant document produced by the search.

If no documents of a more relevant nature for assessing novelty and inventive step are available, the examiner should consider citing any documents relevant to the "technological background" of the invention which he may have noted during the search. Generally speaking, no special extra search effort will be undertaken for this purpose. One single document relevant to the "technological background" is considered a minimum result of the search.

- (iv) End of search – Reasons of economy dictate that the examiner use his judgement to stop his search when the probability of discovering further relevant prior art becomes very low in relation to the effort needed. The search may also be stopped when documents have been found clearly demonstrating lack of novelty in the entire subject-matter of the claimed invention and its elaborations in the description, apart from features which are trivial or common general knowledge in the field under examination, application of which features would not involve inventive step. The search for conflicting applications should always be completed.

#### **4. Use of search results from foreign patent offices**

It seems appropriate to look for foreign search and examination results in cases where relevant prior art is difficult to retrieve at the Office.

Search results from foreign patent offices can be found:

- (a) during consultation of the search tools, e.g. the corresponding EP A1 (or EP A3), WO A or DE C documents can be retrieved,
- (b) by consulting esp@cenet, e.g. the corresponding US A, EP A, WO A, DE C or GB A documents can be located.

If the examiner finds search results from foreign patent offices, he should first analyse these results and then use his judgement in deciding whether he should stop the search or continue a further supplementary search. It seems that in most cases further searching could be omitted for reasons of economy.

## **5. Search report part of examiner communication**

After completion of the search, the examiner should select from the documents retrieved the ones to be cited in the search report part of the examiner communication. These should always include the most relevant documents. Less relevant documents should only be cited when they concern aspects or details of the claimed invention not found in the documents already selected for citation. In cases of doubt or borderline cases in relation to novelty or inventive step, the examiner should cite rather more readily in order to give the opportunity to consider the matter more fully during further office actions.

The examiner should not cite more documents than is necessary, and therefore when there are several documents of equal relevance the search report should not cite more than one of them. Where more than one member of the same patent family is present in the search files, the search need not reveal all of them, nor need the search report part of the examiner communication cite all of them.

Finally the examiner should prepare the search report part of the examiner communication. The identification of a document cited on that search report part should specify three elements:

- (a) the country code
- (b) the document kind code
- (c) the publication number.

Examples: HR P921355A A2, HR P950552 B1, DE 3225515 C

The numbers of the claims to which the document is relevant should be listed in the right-hand column.

On the search report part of the examiner communication the search fields and databases consulted should be further indicated. A possible restriction of the subject of the search should be indicated, e.g. in the case of lack of unity or of technical obscurity.

## **Chapter D-IV.**

### **Substantive examination procedure**

#### **1. Start of substantive examination**

The substantive examination procedure is combined with the search procedure. It starts with the "Request for examination" – See D-I, 1.

The request for search and substantive examination is filed as a "Request for examination" of a Croatian patent. This request should be filed within 6 months after the publication of the application.

#### **2. Examination procedure in general**

##### **2.1 Purpose of the substantive examination**

The purpose of the substantive examination is to ensure that the application and the invention to which it relates meet the substantive requirements set out in the relevant Articles of the Croatian Patent Act (PA) and Patent Regulations (PR). The examiner deals with the substantive requirements. As for the formal requirements, these are initially the responsibility of the Legal Service.

Art. 37(1) PA states: "The substantive examination of a patent application shall establish whether the invention complies with all the requirements for the grant of a patent, i.e. whether the subject-matter of the application is an invention which:

1. is not excluded from patent protection – Art. 5(6) PA, Art. 6-7 PA;
2. is sufficiently disclosed – Art. 20(4) PA;
3. has unity of invention – Art. 18 PA;
4. is new (Art. 8-9 PA), involves an inventive step (Art. 10 PA) and is industrially applicable (Art. 11 PA).

The purpose of the substantive examination is particularly to prevent the grant of a patent under the following circumstances:

- (a) when the application documents filed manifestly do not contain the information necessary for a clear and complete disclosure of the invention;
- (b) where, in relation to the prior art, the patent application manifestly contains nothing patentable; and
- (c) where certain other important fundamental requirements are not met.

Benefit of the doubt – However, the substantive examination has to be so organised and carried out that the inventor is given the benefit of the doubt. Only when the outcome of the examination is clearly negative should a patent application be refused. The main purpose of the Patent Act is, after all, to promote technical innovation and to protect inventions, and the purpose of an intellectual property office is to grant patents.

Furthermore, borderline cases are left to the discretion of the Boards of Appeal or the courts. If divergences become sufficiently important for the validity of the patent to be challenged, the Board of Appeal or the court will have the means of thoroughly elucidating the most complex questions.

## 2.2 Attitude of the examiner

The attitude of the patent examiner is very important. He should always try to be constructive and helpful. While it would of course be quite wrong for an examiner to overlook any major deficiency in an application, he should have a sense of proportion and not pursue unimportant objections. He should bear in mind that, subject to the requirements of the Patent Act, the drafting of the description and claims of an application filed in the Republic of Croatia is the responsibility of the applicant or his representative.

It is up to the examiner to conduct the procedure and especially to determine the order in which the questions are to be dealt with. Matters of major importance should be dealt with before matters of minor importance. Matters of major importance are those which affect the validity of the patent (novelty, inventive step, clarity). They should always be given priority. Matters of relatively minor importance are e.g. unity of invention, redundant claims, imperfections in the wording of dependent claims, the two-part form of independent claims, amendments to the description.

The examination procedure is based on a written "dialogue" between the examiner and the applicant. This dialogue is governed by three factors:

- (a) In most cases – at the stage of substantive examination – the other party is not the applicant himself and still less the inventor. The examiner is in contact with an intermediary, either the representative or the industrial property specialist of a company.
- (b) It is not rare for the applicant to be obliged to resort to a translator and even need a double translation.
- (c) The greater part, if not all, of the procedure is conducted in writing, which allows the necessary time for thought on both sides but is also liable to lead to misunderstandings.

The golden rule that the examiner has to apply to his part of the dialogue is that of objectiveness, which means that he must:

- (a) give reasons for his objections and proposals, and express them clearly;
- (b) listen to the other party, remain open to his viewpoint and be prepared, when appropriate, to revise the position originally adopted;
- (c) nevertheless firmly defend the fundamental principles of the Patent Act and Patent Regulations;
- (d) avoid all controversies, even when the other party raises his tone;
- (e) deal with all applicants on the same footing, i.e. avoid all discrimination;
- (f) not question the extent of the patent applied for, unless there are sufficient reasons for doing so, namely questions regarding patentability.

This objectiveness in the dialogue with the applicant goes together with a "user-friendly" attitude.

In every examiner communication, the examiner specifies a time limit by which the applicant has to reply to his objections and/or to make the necessary amendments to the application. This time limit will normally be between 2 and 4 months. An extension of up to several months is granted on receipt of a request giving justified reasons.

### **3. First examination action**

#### **3.1 Direct grant**

If the examiner can identify patentable subject-matter in the application and if the independent claims are clear and relate to this subject-matter, an attempt should be made to grant the case directly, e.g. by proposing any necessary minor amendments with the communication of intention to grant.

#### **3.2 First examiner communication**

Taking into account the documents cited in the search report part of the communication, the examiner should identify any requirements of the Patent Act and Patent Regulations which, in his opinion, the application does not satisfy. If a "direct grant" seems impossible, he will then write a first examiner communication to the applicant giving reasons for any objections he raises and inviting the applicant to file his observations or submit amendments within a specified time limit.

The examiner's first communication should, as a general rule, be a comprehensive communication. This means it should cover all objections to the application. These objections may relate to formal matters, to substantive matters, or to both.

For each objection the communication should indicate the claim or the part of the application which is deficient and the requirement of the Patent Act which is not met, either by referring to specific Articles, or by other clear indication. It should also give the reason for any objection where this is not immediately apparent.

For example, where prior art is cited and only part of a cited document is relevant, the particular passage relied upon should be identified. If the cited prior art is such as to demonstrate lack of novelty or inventive step in the independent claim(s), and if consequently there is lack of unity between dependent claims, the applicant should be warned of this situation. Substantive matters should normally be set out first. The communication should be drafted in such a manner as to facilitate re-examination of the amended application and, in particular, to avoid the need for extensive rereading after reply from the applicant.

The communication should include an invitation to the applicant to file his observations, to correct any formal deficiencies and otherwise to submit amendments to the description, claims and drawings. It must also state the time limit within which the applicant must reply. Failure to reply in due time will cause the application to be refused by the Office.

A decision on refusal is then issued.

It is emphasised that the principle of the first examiner communication being a comprehensive one only sets out the general rule. There may be cases in which the application is generally deficient. In these cases the examiner should not carry out a detailed examination, but should send a communication to the applicant informing him of this fact, mentioning the major deficiencies and saying that further examination is deferred until these have been removed by amendment. The communication should specify a time limit within which the deficiencies must be removed. Generally the examiner should, with the first examination action, seek to make the maximum impact with the broad aim of bringing matters to a conclusion without any undue delay.

When carrying out the substantive examination, the examiner should concentrate on trying to understand what contribution the invention as defined in the claims makes to the known art. This should normally be sufficiently clear from the application as filed. If it is not, the applicant should be required to elucidate the matter. However, the examiner should not raise an objection of lack of clarity unless he is convinced it is necessary, since to do so might result in the applicant introducing additional subject-matter and thus offending against Art. 33 PA.



Although the examiner must bear in mind all the requirements of the Patent Act and Patent Regulations, the requirements which are most likely to require attention in the majority of cases are sufficiency of disclosure, clarity (especially of the independent claims), novelty and inventive step.

The examiner should not require or suggest amendments merely because he thinks they will improve the wording of the description or claims. A pedantic approach is undesirable. What is important is that the meaning of the description and claims should be clear.

Examiner suggestions – It must be emphasised that it is not part of the duty of an examiner to require the applicant to amend the application in a particular way to meet an objection, since the drafting of the application is the applicant's responsibility. The applicant should be free to amend in any way he chooses provided that the amendment removes the deficiency and otherwise satisfies the requirements of the Patent Act. However, it may sometimes be useful if the examiner suggests at least in general terms an acceptable form of amendment.

The examiner may also sometimes prefer to make suggestions for an allowable new claim. If he does so, however, he should make it clear that the suggestion is merely for the assistance of the applicant and that other forms of amendment will be considered.

Novelty objection – Where the objection concerns novelty, the examiner must quote the facts on which he has based his objection, that is to say the document that forms part of the prior art.

Example:

"The present application does not meet the requirements of Art. 8-9 PA because the subject-matter of claim 1 is not new.

EP-A-..... (see page 3 and figure 1) describes an apparatus for welding metal plates at right angles, which has all the features of claim 1. That is to say, this apparatus comprises a template (19), clamps (22-25) to hold the plates in place, a moving electrode (12), ...".

Inventive step objection – Where the objection concerns inventive step, the examiner has to specify the closest prior art document, indicate the claim objected to, identify the difference(s) between the subject-matter of the claim and the prior art document, and then show how the subject-matter is obvious in relation to this prior art.

Example:

"The present application does not meet the requirements of Art. 10 PA, because the subject-matter of claim 1 does not involve an inventive step.

The European patent document EP-A-..... (see page 3 and figure 1) describes an apparatus for welding metal plates at right angles. That apparatus comprises a template (19), clamps (22-25) to hold the plates in place, a moving electrode (12), ...

Claim 1 differs from what is described in this document in that the shape of the electrode is ...

This shape seems to solve the problem of difficult access to ...

This shape is, however, generally known and usual in the field of electric welding in order to solve the same technical problem, as shown in the following documents:

- Document DE-A-..... (see figure 3 and last paragraph of page 4);
- Document SU-A-..... (see claim 7 and page 3, lines 48 to 52).

The skilled person would therefore regard it as a normal design procedure to combine all the features set out in claim 1."

### 3.3 Format of the examiner communication

The format of the examiner communication has been standardised in line with international PCT practice for search and examination.

It has the following parts:

- Covering letter ("Invitation") with address and bibliographic data,
- Part I: search report on the state of the art,
- Part II: examination results.

### 4. Further examination action

- Intention to grant; or further examiner communication

After receiving the applicant's reply on the first examiner communication, the examiner must re-examine the application taking into account observations or amendments made by the applicant.

The examiner should apply the same standard of examination in relation to matters of substance at all stages in the examination of an application. However, after the first examiner action, he will not normally need to reread the amended application completely if he has drafted his first communication in a comprehensive way. He should concentrate on the amendments themselves and any related passages, and on the deficiencies specified in his first examiner communication.

If this re-examination shows that the applicant has made no bona fide attempt to deal with the objections, the examiner should consider refusing the application. In the majority of cases, however, the re-examination will show that a serious attempt has been made to meet the examiner's objections, e.g. a new set of claims is filed in a further reply.

Now three possibilities exist:

- (a) the application is ready for grant and a communication of intention to grant is sent out;
- (b) there is a good prospect of grant, but there are still minor objections that have to be met. The examiner must consider whether these objections could best be resolved by a further examiner communication, a telephone conversation or a personal interview;
- (c) the application should be refused if the above possibilities do not apply. Where appropriate the applicant should be warned that a refusal will follow if the objections are not dealt with in an acceptable way. A further examiner communication to warn the applicant of refusal should be sent out before a decision on refusal is sent.

If matters are such that the applicant is likely to require time to consider them, it will probably be preferable to deal with them by means of a further examiner communication. If, however, there seems to be confusion about points in dispute, e.g. if the applicant seems to have misunderstood the examiner's argument, or if the applicant's own argument is not clear, then it may expedite matters if the examiner proposes an interview. On the other hand, if the matters to be resolved are minor or can quickly and easily be explained and dealt with, then they might be settled more expeditiously by a telephone conversation. Consultation with the applicant or his representative by a personal interview or by telephone is more fully considered in D-IV, 7.

Similar considerations apply to later stages of re-examination. However, the examiner should be guided at the re-examination stage by the overriding principle that a final action (grant or refusal) should be reached in as few examiner actions as possible. He should control the procedure with

this always in mind. If it is clear that the applicant is not making any real effort to deal with the examiner's objections, either by amendments or by counter-arguments, then even at the first re-examination stage the examiner may decide to refuse the application. If the examiner intends to refuse the application, a written reasoned decision is necessary.

This decision will be prepared by a lawyer on the basis of the earlier examination results.

## **5. Intention to grant a patent**

If the examiner considers that a patent application filed in the Republic of Croatia complies with all the requirements for the grant of a patent, a communication of intention to grant is sent out according to Art. 48(2) PA. The examiner may introduce minor corrections required by the Patent Regulations.

The Office shall provide the applicant with the text of the application on the basis of which it intends to grant a patent. The Office shall invite the applicant to submit written approval of that text within 30 days.

If the applicant does not react to this invitation in time, the Office shall act ex officio as though the approval has been given – Art. 48(3) PA.

If the applicant submits in time a written declaration that he does not approve the text, he shall state the reasons therefor and shall submit an amended text of the claims – Art. 48(4) PA. If the Office accepts these reasons, it shall issue a decision on grant according to the text of the claims proposed by the applicant – Art. 48(5) PA.

If the reasons cannot be accepted, the Office shall notify the applicant thereof. It shall issue a decision on grant according to the final text of the claims as submitted for approval – Art. 48(6) PA.

The intention to grant also requests payment of the administrative fees and procedural charges for printing of the publication and for issuance of a patent certificate and patent specification – Art. 48(7), Art. 16 PA.

## **6. Amendments**

The examiner should allow any amendments necessary to correct any deficiencies which he has indicated in an examiner communication to the applicant. He should also allow any amendments which limit the scope of the claims. He should also give his consent to any amendments which improve the clarity of the description or claims, provided that the subject-matter content is not extended. Also, obvious errors may be corrected at any time. Any subsequent request to withdraw an amendment is itself a request for further amendment. Amendments may be introduced by way of:

- a. deletions
- b. additions
- c. alterations
- d. correction of errors.

### **6.1 Allowability of amendments**

The question of allowability of amendments is legally a question of whether the application as amended is allowable. An amended application must of course satisfy all the requirements of the Patent Act, in particular novelty, inventive step and clarity.

However, especially when the claims have been substantially limited, the examiner should bear in mind that the following questions may require special consideration at the amendment stage:

(i) Unity of invention:

Do the amended claims still satisfy the requirements of Art. 18 PA – Unity? The amended claims may not introduce a lack of unity with the originally claimed invention. If the first examiner communication revealed lack of novelty or inventive step in the inventive concept common to all the claims, but the amended claims do not necessitate a further search, the examiner should not further object to lack of unity of invention.

If, however, the amended claims lack a common inventive concept and a further search is necessary, objection should be raised.

(ii) Agreement between description and claims:

If the claims have been amended, will the description require corresponding amendment to remove serious inconsistency between them? Is e.g. every embodiment of the invention described still within the scope of one or more claims? Conversely, are all of the amended claims supported by the description?

(iii) Additional subject-matter:

It is important also to ensure that no amendment adds to the content of the application as filed and thus offends against Art. 33 PA, as explained in the following paragraphs.

## 6.2 Additional subject-matter (Art. 33 PA)

Art. 33 PA stipulates that "A patent application ... shall not be subsequently amended by extending the subject-matter for which protection has been applied for."

There is normally no objection to an applicant introducing, by amendment, further information regarding prior art which is relevant. Indeed this may be required by the examiner. Nor will the straightforward clarification of an obscurity, or the resolution of an inconsistency, be objected to.

When, however, the applicant seeks to amend the description (other than references to the prior art), the drawings or the claims in such a way that subject-matter which extends beyond the content of the application as originally filed is thereby introduced, the application as so amended cannot be allowed.

Basic principle – The underlying idea of Art. 33 PA is that an applicant is not allowed to improve his position by adding subject-matter not disclosed in the application as filed. This would give him an unwarranted advantage and could become damaging to the legal security of third parties relying on the content of the original application.

Test for additional subject-matter – An amendment should be regarded as introducing subject-matter which extends beyond the content of the application as filed, and therefore as unallowable, if the overall change in the content of the application results in the skilled person being presented with information which is not directly and unambiguously derivable from the information originally presented by the application. That is the case even when matter which is implicitly known to a person skilled in the art in what has been expressly mentioned is taken into account. The test for additional subject-matter therefore corresponds to the test for novelty – see B-II, 5.

Example:

If an application relates to a rubber composition comprising several ingredients and the applicant seeks to introduce the information that a further ingredient might be added, then this amendment should normally be objected to as offending against Art. 33 PA. Likewise, in an application which describes and claims an apparatus "mounted on resilient supports", without disclosing any particular kind of resilient support, objection should be raised if the applicant seeks to add the specific information that the supports are, or could be, e.g. helical springs.

Obvious clarification – If, however, the applicant can show convincingly that the subject-matter in question would, in the context of the invention, be so well known to the person skilled in the art that its introduction could be regarded as an obvious clarification, the amendment may be permitted.

Example:

In the case of the rubber composition referred to above, if the applicant were able to show that the further ingredient which he sought to introduce was a well-known additive normally used in rubber compositions of that kind as an aid to mixing, and that its omission would generally be questioned, then its mention would be allowable on the grounds that it merely clarified the description and introduced nothing not already known to the skilled person. However, if the introduction of this additive brought about some special effects not originally disclosed, an amendment mentioning this should not be allowed. Similarly in the above-mentioned case of the resilient supports, if the applicant were able to demonstrate that the drawings, as interpreted by the skilled person, showed helical springs, or that the skilled person would naturally use helical springs for the mounting in question, the specific mention of helical springs would be allowable.

Further examples – Amendment by the introduction of further examples should always be looked at very carefully in the light of the general considerations outlined in the sections above. The same applies to the introduction of statements of advantage in respect of the invention.

Example:

If the invention as originally presented related to a process for cleaning woollen clothing consisting of treating the clothing with a particular fluid, the applicant should not be allowed to introduce later into the description a statement that the process also has the advantage of protecting the clothing against moth damage.

However, later filed examples or statements of advantage, even if not allowed into the application but stated e.g. in a reply letter, may nevertheless be taken into account by the examiner as evidence in support of the patentability of the claims in the application. For instance, an additional example may be accepted as evidence that the invention can be readily applied, on the basis of the information given in the originally filed application, over the whole field claimed. Or an additional statement of advantage may be accepted as evidence in support of inventive step.

Supplementary technical information – Such information submitted after the filing date of the application will be added to the part of the file which is open to public inspection. From the date on which the information is added to the open part of the file, it forms part of the state of the art.

Alteration or excision of the text, as well as the addition of further text, may introduce additional subject-matter.

Example:

Suppose an invention related to a multilayer laminated panel, and the description included several examples of different layered arrangements, one of these having an outer layer of polyethylene. Amendment of this example either to alter the outer layer to polypropylene or to omit this layer altogether would not normally be allowable. In each case the panel disclosed by the amendment example would be quite different from that originally disclosed. Hence the amendment would introduce additional subject-matter and therefore be unallowable.

### 6.3 Broadening of the original claim

Art. 33 PA says that a patent application may not be belatedly altered by broadening the subject-matter of the protection requested.

At the time of filing the applicant can draft the claims as widely as he wishes. The only constraints are usually that the claimed invention must be new and non-obvious having regard to the state of the art, the claims must be adequately supported by the description, and there must be unity of invention.

After the application has been filed, the patent application filed in the Republic of Croatia or the patent granted in the Republic of Croatia may not be amended in such a way that it contains subject-matter which extends beyond the content of the application as originally filed.

Generally speaking, the broadening of a claim is not permissible unless there was some basis in the original application (not necessarily *expressis verbis*) for the consequent broader claim. The basis must be sufficiently clear to be recognisable as such by the skilled person and not of a vague and general character.

One instance of broadening is where a specific feature is replaced by a general functional term. Such broadening may be permissible under certain circumstances.

Example 1:

According to the originally filed claim, a component in an apparatus is made of rubber. However, from the description as filed it is implicit, e.g. from the definition of the problem, that rubber is chosen essentially because of its elastic properties. Such indirect disclosure constitutes a sufficient basis for generalising the claim from the specific feature ("rubber") to the general one ("elastic material").

Example 2:

The original claim lists a number of alternative fastenings, such as a nut and bolt, a spring catch and a toggle-operated latch, for a particular apparatus. This constitutes an indirect disclosure of the possibility of releasing such fastenings. It therefore justifies corresponding broadening of the claim to "releasable fastenings" in general.

#### 6.4 Correction of errors

Linguistic errors, typing errors and other similar deficiencies in documents filed with the Office may be corrected at any time by a decision on the basis of a written request of the applicant or the patent owner or ex officio – Art. 56 PA.

However, where the mistake is in the description, claims or drawings, the correction must be "obvious" in the sense that it is immediately evident

(a) that an error has occurred; and

(b) what the correction should be.

Regarding (a), the existence of an error must be obvious from the originally filed application documents taken by themselves.

Regarding (b), the priority document is an important element and must be taken into account in appropriate cases.

#### 6.5 Procedure for amendments to documents

Superseding new pages – Amendments to the text of a patent application will normally be incorporated by filing superseding new pages, which supersede the corresponding pages in the file. Where it is not obvious how the text has been amended, the applicant should explain in his reply letter from which of the original application pages the amendments are derived.

Example: Original page 2 is superseded by four replacement pages numbered 2, 2A, 2B and 2C.

The applicant may also submit annotated copies of one or more amended pages on his own initiative. If, however, the amendments are so extensive as to affect the legibility of the copies, superseding pages must be filed.

## **7. Telephone conversations; personal interviews**

A telephone conversation or personal interview with the applicant or his representative is normally only appropriate after a first examiner communication and after the first reply letter. Such consultation is also not appropriate if the applicant/representative is likely to require time for consideration of the case.

The circumstances in which it may be appropriate for the examiner to communicate with the applicant/representative by telephone or propose a personal interview rather than send a further examiner communication are:

- (a) if confusion exists about some points in the examiner communication or in the applicant's reply, e.g. a misunderstanding or an argument that is not clear;
- (b) if minor matters can be resolved easily and quickly.

Where the applicant has appointed a representative, the communication should be with that representative. If the applicant or his representative requests a personal interview the request should be granted unless the examiner believes that no useful purpose would be served by such a consultation.

When a personal interview is arranged, whether by telephone or in writing, and whether by examiner or applicant, the matters for discussion should be stated. If an interview arrangement is made by telephone, the examiner should briefly indicate, on a special form, the matters to be discussed.

A special form for the "Result of consultation by interview/telephone" should be used. The written records of the personal interview depend upon the nature of the matters under discussion. Where the interview is concerned with the clarification of obscurities, the resolution of uncertainties, or putting the application in order for grant by clearing up a number of minor points, it will usually be sufficient if the examiner makes a note on the form of the matters discussed and the conclusions reached or amendments agreed. If, however, the interview is concerned with resolving important matters, such as questions of novelty, inventive step, or whether the amendment introduces additional subject-matter, then a fuller note of the matters discussed should be made on the form or its annex pages. The results are to be signed also by the applicant/representative at the end of the personal interview.

If a fresh objection of substance is raised at a personal interview and no amendment to meet it is agreed at the time, the objection must be confirmed by a letter giving the applicant a new time limit within which he may reply if he so wishes. Otherwise time limits may not be altered as a result of an interview.

When the examiner takes the initiative for a telephone conversation, the normal procedure should be first to telephone the representative/ applicant stating the P number of the application he wishes to discuss and requesting the representative to telephone back at a specified time. After the conversation, written records must be made on the special form, identifying the matters discussed and any agreements reached. Any matters on which agreement was not reached should also be noted and the arguments put forward by the representative/applicant should be summarised. A copy of the "Result of consultation" is sent or given to the representative/ applicant.

The records of personal interviews or telephone conversations should always indicate whether the next action is due to come from the applicant – with an indication of a time limit – or from the examiner. Appropriate instructions for the Legal Service are marked on the form.

## **8. Observations of third parties**

Following the publication of the Croatian patent application, any person may present observations concerning the patentability of the invention. Such observations must be filed in writing and must usually cite new documents from the prior art. That person is not a party in the substantive examination proceedings before SIPO.

The observations are not taken into account unless a request for substantive examination is filed. If a document presented is more relevant than the closest prior art document revealed during the search, then this new document should be used as a starting document for assessment of inventive step or novelty. It must be introduced into the search and examination proceedings. If observations are presented after the conclusion of these proceedings, they will not be taken into account and will simply be added to the file. The observations may relate to alleged prior art available other than from a document, e.g. from prior use. This should be taken into account only if the alleged facts are either not disputed by the applicant or are established beyond reasonable doubt.

## **9. Divisional applications**

Subsequent to the filing of an application, the subject-matter of such application may be divided into two or more applications by filing a divisional application– Art. 32(1) PA.

Such an application can only be filed in respect of subject-matter which does not extend beyond the content of the earlier application as filed – Art. 32(2) PA.

The divisional application shall maintain the filing date of the original application, and shall enjoy the right of priority thereof– Art. 32(4) PA.

According to Art. 32(3) PA the filing of a division of the original patent application shall be permitted up to the decision made after the request for examination.

Lack of unity – The most common reason for filing a divisional application is to meet an objection under Art. 18 PA of lack of unity of invention. If the examiner objects that the application does not meet the requirements of unity of invention, the applicant is allowed a time limit of 2 to 4 months in which to limit his application, and a further time limit of 2 to 4 months after limitation is given in which to file a divisional application or applications for the matter excised from the earlier application.

If no objection of lack of unity of invention is raised by the examiner, it is still possible that the applicant will take the initiative to file a divisional application in respect of some particular subject-matter in the original application.

Up to the date of the decision to grant, the filing of a divisional application should normally be allowed at any time, provided that this application satisfies the substantive conditions:

- (a) that it is confined to subject-matter contained in the earlier application; but
- (b) nevertheless claims a different invention.

The examination of a divisional application should be carried out exactly as for any other application.

Comparison of the divisional application with the earlier application is necessary to ensure that:



- (c) no additional subject-matter is added,
- (d) as far as possible each application describes only the matter coming within the scope of its claims.

The same comparison should be made between divisional applications where there is more than one. When it is necessary for one application to describe matter claimed by another application (e.g. the description of one of the inventions may not be understandable without a description of the other invention), it must include a cross-reference to that other application. The cross-reference should make it clear that the matter in question is claimed in the other application.

Although the claims in a divisional application must relate to subject-matter contained in the earlier application, they need not be limited in their scope to that of the claims in the earlier application which were directed to the same subject-matter. These claims can relate to subject-matter described in the description.

The earlier application and divisional applications may not claim the same invention. This means not only that they must not contain claims of substantially identical scope, but also that one application must not claim the subject-matter claimed in the other, even in different words.

## **10. Patent certificate, patent specification, mention of grant**

After receipt of approval by the applicant of the text proposed in the intention to grant or after a lack of reaction from the applicant within the time limit, the formal preparations for the official decision to grant are made by the Legal Service:

- (i) Recording in Patent Register – Art. 49 PA and Art. 26 PR

The data specified in the decision on the grant shall be entered into the Patent Register on the date of decision to grant.

- (ii) Issuance of patent certificate – Art. 50 PA, Art. 31 PR

The patent owner shall be issued a patent certificate as soon as possible from the date of decision to grant. The consensual patent owner shall be issued a consensual patent certificate.

- (iii) Issuance of Patent Specification – Art. 52 PA, Art. 34 PR.

The patent owner shall be issued the Patent Specification before or on the grant date.

- (iv) The mention of a patent grant shall be published in the Official Gazette published on the last day of each month. This mention of the grant shall be in its first issue after the grant date.

The decision to grant shall take effect on the publication date of the Official Gazette – Art. 51(1) PA.

## **11. Suspension of the procedure; Withdrawal; Considered to be withdrawn;**

The applicant may abandon his request, i.e. withdraw his application, by a written statement, during the whole course of the procedure. In such a case, the Office shall stop all further proceedings and issue a decision on the suspension of the procedure.

A particular act or failure by the applicant may be considered as his abandonment of the request (the application is considered withdrawn) only where it is prescribed by the law. Thus, if no request for the grant of a patent is filed within the 6-month time limit after publication of the application, then the application is considered to be withdrawn, and the Office shall issue a

decision on the suspension of the patent granting procedure.

If the administrative fees and procedural charges for the patent granting procedure are not paid, the patent application shall be considered to be withdrawn.

Suspension of the procedure – According to the Act on General Administrative Procedure a final written decision is to be issued on all the initiated procedures.

In all cases a final decision is taken by SIPO.

## **Chapter D-V. Decision on refusal**

### **1. Basis of decision on refusal**

If the examiner has established that the patent application does not comply with all the requirements for the grant of a patent (according to one of the possible requests for examination), the examiner shall issue a written decision, on the basis of which the Legal Service shall invite the applicant to comment on the reasons for which the patent shall not be granted within the period of 2 – 4 months (Art. 47(1) PA). He shall invite the applicant to comment in writing on the specified reasons. This means that the final decision on refusal must be based on grounds or evidence on which the applicant has had the opportunity to present his comments.

This provision is intended to ensure the application of the principle of hearing a party provided for by the Act on General Administrative Procedure, since the applicant shall be given an opportunity to comment on the facts and circumstances which are important for a decision, before the decision on a request is issued.

No applicant can be taken by surprise by the grounds for a decision against his application, since he had an opportunity to present his comments on them.

If the applicant does not comply with this invitation to comment, the examiner shall issue a decision on refusal, on the basis of which the Legal Service prepares a decision on refusal – Art. 47(3) PA.

A decision on refusal of a patent application may thus not be issued by the Office if:

- (a) the Office has not previously notified the applicant in writing of the reasons why the requested patent may not be granted, and
- (b) the applicant has not been invited to react to these reasons or to amend the submitted application within the prescribed time limit.

Art. 47(2) PA further specifies that the time limit may, upon reasoned request of the applicant, be extended.

### **2. Written form of the refusal decision**

#### **2.1 General remarks**

The decision on refusal is drafted by a SIPO lawyer of the Patent Administration – Legal Section on the basis of the application file examined by the examiner.

Decisions are to be produced in writing. The rules about the form and content of decisions are laid down by the Act on General Administrative Procedure and depend, among other things, on the requirements of each particular case.

#### **2.2 Different parts of the decision on refusal**

##### **(i) Preamble:**

The name of the authority, a reference to relevant Articles of the Patent Act, e.g. Art. 15 PA – SIPO competence; Art. 47(3) PA – Refusal, a brief description of the subject of the procedure.

##### **(ii) Order:**

The order contains a decision on the subject matter of a procedure.

(iii) Reasoning of decision

Subject to the requirements laid down by the Act on General Administrative Procedure, here is a detailed description of the preferable manner of presenting facts and evidence on which the decision is based.

Under facts, a brief description of the case and a summary of the main reasons on which the decision is based and of the most important replies of the applicant should be given.

Facts and submissions which are irrelevant to the decision, e.g. requests for amendment which are not maintained, are to be omitted.

The facts and submissions must clearly indicate what the subject of the application is and show on which documents (in particular which claims) the decision is based.

The reasoning must contain, in logical sequence, those arguments which justify the order. It should be complete and independently comprehensible, i.e. generally without references. If, however, a question has already been raised in detail in a particular communication contained in the file, the reasoning of the decision may be summarised accordingly and reference may be made to the relevant communication for the details.

The conclusions drawn from the facts and evidence, e.g. publications, must be made clear. The parts of a publication which are important for the decision must be cited in such a way that those conclusions can be checked without difficulty. It is not sufficient, for example, merely to assert that the cited publications show that the subject of a claim is known or obvious. Instead, reference should be made to each particular passage in the publications to show why this is the case.

It is particularly important that special attention should be paid to important facts and arguments which may speak against the decision made. If not, the impression might be given that such points have been overlooked. Documents which cover the same facts or arguments may be treated in summary form, in order to avoid unnecessarily long reasoning.

The need for complete and detailed reasoning is especially great when dealing with contentious points which are important for the decision. On the other hand, no unnecessary details or additional reasons should be given which are intended to provide further proof of what has already been proven.

(iv) Information for remedy

Decisions on refusal by SIPO which are open to legal remedy or appeal must be accompanied by a written communication of the possibility of legal remedy or appeal. The communication must also draw the attention of the applicant to the provisions laid down in Art. 15(2) PA, the text of which could be incorporated.

**3. Appeal procedure – Art. 88-94 PA.**

The Act on Amendments to the Patent Act introduces the possibility of filing an appeal as of 1 June 2008. Art. 88(1) PA stipulates that "Any party entirely or partially adversely affected by the decisions of the Office issued in the first instance shall have the right to file an appeal within 30 days from the date of communication of the decision."

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## PART E – NATIONAL PHASE OF PCT APPLICATIONS

### Chapter E-I.

#### National phase of PCT applications

##### 1. PCT procedures

###### 1.1 Roles of SIPO and Croatia in the PCT international phase

The Republic of Croatia has been a Member State of the Patent Cooperation Treaty (PCT) since 1 July 1998. Most patent applications of foreign origin seeking patent protection in Croatia are filed through the PCT system. SIPO of Croatia may fulfil the following roles in the PCT system:

###### (i) Receiving Office (PCT/RO).

If a PCT application is filed through the SIPO Receiving Office by a natural person having a domicile or a legal person having a principle place of business in the Republic of Croatia, the EPO is:

the International Searching Authority (PCT/ISA)

the International Preliminary Examining Authority (PCT/IPEA)

###### (ii) Designated state in PCT Chapter I procedure

The results of this PCT Chapter I procedure, used by both foreign and resident applicants, are:

international publication of the application (WO A document),

International Search Report (PCT/ISR),

Written Opinion on patentability (PCT/WOISA).

###### (iii) Elected state in PCT Chapter II procedure

This PCT Chapter II procedure is optional for the applicant.

The result is an International Preliminary Examination Report (PCT/IPER).

###### 1.2 Direct national phase or via Euro-PCT route?

PCT applications filed between 1 July 1998 (date of entry into force of the PCT in Croatia) and 1 April 2004 (date of entry into force of the EPO Extension Agreement) could only enter directly into the national phase in Croatia. This entry into the national phase has to take place within 31 months after the international filing date or the priority date respectively.

Because of the Extension Agreement between the Republic of Croatia and the European Patent Organisation, for PCT applications filed after 1 April 2004 PCT applicants can choose the regional Euro-PCT route after the PCT international phase. The PCT application will then follow the European grant procedure at the EPO. The European patent (EP B1) can then be extended to or validated for Croatia only after its grant at the EPO.

However, the PCT applicant can also choose to enter the national phase directly in Croatia, without using the Euro-PCT route. The possibility of direct entry into the PCT national phase in

Croatia has not been closed. However, only a very limited number of PCT applications is expected to opt for the direct national phase.

## **2. Working procedures in the PCT national phase**

### **2.1 Tasks before start of substantive examination**

#### **(i) Formalities examination**

Some formal requirements are:

- authorised patent representative in Croatia,
- national fees and administrative charges paid,
- translation into the Croatian language of PCT application as amended.

#### **(ii) Publication of the translated PCT application (e.g. HR P20060200A2)**

#### **(iii) One of the requests for examination**

### **2.2 Substantive examination procedure**

This procedure is analogous to the different examination procedures possible for national applications. However, when a PCT application enters into the national phase in Croatia, the file already contains:

- the published international application (WO A document),
- the International Search Report (PCT/ISR),
- the Written Opinion on patentability (PCT/WOISA),
- the International Preliminary Examination Report (PCT/IPER).

This means that most of the patent search and examination work has already been performed by the relevant PCT International Authorities.

Maximum use of these results should be made by SIPO examiners.

However, many different situations can arise after direct entry into the national phase. Further examiner action is in line with the practice for national patent applications.

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## **PART F – EUROPEAN PATENTS VALID IN CROATIA**

### **Chapter F-I.**

#### **Co-operation and Extension Agreement and the EPC**

##### **1. Three different routes to a patent in Croatia**

A foreign or domestic applicant has 3 alternative routes at his disposal for obtaining patent rights on the territory of the Republic of Croatia.

These routes are:

(i) National route:

by an application for a national patent filed at SIPO.

(ii) European route:

by an application for a European patent filed at the EPO or at the national patent office of an EPC (European Patent Convention) Contracting State, as a Receiving Office.

However, the applicant has to designate Croatia (HR) as an Extension State when filing the European application, that he wants to extend to the territory of the Republic of Croatia, and has to pay an extension fee.

After the accession of Croatia to the EPC (1 January 2008), the applicant could designate all EPC Contracting States, and after 1 April 2009 all Contracting States are automatically designated when European patent application is filed.

(iii) International route:

by a PCT application which is filed at one of the many PCT Receiving Offices, e.g. at SIPO, as a Receiving Office for Croatian applicants.

Croatia shall be designated automatically in an international application as filed (the system of automatic designation of all the PCT Member Countries).

At the end of the PCT international phase (31 months after the priority date), the PCT application may follow one of the 2 different routes:

(a) the regional Euro-PCT phase, or

(b) the direct PCT national phase in Croatia. See Part E.

##### **2. European patent system and national law**

The centralised, fundamentally autonomous and uniform procedure for the grant of European patents, introduced by the European Patent Convention (EPC), is linked in a special way with the national patent law of the Member States of the European Patent Organisation. At a number of stages it "interfaces" with the national legal systems. This is a feature essential to smooth interaction between European and national law.

In each of the Contracting States for which it is granted, the European patent has the effect and is subject to the same conditions as a national patent granted by that state.

The salient characteristic of these interfaces is that, at the outset or in the course of the European patent grant procedure or after it has been completed, the patent applicant or proprietor may or must take certain steps before the patent office of the Contracting States in order to acquire or maintain certain rights in those states, e.g. in Croatia.

It is therefore of primordial importance for all European applicants and proprietors to be familiar with and carefully observe such procedural steps laid down by national law in Croatia and the conditions for their validity, if full advantage is to be derived from the European patent system and loss of rights is to be avoided.

### **3. Basics of Extension Agreement with the European Patent Organisation**

The "Co-operation and Extension Agreement" between the Republic of Croatia and the European Patent Organisation entered into force on 1 April 2004. This Agreement allows the extension of the protection conferred by European patent applications and European patents to states which are not yet party to the European Patent Convention (EPC) (such as Croatia until 1 January 2008).

This Agreement forms the basis of an extension system providing patent applicants with a simple and cost-effective way of obtaining patent protection in Croatia and other extension states.

- (i) Request for extension – At the applicant's request and on payment of the extension fee, European applications and European patents can be extended to Croatia, where they will have the same effects as national applications or patents – Art. 99-108 PA. They will enjoy substantially the same scope of protection as patents granted by the EPO for Contracting States of the Organisation.

The European applications may be direct EP or Euro-PCT, provided the PCT applications include the designation both for a European patent and for Croatia.

The extension system largely corresponds to the EPC system operating in EPC Contracting States. However, it is not based on the direct application of the EPC, but solely on national law of Croatia modelled on the EPC. It is therefore subject to the national extension rules of Croatia. See F-II, 1.

- (ii) Extension fee – The extension fee (EUR 102 in 2007) is payable directly to the EPO – Art. 101 PA.

The time limit for payment of the extension fee is:

for direct European applications: 6 months from the date on which the "European Patent Bulletin" mentions the publication of the European search report; 2-month period of grace is possible, provided a 50% surcharge is paid.

for Euro-PCT applications: 31 months from the priority date.

- (iii) Withdrawal of request for extension – The request for extension is deemed withdrawn if the extension fee is not paid or the application is withdrawn, refused or deemed withdrawn – Art. 100(3) PA.

### **4. Accession to EPC terminates Extension Agreement**

The Extension Agreement between the Republic of Croatia and the European Patent Organisation was terminated with the entry into force of the EPC in Croatia, i.e. on 1 January 2008.

After this date it is no longer possible to extend European patent applications and patents to Croatia. The extension system, however, continues to apply to all European and international applications filed prior to the date of entry into force of the EPC in Croatia. It also continues to apply to all European patents granted in respect of such applications.



## Chapter F-II.

### Extended European patents at SIPO

#### 1. Legal framework for the extended European patent system

The legal framework for the extended European patent system in Croatia is provided by Art. 99-108 PA.

Here follows an enumeration of these Articles and their subjects:

Art. 99 PA: Extension of the effects of the extended European patents

Art. 100 PA: Request for extension

Art. 101 PA: Extension fee

Art. 102 PA: Effects of extended European patent applications

Art. 103 PA: Effects of extended European patents

Art. 104 PA: Authentic text of European patents/applications

Art. 105 PA: Rights of earlier date

Art. 106 PA: Simultaneous protection

Art. 107 PA: Renewal fees for extended European patents

Art. 108 PA: Applicability of the EPC (European Patent Convention).

#### 2. Formalities examination

Art. 103(2) PA stipulates that:

The patent owner shall communicate to SIPO within 3 months from the publication date of the mention of the grant of the European patent:

- a request for the entry of the extended European patent into the Croatian Register of Patents (Form PE, pages 1-2),
- a specification of the European patent as published in the EPO Official Journal,
- a translation of the EP specification into the Croatian language, and
- evidence of payment of the prescribed administrative fee and procedural charges for publication and printing of the translation of the specification of the European patent in the Croatian language.

Art. 114(1)(2) reads as follows:

(1) The provisions of Article 103, paragraphs (2) and (3) of this Law, providing for the obligation of the owner of the extended European patent to furnish the translation in Croatian language of the specification and amended claims, shall apply until the entry into force of the Agreement on the Application of Article 65 of EPC, dated 17 October 2000.

(2) After the entry into force of the Agreement referred to in paragraph 1, the owner of a patent shall furnish to the Office the following:

1. a patent specification in English language or, a translation in English language of the specification, and the translation in Croatian language of claims, where a patent has been granted in a language of the proceedings other than English, within the time limit and subject to payment of the prescribed administrative fee and procedural charges for publication as provided for under Article 103, paragraph (2) of this Law;

2. a translation in the English and Croatian language of the amended claims, where the extended European patent is maintained with amended claims, within the time limit and subject to payment of the prescribed administrative fee and procedural charges for publication as provided for under Article 103, paragraph (3) of this Law.

The Agreement from the Article cited above entered into force on 1 May 2008.

All these actions are checked by the Legal Service of SIPO.

A Croatian filing number is allocated, e.g. P20060200T (suffix T for "Translation" of the European patent).

A decision on entry of the extended European patent into the Croatian Register of Patents is issued.

### **3. Publication of the translation of extended European patents**

If all formal requirements are met, the translation of the extended European patent is published, e.g. HR P20060200 T3.

This publication is entered into the Croatian Patent Register and mentioned in the Official Gazette.

**Chapter F-III.****Implementation of the EPC by the Republic of Croatia as a Contracting State****1. Accession date of Croatia to the EPC**

The accession of Croatia to the EPC is 01 January 2008.

**2. Legal framework for European Patent Convention in Croatia**

The legal framework for the European Patent Convention (EPC) in Croatia is provided by Art. 108a-108o PA.

Here follows an enumeration of these Articles and their subjects:

Art. 108a PA: Effect of European patents in the Republic of Croatia

Art. 108b PA: Filing of the European patent application (EP)

Art. 108c PA: Fees and procedural charges for EP applications

Art. 108d PA: Effects of European patent applications

Art. 108e PA: Effects of European patents

Art. 108f PA: Authentic text of European patents/applications

Art. 108g PA: Rights of earlier date

Art. 108h PA: Simultaneous protection

Art. 108i PA: Conversion into a national patent application

Art. 108j PA: Renewal fees for European patents

Art. 108k PA: Dispositions of European patents/applications

Art. 108l PA: Protection against infringement

Art. 108m PA: Declaration of nullity of the European patent

Art. 108n PA: Application of EPC

Art. 108o PA: Translations in accordance with the Agreement on the application of Art. 65 EPC.

**3. Formalities examination****(i) SIPO as EPC Receiving Office**

SIPO has been a Receiving Office for European patent applications filed by Croatian residents since the date of entry into force of the EPC in Croatia.

**(ii) Validation at SIPO of EP patents in the national phase**

The formalities for the validation of EP patents in Croatia are similar to those under the European extension system.

Art. 108e(2) PA stipulates the following:

Within 3 months from the date on which the mention of the grant of the European patent has been published, the owner of the patent shall furnish the Office with:

- a request for the entry of the European patent into the Croatian Register of Patents (Form PE, pages 1-2),
- a specification of the European patent as published in the Official Journal of the EPO,
- a translation of the EP specification into the Croatian language, and
- shall pay the prescribed administrative fee and procedural charges for publication and printing of the translation of the specification of the European patent in the Croatian language.

All these actions are checked by the Legal Service of SIPO.

A Croatian filing number is allocated, e.g. P20060200T (suffix T for "Translation" of the European patent).

A decision on entry of the European patent into the Croatian Register of Patents is issued.

#### **4. Publication of the translation of European patents**

If all formal requirements are met, the translation of the European patent is published, e.g. HR P20080203T3.

This publication is entered into the Croatian Patent Register and mentioned in the SIPO Official Gazette.

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## PART G – SUPPLEMENTARY PROTECTION CERTIFICATES

### Chapter G-I.

#### General provisions; Legal framework

This section relates to Supplementary Protection Certificates for medicinal products and plant protection products (hereinafter: Certificate or SPC).

The SPC is not a whole patent extension; it provides legal protection that extends the protection conferred by a patent (called "basic patent") in respect of an active substance of a medicinal or plant protection product.

In various technical fields, after filing a patent application the applicant can immediately exploit the solution of the invention; that is to say, he can place his product on the market. However, in the case of medicinal and plant protection products the exploitation of the new product has to be postponed until authorization for placing the product on the market is received from the health and agricultural authorities.

This "lost" period of time considerably reduces the official 20-year protection conferred by the patent, and the period of effective protection would be insufficient to cover the investment put into the research and development and other investments.

The Certificate takes effect at the end of the lawful term of the basic patent for a period equal to the period which elapsed between the date on which the application for a basic patent was lodged and the date of the first authorization to place the product on the market in the Community, reduced by a period of five years. The duration of the Certificate may, however, not exceed five years from the date on which it takes effect. The exception to this rule applies to medicines for pediatric use, in which case it is possible to extend the duration of the Certificate by another 6 months.

This special calculation method ensures that the product covered by the basic patent enjoys an overall maximum of fifteen years of adequate and effective protection, and furthermore a uniform solution at European Community level is provided.

#### Legal framework

The field of supplementary protection certificates in the Republic of Croatia is regulated by:

- (1) the Regulation (EC) No. 469/2009 of the European Parliament and of the Council of 6 May 2009 concerning the creation of a supplementary protection certificate for medicinal products, (SL L 152, 16.6.2009. with all amendments – further: the Regulation (EC) No 469/2009).
- (2) the Regulation (EC) No. 1610/96 of the European Parliament and of the Council of 23 July 1996 concerning the creation of a supplementary protection certificate for plant protection products, (SL L 198, 8.8.1996. with all amendments – further: the Regulation (EZ) No 1610/96).

The Regulations are directly applicable in Croatia as of the day of accession to the EU, which is 1 July 2013. However, the Certificate, as well as its extension, produces effects exclusively within the territory of the country in which it was issued.

These Regulations largely relate to almost identical substance, and the instructions in this Guidelines, except where otherwise stated, apply to both Regulations.

- (3) the Patent Act (PA) which provides the conditions for carrying out the procedure for issuing the Certificate and its extension under the said Regulations.

#### (4) Patent Regulations (PR).

### 1. Conditions for obtaining a Certificate

The conditions for obtaining a Certificate for a medicinal product or a plant protection product are set out in Art. 3 of the Regulation (EC) No. 469/2009 and Art. 3 of the Regulation (EC) No. 1610/96.

"The Certificate shall be granted if, in the Member State in which the application referred to in Article 7 is submitted and at the date of that application:

- a) the product is protected by a basic patent in force;
- b) a valid authorization to place the product on the market as a medicinal product has been granted in accordance with Directive 2001/83/EC or Directive 2001/82/EC, as appropriate;
- c) the product has not already been the subject of a Certificate;
- d) the authorization referred to in point b) is the first authorization to place the product on the market as a medicinal product.

### 2. Meaning of terms

The SPC protects the active substance of a medicinal or plant protection product within the limits conferred by the basic patent.

According to Article 87a (3) PA, the terms referring to the Certificate in the PA have the same meaning and must be interpreted within the meaning of the Regulation (EC) No. 469/2009. and Regulation (EC) No. 1610/96.

Important definitions are contained in Article 1 of the Regulation (EC) No. 469/2009 and Article 1 of the Regulation (EC) No. 1610/96.

#### 2.1 "Medicinal product", "product"

"Medicinal product" is any substance or combination of substances intended for treating or preventing disease in human beings or animals, and any substance or combination of substances which may be administered to human beings or animals with a view to making a medical diagnosis or to restoring, correcting or modifying physiological functions in humans or in animals".

"Product" is the active ingredient or combination of active ingredients of a medicinal product.

#### 2.2 "Plant protection product", "product"

"Plant protection product" is an active substance or a preparation containing one or more active substances, put up in the form in which they are supplied to the user, intended to:

- protect plants or plant products against all harmful organisms or prevent the action of such organisms, in so far as such substances or preparations are not defined otherwise;
- influence the life processes of plants, other than as a nutrient (e.g. plant growth regulator);
- preserve plant products, in so far as such substances or products are not subject to special provisions on preservatives;
- destroy undesirable plants; or

- destroy parts of plants, check or prevent undesirable growth of plants.

"Substance" is a chemical element or its compounds, as they occur naturally or by manufacture, including any impurity inevitably resulting from the manufacturing process.

"Active substance" is a substance or a microorganism, including viruses, having general or specific action against harmful organisms or on plants, parts of plants or plant products.

"Preparation" is a mixture or a solution composed of two or more substances, of which at least one is an active substance, intended for use as a plant protection product.

"Plant" is a live plant and live part of plants, including fresh fruit and seeds.

"Plant product" is a product in the unprocessed state or having undergone only simple preparation such as milling, drying or pressing, derived from plants, but excluding plants themselves.

"Harmful organism" is a pest of a plant or plant product belonging to the animal or plant kingdom, such as viruses, bacteria and mycoplasmas and other pathogens.

"Product" is the active substance or combination of active substances of a plant protection product.

### 2.3 Basic patent

According to Art. 1(9) of the Regulation (EC) No. 1610/96 and Art. 1(c) of the Regulation (EC) No. 469/2009, the basic patent is a patent which is designated by its holder for the purpose of the procedure for the grant of an SPC, protecting a product as such, or a process for obtaining a product or an application of a product.

The term "basic" does not mean that the patent must be the first patent to the product: the patent holder is free to designate any patent fulfilling the requirements of Art. 1(9) of the Regulation (EC) No. 1610/96 and Art. 1(c) of the Regulation (EC) No. 469/2009.

The basic patent may be either a Croatian patent or a European patent valid in Croatia but cannot be a consensual patent – Art. 87I PA.

A basic patent "in force" means a granted patent valid in the territory of the Republic of Croatia.

### 2.4 Marketing authorizations

One of the conditions for obtaining the Certificate is that on the date of filing of the application for a Certificate a marketing authorization for the product as a medicinal or plant protection product must have been granted in the Republic of Croatia, and is in force.

Art. 3(1)b of the Regulation (EC) No. 1610/96 and Art. 3(b) of the Regulation (EC) No. 469/2009 stipulates that the authorization to place the product on the market should have been issued by the competent authority in the procedure prescribed by special regulation.

#### (i) Marketing authorization for a medicinal product

The marketing authorization must have been granted in accordance with Directive 65/65/EEC for human use, or for veterinary use in accordance with Directive 81/851/EEC.

Directive 65/65/EEC was repealed by Article 128 of Directive 2001/83/EC on the Community code relating to medicinal products for human use ordering that references to Directive 65/65/EEC shall be construed as references to Directive 2001/83/EC.

Directive 81/851/EEC was repealed by Article 96 of Directive 2001/82/EC on the Community

code relating to veterinary medicinal products ordering that references to 81/851/EEC shall be construed as references to Directive 2001/82/EC.

(ii) Marketing authorization for a plant protection product

The marketing authorization for plant protection products must have been granted in accordance with Article 4 of Directive 91/414/EEC or an equivalent provision of national law.

Directive 91/414/EEC was recently modified by Regulation 806/2003/EC.

### **3. Subject-matter of protection**

Within the limits of the protection conferred by the basic patent, the protection conferred by a Certificate shall extend only to the product covered by the authorization to place the corresponding medicinal product, or the plant protection product, respectively, on the market and for any use of the product as a medicinal product, or as a plant protection product, that has been authorized before the expiry of the certificate – Art. 4 of the Regulation (EC) No. 1610/96 and Art 4 of the Regulation (EC) No. 469/2009.

The product in respect of which the Certificate is granted is an active ingredient or combination of active ingredients of a medicinal or plant protection product.

A substance which does not have any therapeutic effect of its own and which is used to obtain a certain pharmaceutical form of the medicinal product is not covered by the concept of "active ingredient", which in turn is used to define the term "product". Combinations with non-active ingredients could not be considered to be a "product" in the light of the decision in ECJ Case C-431/04, Massachusetts Institute of Technology.

### **4. Effects of protection and entitlement to the Certificate**

Art. 5 of the Regulation (EC) No. 1610/96 and Art. 5 of the Regulation (EC) No. 469/2009 stipulates that "The Certificate shall confer the same rights as conferred by the basic patent and shall be subject to the same limitations and the same obligations."

Art. 6 of the Regulation (EC) No. 1610/96 and Art. 6 of the Regulation (EC) No. 469/2009 stipulates that the Certificate shall be granted to the holder of the basic patent or his successor in title.

The provisions of the Patent Act shall also apply to the rights and obligations resulting from a Certificate, to exploitation licences in respect of Certificates, to compulsory licences, and to the infringement of Certificates.

The Certificate may not be issued for the licensee or for the owner of the marketing authorization if he is not the owner of the basic patent.

### **5. Duration of the Certificate**

The Certificate shall take effect at the expiration of the lawful term of the basic patent.

The duration of the Certificate is determined by Art. 13 of the Regulation (EC) No. 469/2009 and Art. 13 of the Regulation (EC) No. 1610/96. It is equal to the period which elapsed between the date of filing of the application for a basic patent, and the date of the first authorization to place the medicinal product intended for humans or animals, or the plant protection product protected by a patent on the market, reduced by a period of five years.

However, the maximum duration of the Certificate is five years from the date on which it takes effect.



This calculation ensures that compensation is provided for the period "lost" under the 20-year patent term because of the lengthy process of obtaining the marketing authorization, which is on average 8-12 years between the discovery of a medicine, at which time the patent application is filed, and the medicine being made available to patients.

However, Article 13(3) of the Regulation (EC) No. 469/2009 provides for an exception to the rule, and provides that the duration of a Certificate may be extended only once by six months in the case where Article 36 of the Regulation (EC) No. 1901/2006 applies. The extension of the Certificate will be granted when all the necessary investigations have been completed for a medicine protected by a Certificate or by patent which is eligible for grant the Certificate, in accordance with an agreed completed paediatric investigation plan and provided that no other alternative reward or incentive was possible.

## **6. Competence and decisions of SIPO in SPC matters**

Art. 15(1) PA states that the State Intellectual Property Office (hereinafter: the Office) shall carry out the administrative procedures for the grant of patents, consensual patents and Supplementary Protection Certificates, and shall perform other administrative and professional tasks concerning the protection of inventions.

This means that the Office shall have authority in the following matters concerning Certificates:

- grant of Certificates and decision on extension of its duration
- decision on lapse of Certificates
- decision on nullity of Certificates
- decision on *Restitutio in Integrum* or the continued processing
- keeping the Register of applications for a Certificate and Register of Certificates, including matters concerning their maintenance
- providing official information on applications for a Certificate and granted Certificates.

The decisions of the Office shall be open to the same appeals as those provided for in national law against similar decisions taken in respect of national patents. The decision to grant shall be open to an appeal to rectify the duration of a Certificate where the date of the first marketing authorization in the European Union contained in the application was incorrect.

## **7. Procedural matters**

PA and PR define certain matters relating to the procedures concerning Certificates carried out before the Office.

According to Art. 87a(4) PA, the provisions of PA shall apply *mutatis mutandis* to particular matters of the procedure relating to Supplementary Protection Certificates which are not regulated by the Regulations (EC) No. 469/2009 and 1610/96.

For example, provisions referring to *restitutio in integrum*, representation or use of languages shall be applied *mutatis mutandis*. However, according to Art. 87a(4) PA, provisions of Articles 57 and 57a which relate to *Restitutio in Integrum* and to Continued Processing, shall not apply in the case of failing to comply with the time limits provided for in Article 7 of the Regulation (EC) No. 469/2009 and Article 7 of the Regulation (EC) No. 1610/96.

Further, the SPC file is open for public inspection as from the filing date of the application for a Certificate (Art. 87d(2) PA), as there is no requirement for exclusion of the file from public inspection before publication as in the case of patents.

Typing errors and similar deficiencies in the application for a Certificate or in the Certificate shall be corrected on the basis of the written request of the applicant or owner of the Certificate respectively or ex officio – Art. 56 PA. If the Office considers the request to be allowable, the data are corrected by a decision. Where a proposed correction affects the data of the application for a Certificate or granted Certificate already published, the details of the correction also need to be published.

## **8. Register of applications; register of Certificates**

According to Art. 87b PA, the Office shall keep a Register of applications for a Certificate, which shall also include requests for an extension of the duration of Certificate and a Register of Certificates. The content and the manner of keeping these Registers are defined in more detail by Article 42 of the PR.

Article 87b(3) further stipulates that the provisions of PA relating to the Register of patent applications and the Register of patents shall apply *mutatis mutandis* to the Register of application for a Certificate and Register of Certificates. For example, if a change of the applicant occurs during the examination of application for a Certificate, the procedure for entry and change in the Register will be conducted according to Article 61a PA and Articles 36 and 37 PA.

According to Art. 42(1) PR the Office should keep a Register of applications for a Certificate and a Register of Certificates containing all facts and circumstances concerning Certificates. The Register of applications for a Certificate should contain in particular the following entries:

- the number of the application for a Certificate,
- the filing date of the application
- the name of the product for which the grant of the Certificate is applied for (chemical or generic name),
- indications concerning the applicant: family name, given name and domicile, if a natural person is concerned, or a company name and the principal place of business, if a legal person is concerned;
- indications concerning a representative: family name, given name and domicile, if a natural person is concerned, or a company name and the principal place of business, if a legal person is concerned,
- the number and the filing date of the basic patent application, and the title of the invention,
- the number and date of the authorization to place the product on the market and the name of the product indicated in the authorization, as prescribed in Article 8 paragraph (1) items (b) and (c) of the Regulation (EC) No. 469/2009 and Article 8 paragraph (1) items (b) and (c) of the Regulation (EC) No 1610/96,
- indication concerning an extension of the duration of the Certificate as applied for;
- other indications, if necessary.

According to Article 42(2) PR, the Register of Certificates should contain the following entries:

- the number of a Certificate,
- the date of issue of a decision on the grant of a Certificate,

- indications concerning the holder of a Certificate: family name, given name and domicile, if a natural person is concerned, or a company name and the principal place of business, if a legal person is concerned,
- the duration of a Certificate,
- indication concerning an extension of the duration of a Certificate,
- indications concerning the paid annual charges for the maintenance of a Certificate,
- indications concerning the manner of conclusion of the administrative procedure by a decision of the Office,
- indications concerning the lapse of rights due to failing to pay the annual fee and maintenance charges,
- indications concerning the procedure to declare the Certificate null and void (filing date, the applicant, type and date of the decision),
- indications concerning the appeal procedure (filing date, appellant, type and date of the decision),
- indications on the lapse of the validity of a Certificate: legal basis and the date of lapse,
- other indications, if necessary.

Indications concerning the changes regarding the applicant or the holder of the Certificate, representative or something else, as well as transfer of rights, licenses, right in rem, levy of execution, bankruptcy and other, shall be entered in the corresponding Register.

## Chapter G-II.

### Granting procedure for Certificates

#### 1. Application for a Certificate

The Certificate granting procedure shall be instituted by filing the application for a Certificate at the Office within the time limits set out in Article 7(1)(2) of the Regulation (EC) No. 469/2009 and Article 7 of the Regulation (EC) No. 1610/96.

Article 8(1) of the Regulation (EC) No. 469/2009 and Article 8(1) of the Regulation (EC) No. 1610/96 stipulates that the application for a Certificate shall contain:

- (1.) a request for the grant of a Certificate, which shall be filed on the Form P-3 (Article 87c(4) PA), stating in particular:
  - (a) the name and address of the applicant;
  - (b) the name and address of the representative, if any;
  - (c) the number of the basic patent and the title of the invention.
  - (d) the number and date of the first authorization to place the product on the market in Croatia, or
  - (e) the number and date of the first authorization to place the product on the market if the filed (Croatian) authorization is not the first authorization for placing the product on the market;
  - (f) the name of product for which the grant of the Certificate has been applied for (Article 87c(2) PA).

When multiple authorizations are granted for the same product on the same day, the application should include information on all relevant authorizations.

The content of Form P-3 is provided by Article 41 PR -. SEE ANNEX I.

- (2.) a copy of the authorisation to place the product on the market (in Croatia), as referred to in:
  - (i) Article 3(b) of the Regulation (EC) No. 469/2009, issued by the competent authority in the procedure according to special regulation, in which the product is identified, containing in particular the number and date of the authorisation and the summary of the product characteristics listed in Article 11 of Directive 2001/83/EC or Article 14 of Directive 2001/82/EC, in the case of medicinal products, respectively
  - (ii) Article 3(1)(b) of the Regulation (EC) No 469/2009, issued by the competent authority in the procedure according to special regulation, in which the product is identified, containing in particular the number and date of the authorisation and the summary of the product characteristics listed in Part A.I (points 1-7) or B.I (points 1-7) of Annex II to Directive 91/414/EEC or in equivalent national laws of the Member State in which the application was lodged, in case of plant protection products.
- (3.) information regarding the identity of the product thus authorised and the legal provision under which the authorisation procedure took place, together with a copy of the notice publishing the authorisation in the appropriate official publication, if the Croatian authorisation is not the first authorisation for placing the product on the market as a medicinal product in the Community,

(4.) evidence as to payment of the administrative fee and procedural charges for the grant of a Certificate (Article 87c(3)).

## **2. Registration, data processing**

The procedure on filing of applications for a Certificate, comprising the registration of the documents and the creation of a file, is carried out in the same way as in the procedure for patent applications.

According to Article 87d PA, the accordance of the filing date of the application for a Certificate shall require that on that date the application contains at least:

- an express indication of the fact that the Certificate is applied for;
- data on the identity of the applicant;
- the number of the basic patent and the title of the invention;
- the number and date of the first authorization to place the product on the market, in accordance with Article 3(b) of the Regulation (EC) No. 469/2009 and Article 3(1)(b) of the Regulation (EC) No. 1610/96, and indication of the number and date of the first authorization, if the authorization as filed is not the first authorization to place the product on the market.

Additionally, according to Article 87c(2) PA, application for a Certificate shall also contain the name of the product for which the grant of the Certificate has been applied for.

The application which is accorded a filing date shall be entered in the Register of Applications for a Certificates and shall be available to the public.

## **3. Examination procedure of an application for a Certificate before publication**

Pursuant to Article 87e(1) PA, the Office shall establish in the examination procedure of the application for a Certificate:

- whether the application complies with the requirements for granting the filing date as referred to in Article 87d of this Act, i.e. whether the request was filed in the form as prescribed (Form P-3 or the form entirely matching it in contents and appearance) and whether it contains all the data provided for by Article 8(1)(a) of the Regulation (EC) No 469/2009 and Article 8(1)(a) of the Regulation (EC) No 1610/96, including the name of the product for which the grant of the Certificate is applied for, and
- whether the administrative fee and procedural charges for filing the application have been paid.

If the application does not meet the requirements as referred to in Article 87e(1) and Article 87c(2) PA, the Office shall order the applicant by a conclusion to correct the found deficiencies within two months upon its receipt. If the applicant acts in accordance with the conclusion and corrects deficiencies within a set time limit, the Office shall inform the applicant that the date of receipt of the required corrections shall be accorded as the filing date of the proper application for a Certificate. Otherwise, the Office shall reject the application by a decision.

## **4. Publication of an application for a Certificate**

Article 87e(7) PA stipulates that the Office shall publish data concerning the filing of an application for a Certificate which complies with the requirements for the accordance of the filing date referred to in Article 87d PA and for which the administrative fee and procedural charges for filing the application have been paid, in its Official Gazette according to provision from Article 9(2)

of the Regulation (EC) No. 469/2009 and Article 9(2) of the Regulation (EC) No. 1610/96. The data to be published shall be defined by the Regulations – Article 43 PR.

## 5. Examination procedure of the conditions for obtaining a certificate

Article 87f PA indicates that the examination procedure shall be conducted by establishing if the application for a Certificate (on the filing date as determined) meets all the conditions provided for by Regulations (EC) No. 469/2009 and 1610/96, and the conditions provided for by the Patent Act.

### 5.1. Formalities and legal examination procedure,

(i) In the formalities examination procedure, the organisation unit of the Patents Department responsible for international, legal and administrative affairs shall establish the following:

(a) whether the application is filed by an authorised person;

Although Regulations (EC) do not provide for the person who can file the application for a certificate, Article 6 of the Regulation (EC) No. 469/2009 and Article 6 of the Regulation (EC) No. 1610/96 unequivocally provide that the Certificate shall be granted to the holder of the basic patent or his successor in title. If the applicant for a certificate and the basic patent holder or his successor in title are different persons, the Office shall notify the applicant thereon and request evidence as to his legitimacy.

With interpreting the Regulation (EC) No. 1768/92 of 18 June 1992 (OJ 1992 L 182, p.1), the Court of Justice of the European Union indicates in its judgment that the application cannot be rejected only for the reason that the patent holder cannot deliver a copy of the marketing authorisation where the basic patent holder and the marketing authorisation holder are different persons. In simple cooperation with a state authority responsible for issuing the marketing authorisation, the Office may request and obtain a copy of such authorisation. (Please refer to the case of the Court of Justice of the European Union C-181/95 Biogen vs. SmithKline Beecham Biologicals SA).

(b) whether the application is filed within the time limit provided for by Article 7(1)(2) of the Regulation (EC) No. 469/2009 and Article 7 of the Regulation (EC) No. 1610/96.

The application is proper if filed within six months upon the date of the Croatian authorisation having been granted. However, where the authorisation has been filed before granting the basic patent, the six-month time period shall start as of the date of granting the patent.

The date of grant the national marketing authorisation is the date printed on the authorisation itself.

The date of granting the European patent is the date of the European Patent Gazette having published the granting data.

### - Special rights in the transitional period

Article 19 of the Regulation (EC) No. 1610/96 and Article 20 of the Regulation (EC) No. 469/2009 providing for additional provisions in relation to the expansion of the Community regulate special rights in the transitional period referring to certificates. These Articles offer special opportunity of derogation from general rules concerning the time limit for applications, which enable “retrospective” filing of applications for those patented products which will already be on the market at the time of the accession of the Republic of Croatia to the European Union.

The holder of the basic patent in the Republic of Croatia, granted for a medicinal product intended for humans or animals or a plant protection product, respectively, for which the marketing authorisation was granted by a competent authority in any of the Member States of the European Union, on the day of the accession of the Republic of Croatia into full membership of the European Union, or, in the Republic of Croatia, after 1 January 2003, may apply for a Supplementary

Protection Certificate in the Republic of Croatia, within 6 months as of the day of the accession of the Republic of Croatia into full membership of the EU.

Such applications are not subject to the time limits provided for by Article 7(1)(2) of the Regulation (EC) No. 469/2009 and Article 7 of the Regulation (EC) No. 1610/96.

(c) whether the application is accompanied by evidence provided for by Article 8(1)(b) and (1)(c) of the Regulation (EC) No. 469/2009 and Article 8(1)(b) and (1)(c) of the Regulation (EC) No. 1610/96.

(d) whether the basic patent is in force.

In addition hereto, it should be checked, by means of the Patent Register data, whether the basic patent indicated in the application for a certificate was in force at the time of filing the application for a Certificate.

(ii) Rectification of the irregularities

If the application for a Certificate does not meet the mentioned requirements, the Office shall warn the party thereof by a conclusion and set it a period of 60 days upon receipt of the conclusion to correct the deficiencies - Article 73(1) of the General Administrative procedure Act.

(iii) Refusal on formal grounds

If the applicant fails to remedy the found deficiencies within a prescribed time limit, the Office shall issue a decision on the rejection of the application for a Certificate - Article 73(2) of the General Administrative procedure Act.

## 5.2 Substantive examination

Following this part of the procedure, the organisation unit of the Patents Department responsible for international, legal and administrative affairs shall refer the matter for examination to patent examiners, who shall then determine the following:

(a) have all the evidence been enclosed

According to Article 8(1)(b) of the Regulation (EC) No. 469/2009 and Article 8(1)(b) of the Regulation (EC) No. 1610/96, the application shall also contain a copy of the authorization to place the product on the market, in which the product is identified – See G-I,2.4.

The marketing authorization that is effective in the Republic of Croatia is an essential prerequisite for the issuance or grant of an SPC. This authorization shall contain in particular the number and the date of the authorization and the summary of product characteristics.

The question of the applicant's obligation to provide a copy of the authorization was dealt by the CJEU in decision mentioned in G-II,5.1 and it was stated that, where different persons hold the basic patent and the marketing authorization and the patent holder is unable to file the copy of that authorization, an application must not be refused on that ground alone. By simple cooperation with the competent national authority which issued the marketing authorization, Office can obtain a copy of such authorization.

If the marketing authorization were to be precluded from being communicated to the basic patent holder on account of any hypothetical confidentiality, there are other possible ways of saving the confidentiality of the authorization. (See CJEU C-181/95 Biogen vs. SmithKline Beecham Biologicals SA).

Copies of confidential authorizations obtained from the authorization authorities are filed in a separate envelope marked "Not open to the Applicant or the Public".

In addition, when the Croatian authorization is not the first authorization in the European Union – which is often the case – the following evidences concerning the first authorization in the EU should be filed – Article 8(1)(c) of the Regulation (EC) No. 469/2009 and Article 8(1)(c) of the Regulation (EC) No. 1610/96:

- evidence showing the identity of the product,
- the content of the authorization procedure (this means the legal provision under which the authorization procedure took place),
- the Gazette in which the indication concerning the authorization was published (a copy of the notice in the relevant official publication).

In practice any other document is acceptable which proves that the first authorization in the EU has been issued, and which contains the date on which it was issued and the identity of the product.

(b) whether the product is protected by the basic patent

The question of whether the product is protected by the basic patent can be answered by comparing the basic patent specification with the summary of product characteristics.

The terminology used in the marketing authorization and in the patent is not similar. The marketing authorization indicates the International Non-proprietary Name (INN) of the product, which is an official name given to a pharmaceutical substance, as designated by the World Health Organization (WHO).

Example:

INN :	Paracetamol
IUPAC chemical name:	N-(4-hydroxyphenyl)acetamide
Trade name of the authorized medicinal product:	Panadol®

On the other hand, the patent specification may disclose the same compound, generally defined by its chemical structure, name and certain salts or bases of the substance, although they cannot be found in the marketing authorization (or vice versa).

The scope of the patent shall be determined by the claims, whereas the description and drawings shall serve to interpret the patent claims – Art. 61 PA.

Where the basic patent covers an active substance and its various derivatives such as salts and esters, the Certificate confers the same protection. A product which is defined as a pharmacologically active free base or parent compound in the marketing authorization should be considered also as protected by the basic patent where it comes within the terms of the claims of the patent. (CJEU Case C-392/97 Farmitalia Carlo Erba, Srl Application)

The Office has to consider the "product identified in the MA" in a broader sense, to define the product in terms of the active principle and its derivatives (salts and esters).

The applicant for the Certificate may furnish information about where the product is to be found in the patent description, he may designate a claim, a working example supporting the claims, or he may refer to the general formula according to a specific claim by giving the meaning of the substituents.



(c) whether the marketing authorization is in accordance with the provision of the Article 3(b) of the Regulation (EC) No. 469/2009 and Article 3(1)(b) of the Regulation (EC) No. 1610/96, granted in accordance with:

- Directive 2001/83/EC or Directive 2001/82/EC, relating to medicinal product for humans or animals, or
- Article 4 of Directive 91/414/EEC, or an equivalent provision of national law, for plant protection products.

The product should have a marketing authorization effective in the particular country for which the SPC is sought. Accordingly, the Croatian SPC can be granted only on the basis of a marketing authorization which is effective in the territory of the Republic of Croatia.

The most essential part of the marketing authorization is the so-called **"Summary of product characteristics"** where the name of the authorized product can be found. Here the qualitative and quantitative composition of the medicinal product is given and all the active ingredient(s) and excipients contained in the composition are listed.

The validity of the marketing authorization for the product is also checked via databases accessible via the web pages of the national health authorities or the European Medicines Agency (EMA).

(d) has the product already been subject to Certificate (one product – one Certificate)

According to provision of Article 3(c) of the Regulation (EC) No. 469/2009 and Article 3(1)(c) of the Regulation (EC) No. 1610/96, the Certificate can be granted only when the product has not already been the subject of a Certificate.

The grant of a second certificate for a product is precluded if a first certificate has been granted before the date of application for the second certificate.

However, the provisions of Article 3(2) of the Regulation (EC) No. 1610/96 should also be taken into consideration. They point out that if the applicant for the Certificate is the holder of more than one patent for the same product, he shall be granted only one Certificate for that product."

However, if two or more applications for a Certificate concerning the same product, and are emanating from two or more holders of different patents are pending, one Certificate for this product may be granted to each of these holders.

This means that if the applicant for a Certificate is the holder of more than one patent for the same product, he shall decide which patent to designate as a basic patent, as only one Certificate for that product can be granted.

However, where a product is protected by a number of basic patents belonging to different patent holders, each of those patents may be designated for the purpose of the Certificate.

The question of whether an earlier Certificate for the product exists can be answered by searching for the name of the product in the future SPC database of the Office, or from the Register.

## 6. Grant of the Certificate

If in the course of the examination procedure it has been established that application complies with all the requirements prescribed by the Regulation (EC) No. 469/2009 and No. 1610/96, and with requirements prescribed by PA, and if the administrative fees and procedural charges for the maintenance, printing and publication of a Certificate have been paid,, the Office shall issue a decision on the grant of the Certificate.

The decision shall also specify the duration of the Certificate – Article 87f(1)PA.

#### 6.1 Calculation of the duration of the Certificate

The duration of the Certificate is determined by Article 13 of the Regulation (EC) No. 469/2009 and by Article 13 of the Regulation (EC) No. 1610/96.

The marketing authorizations issued in Switzerland (which, in the framework of the customs union with Liechtenstein, are automatically effective in Liechtenstein) are to be considered as a "first authorization to place the product on the market in the Community". (See CJEU C-207/03 Novartis and C-252/03 Millenium Pharmaceuticals Inc.).

For the purposes of calculating the duration of the Certificate for a plant protection product, a provisional marketing authorization shall be taken into account only if it is directly followed by a definitive authorization. In this case the duration of the Certificate shall be calculated on the basis of the date of the provisional marketing authorization.

The calculated duration according to Article 13 of the Regulation (EC) No. 469/2009 and Article 13 of the Regulation (EC) No. 1610/96 can be defined and published by giving the date of entry into force and the day of expiry of the Certificate. See ANNEX II.

#### 6.2 The content of a Certificate

Article 87g PA states that the Certificate shall contain:

- (a) the number of the Certificate,
- (b) the name and address of the holder of the Certificate,
- (c) the name of the product for which the Certificate is granted,
- (d) the number of the basic patent,
- (e) the title of the invention;
- (f) the number and date of the first authorization to place the product on the market in accordance with Article 3(b) of the Regulation (EC) No. 469/2009 and Article 3(1)(b) of the Regulation (EC) No. 1610/96,
- (g) the number and date of the first authorization to place the product on the market, if the authorization as filed is not the first authorization to place the product on the market,
- (h) the duration of the Certificate.

### 7. Refusal of the application for a Certificate

If, in the course of the examination procedure, the Office establishes that not all the prescribed conditions are complied with, it shall refuse an application for the Certificate by a decision – Art. 87f(3) PA.

Previously the applicant shall have been invited to rectify the irregularities or to submit his comments during the substantive examination. Otherwise the application cannot be refused.

## **8. Publication of granted Certificates and refused applications**

The Office shall publish, in its Official Gazette, data concerning the grant of a Certificate, or the rejection of the application for a Certificate, and the termination of a Certificate – Article 11 of the Regulation (EC) No. 469/2009 and Article 11 of the Regulation (EC) No. 1610/96.

The data to be published are defined by the Patent Regulations (Article 43 and 44 PR).

Data concerning the Certificate shall be entered in the Register of Supplementary Protection Certificates – Article 42 PR.

Data concerning the Certificate shall also be entered in the Register of Patents – Article 26(2)25 PR.

## **9. Maintenance fees**

According to Article 16 PA, the procedures provided for by PA, including also the maintenance of a Certificate, shall be subject to payment of the fees and procedural charges in compliance with special regulations. The detailed rules of the payment are laid down in the Act on the Administrative Fees in the Field of Intellectual Property Rights and the Regulation on Special Charges and Charges for Information Services Provided by SIPO.

The maintenance fee shall be paid after the expiry of the 20-year protection of the basic patent when the certificate enters into force with its calculated duration (Article 87k PA).

The annual fee for the maintenance of the Certificate shall be paid to the Office for each year of its duration; it shall cover a 12 month period, starting to run on the date of expiration of the basic patent and shall be paid for each year separately.

If the last period of the duration of the Certificate is shorter than twelve months, the annual fee shall be paid in advance in the amount which is proportionate to the duration of the Certificate, together with the payment of the total amount of the annual fee for the last complete year.

## ANNEX I

## FORM-Request for grant of a Certificate

DRŽAVNI ZAVOD ZA INTELEKTUALNO  
VLASNIŠTVO REPUBLIKE HRVATSKE  
Ulica grada Vukovara 78  
10000 ZAGREB

Obrazac P-3, stranica 1

**ZAHTJEV ZA IZDAVANJE  
SVJEDODŽBE O DODATNOJ ZAŠTITI/  
ZAHTJEV ZA PRODULJENJE  
TRAJANJA SVJEDODŽBE O  
DODATNOJ ZAŠTITI**

(popuniti čitko tiskanim slovima)

Rubrike 1-3 popunjava Zavod

<b>BROJ ZAHTJEVA</b>	1	Klasa, urudžbeni broj, datum zaprimanja	3
<b>DATUM PODNOŠENJA</b>	2		

Rubrike 4-17 popunjava podnositelj zahtjeva

<input type="checkbox"/> OVIME SE ZAHTIJEVA IZDAVANJE SVJEDODŽBE O DODATNOJ ZAŠTITI <input type="checkbox"/> OVIME SE ZAHTIJEVA PRODULJENJE TRAJANJA SVJEDODŽBE O DODATNOJ ZAŠTITI Upisati znak "x" u odgovarajuću kućicu/e	4
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<b>PODNOŠITELJ ZAHTJEVA</b> Osobni identifikacijski broj (OIB) * Prezime i ime (za fizičke osobe) Tvrtka (za pravne osobe) Ulica i broj Poštanski broj i mjesto / Država Telefon, Telefaks E-pošta		5
<b>IZJAVA O ZAJEDNIČKOM PREDSTAVNIKU</b>	<input type="checkbox"/> Upisati znak "x" ako postoji više podnositelja, a pisanu izjavu o zajedničkom predstavniku dati u prilogu	6
<b>PODACI O OSTALIM PODNOŠITELJIMA</b>	<input type="checkbox"/> Upisati znak "x" ako postoji više podnositelja; podatke dati na posebnom listu u prilogu	7
<b>ZASTUPNIK</b> Osobni identifikacijski broj (OIB) * Prezime i ime (za fizičke osobe) Tvrtka (za pravne osobe) Broj iz registra DZIV-a Ulica i broj Poštanski broj i mjesto / Država Telefon, Telefaks E-pošta		8
<b>PODACI O OSTALIM ZASTUPNICIMA</b>	<input type="checkbox"/> Upisati znak "x" ako postoji više zastupnika; podatke dati na posebnom listu u prilogu	9
<b>ZAHTIJEVA SE IZDAVANJE SVJEDODŽBE ZA</b> <input type="checkbox"/> proizvod kao sastavni dio lijeka za ljude i životinje <input type="checkbox"/> proizvod kao sastavni dio sredstva za zaštitu bilja Upisati znak "x" u odgovarajuću kućicu		10

\* Na temelju članka 6. Zakona o osobnom identifikacijskom broju („NN“ 60/08) obveznici broja obvezni su od 1.1.2010. koristiti dodijeljeni im OIB na svim prijavama i ostalim podnescima kojima komuniciraju s korisnicima broja (Zavodom).

<b>BROJ TEMELJNOG PATENTA I NAZIV IZUMA</b>		11
<b>BROJ I DATUM PRVOG ODOBRENJA ZA STAVLJANJE PROIZVODA U PROMET NA PODRUČJU REPUBLIKE HRVATSKE</b> (članak 3. i članak 8. stavak 1.(b) Uredbe (EZ) broj 469/2009 i Uredbe (EZ) broj 1610/96)		12
<b>AKO ODOBRENJE IZ RUBRIKE 12. NIJE PRVO ODOBRENJE U EU, NAVEDITE SLJEDEĆE PODATKE:</b> (članak 8. stavak 1.(c) Uredbe (EZ) broj 469/2009 i Uredbe (EZ) broj 1610/96)  <b>BROJ, DATUM I DRŽAVU EU PRVOG ODOBRENJA</b>  <b>PODATKE O IDENTITETU TAKO ODOBRENOG PROIZVODA</b>  <b>PRAVNU ODREDBU PREMA KOJOJ JE PROVEDEN POSTUPAK IZDAVANJA ODOBRENJA</b>		13
<b>BROJ ZAHTEJA ZA IZDAVANJE SVJEDODŽBE ZA KOJU SE ZAHTIJEVA PRODULJENJE ILI BROJ SVJEDODŽBE ZA KOJU SE ZAHTIJEVA PRODULJENJE*</b>  *Ako se zahtjev za produljenje svjedodžbe podnosi istovremeno sa zahtjevom za izdavanje svjedodžbe, rubriku popunjava Zavod		14
<b>NAZIV PROIZVODA ZA KOJE SE ZAHTIJEVA IZDAVANJE ILI PRODULJENJE SVJEDODŽBE (kemijsko ili generičko ime)</b>		15
<b>BROJ I DATUM ODOBRENJA KOJE SADRŽI IZJAVU KOJA POTVRĐUJE USKLAĐENOST SA ZAVRŠENIM USUGLAŠENIM PLANOM PEDIJATRIJSKOG ISPITIVANJA PREMA ČLANKU 36. STAVKU 1. UREDBE (EZ) broj 1901/2006.</b>		16
<b>ADRESA ZA DOPISIVANJE</b> Ova osoba ujedno je i: PODNOSITELJ ZAHTEJA ZASTUPNIK ZAJEDNIČKI PREDSTAVNIK	<input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>	Naziv, OIB*, ulica i broj, (pravne osobe sjedište) poštanski broj i mjesto, država, telefon, Telefaks, E-pošta:

\* Na temelju članka 6. Zakona o osobnom identifikacijskom broju („NN“ 60/08) obveznici broja obvezni su od 1.1.2010. koristiti dodijeljeni im OIB na svim prijavama i ostalim podnescima kojima komuniciraju s korisnicima broja (Zavodom).

<b>PRILOZI UZ ZAHTEJEV:</b>		17
<input type="checkbox"/>	Primjerak prvog odobrenja iz točke 12. za stavljanje proizvoda odnosno u promet na području Republike Hrvatske (članak 8. stavak 1.(b) Uredbe (EZ) broj 469/2009 i Uredbe (EZ) broj 1610/96)	17
<input type="checkbox"/>	Primjerak obavijesti kojom se odobrenje iz točke 13. objavljuje u odgovarajućoj službenoj publikaciji (članak 8. stavak 1.(c) Uredbe (EZ) broj 469/2009 i Uredbe (EZ) broj 1610/96) i glasilo u kojem je objavljen podatak o odobrenju, ako odobrenje iz rubrike 12. nije prvo odobrenje za stavljanje proizvoda u promet	
<input type="checkbox"/>	Primjerak već izdane Svjedodžbe za koju se zahtjeva produljenje trajanja, ako se zahtjeva produljenje trajanja Svjedodžbe	
<input type="checkbox"/>	Primjerak izjave ili odobrenja koje sadrži izjavu koja potvrđuje usklađenost sa završenim usuglašenim planom pedijatrijskog ispitivanja, iz točke 16. (članak 8. stavak 1.(d) i. Uredbe (EZ) broj 469/2009), ako se zahtjeva produljenje trajanja Svjedodžbe	
<input type="checkbox"/>	Dokaz o posjedovanju odobrenja za stavljanje proizvoda u promet svih drugih članica EU (članak 8. stavak 1.(d) ii. Uredbe (EZ) broj 469/2009), ako se zahtjeva produljenje trajanja Svjedodžbe	
<input type="checkbox"/>	Punomoć	
<input type="checkbox"/>	Dokaz o izvršenoj uplati upravne pristojbe i naknade troškova upravnog postupka za izdavanje Svjedodžbe i/ili za produljenje trajanja Svjedodžbe	
<input type="checkbox"/>	Ostali podaci (navesti)	
	<div style="border-bottom: 1px solid black; height: 15px; margin-bottom: 5px;"></div> <div style="border-bottom: 1px solid black; height: 15px; margin-bottom: 5px;"></div> <div style="border-bottom: 1px solid black; height: 15px;"></div>	
<p><i>Upisati znak "x" u odgovarajuću kućicu</i></p> <p><b>Potpis podnositelja zahtjeva odnosno potpis zastupnika</b></p> <div style="border: 1px solid black; height: 100px; margin-top: 10px;"></div>		
<p><b>Potpis i pečat Državnog zavoda za intelektualno vlasništvo</b></p> <div style="border: 1px solid black; height: 100px; margin-top: 10px;"></div>		

\* Na temelju članka 6. Zakona o osobnom identifikacijskom broju („NN“ 60/08) obveznici broja obvezni su od 1.1.2010. koristiti dodijeljeni im OIB na svim prijavama i ostalim podnescima kojima komuniciraju s korisnicima broja (Zavodom).

Obrazac P-3, Dodatni list 1

**ZAHTJEV ZA IZDAVANJE/PRODULJENJE SVJEDODŽBE O DODATNOJ ZAŠTITI****BROJ ZAHTJEVA**

**PODACI O OSTALIM PODNOSITELJIMA ZAHTJEVA**

<b>PODNOŠITELJ ZAHTJEVA</b>  Osobni identifikacijski broj (OIB)* Prezime i ime (za fizičke osobe) Tvrtka (za pravne osobe) Ulica i broj Poštanski broj i mjesto / Država Telefon, Telefaks E-pošta	
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<b>PODNOŠITELJ ZAHTJEVA</b>  Osobni identifikacijski broj (OIB)* Prezime i ime (za fizičke osobe) Tvrtka (za pravne osobe) Ulica i broj Poštanski broj i mjesto / Država Telefon, Telefaks E-pošta	
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<b>PODNOŠITELJ ZAHTJEVA</b>  Osobni identifikacijski broj (OIB)* Prezime i ime (za fizičke osobe) Tvrtka (za pravne osobe) Ulica i broj Poštanski broj i mjesto / Država Telefon, Telefaks E-pošta	
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<b>PODNOŠITELJ ZAHTJEVA</b>  Osobni identifikacijski broj (OIB)* Prezime i ime (za fizičke osobe) Tvrtka (za pravne osobe) Ulica i broj Poštanski broj i mjesto / Država Telefon, Telefaks E-pošta	
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\* Na temelju članka 6. Zakona o osobnom identifikacijskom broju („NN“ 60/08) obveznici broja obvezni su od 1.1.2010. koristiti dodijeljeni im OIB na svim prijavama i ostalim podnescima kojima komuniciraju s korisnicima broja (Zavodom).

Obrazac P-3, Dodatni list 2

**ZAHTJEV ZA IZDAVANJE/PRODULJENJE SVJEDODŽBE O DODATNOJ ZAŠTITI****BROJ ZAHTJEVA**

**PODACI O OSTALIM ZASTUPNICIMA**

<b>ZASTUPNIK</b>  Osobni identifikacijski broj (OIB)* Prezime i ime (za fizičke osobe) Tvrtka (za pravne osobe) Broj iz registra DZIV-a Ulica i broj Poštanski broj i mjesto / Država Telefon, Telefaks E-pošta	
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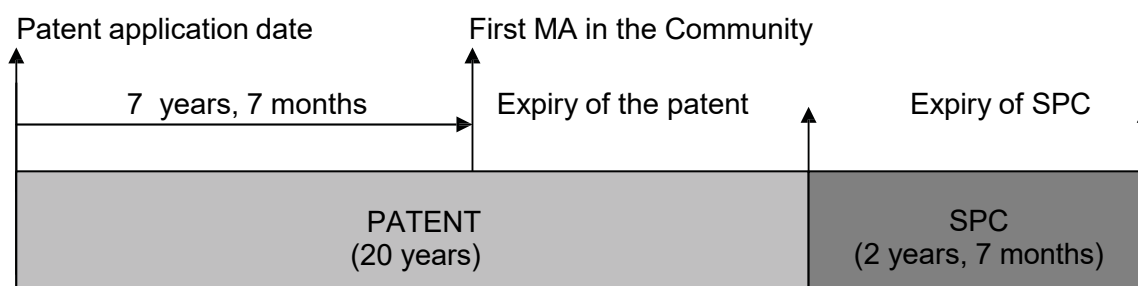
\* Na temelju članka 6. Zakona o osobnom identifikacijskom broju („NN“ 60/08) obveznici broja obvezni su od 1.1.2010. koristiti dodijeljeni im OIB na svim prijavama i ostalim podnescima kojima komuniciraju s korisnicima broja (Zavodom).



**ANNEX II****Example – Calculation of duration of the Certificate**

Filing date of the basic patent: 05 October 1992  
First marketing authorization in the Community: 05 May 2000  
Expiry of the basic patent: 05 October 2012  
The time period elapsed between 05 October 1992 and 05 May 2000 = 7 years 7 months

Duration of SPC 7 years 7 months – 5 years = 2 years 7 months  
0 days  
Expiry of SPC 05 May 2015.



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