

Practical Examination Case in Biotechnology



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➤ RO Patent Application No: 96-02348 based on the International Appl. PCT/ IB95/00452 (WO95/34659)



➤ Title: “*Manipulation of Protoporphyrinogen Oxidase Enzyme Activity in Eukaryotic Organisms*”

➤ Granted Patent: RO 120003 B1

□ *The application relates to:*

- ✓ eukaryotic DNA sequences encoding for native protoporphyrinogen oxidase (protox) or modified forms of the enzyme which are herbicide tolerant;
- ✓ plant genes encoding for wild type and altered protox;
- ✓ plants - having altered protox activity → tolerance to herbicides;
 - which may be bred or engineered for resistance to protox inhibitors;
 - which may be transformed with modified eukaryotic or prokaryotic protox – encoding sequences or wild type prokaryotic protox sequences;
- ✓ methods of isolating protox from plants;
- ✓ methods of using protox-encoding genes.



□ Which were the objects originally claimed by the applicant ?

(I)

- An isolated DNA molecule (claims 1-28);
- A chimeric gene (claims 29-36);
- A recombinant vector (claims 37-38);
- A host cell (claims 39-40);
- A plant or plant cell including the progeny thereof (claims 41-52, 54);
- The plant seed (claim 53);
- Propagating material of a plant (claims 55-57);
- Methods, i. e. for controlling the growth of undesired vegetation (claims 58-63), of selecting plants, plant tissue or plant cells transformed with a transgene of interest from non-transformed plants (claim 66);
- A probe capable of specifically hybridizing to a eukaryotic protoporphyrinogen oxidase gene or mRNA (claims 67 and 68);



□ Which were the objects originally claimed by the applicant ?

(II)

- Methods of producing a host cell (claim 69), a plant cell (claim 70), a transgenic progeny of a transgenic parent plant (claim 71), a DNA molecule encoding a protein from an eukaryote having protoporphyrinogen oxidase(protox) activity (claims 72 and 73);
- Uses of DNA molecule (claims 74-76): to confer tolerance to a herbicide in amounts which inhibit naturally occurring protox activity from a parent plant to its progeny; to prepare a medical tool for the treatment/diagnosis (of) deficiencies in protoporphyrinogen oxidase activity in animals and particularly in humans;
- A pharmaceutical composition (claim 77) comprising an eukaryotic protein having protoporphyrinogen oxidase activity together with a pharmaceutically acceptable carrier.



□ **Romanian Legal Provisions for Examination Procedure**

1. The claimed objects are patentable according to the provisions of Art. 7 of the Romanian Patent Law 64/1991 amended and republished on 15.10.2002, since:

- they refer to biological products and processes, respectively;
- they fulfill the provisions that are specifically set forth by the

Romanian Patent Law regarding the inventions in the field of biotechnology, that are:



“The inventions in the field of biotechnology shall be patentable if they refer to:

- a) a biological material existing in natural environment or produced by any technical process, even if it used to be produced in nature before;*
- b) plants or animals, if the technical achievement of the invention is not limited to a certain plant variety or animal breed;*
- c) a microbiological process or a technical process and a product, other than a plant variety or animal breed, thus obtained;*
- d) an isolated element of the human body or otherwise produced by a technical process, including the sequence or partial sequence of a gene, even if the structure of that element is identical with the structure of a natural element.”*

□ Romanian Legal Provisions for Examination Procedure

2. According to the provisions of Art. 12 of the Romanian Patent Law, the following biotechnological inventions shall not be patentable:



- a) plant varieties and animal breeds;
- b) essentially biological processes for the production of plants or animals.

→ *the claimed invention is not exempted from patentability*

□ Romanian Legal Provisions For Examination Procedure

3. The claimed inventions were examined from the point of view of clarity and completeness of the disclosure according to Art. 18 of the Romanian Patent Law, and specific provisions regarding biotechnological inventions, that are:



“If the invention relates to a biological material which was not made available to the public, the requirements provided for in the first paragraph shall be regarded as complied with only where the applicant produces a document attesting that, prior to the date of filing of the patent application or of the recognized priority, the biological material was deposited with an international depository institution.”

□ Analysis

1. Examination of unity of invention



- ✓ The patent application *lacks unity* (the group of inventions fails to fulfill the requirements of Art. 19 (1) under Romanian Patent Law) because:
 - it lacks the common inventive concept for the different claimed objects;
 - the only common element for different claims is a relatedness to eukaryote protox enzymes.

□ Analysis

✓ A first group of inventions that would fulfill the unity criterion could be represented by:

- an isolated DNA molecule that encodes a protein with protoporphyrinogen oxidase activity,
- a chimeric gene comprising a promoter operably linked to the said DNA molecule,
- a recombinant vector comprising the chimeric gene,
- a host cell and a plant with altered protoporphyrinogen oxidase activity,



that are linked by the DNA sequences encoding for a protein having protoporphyrinogen oxidase activity so that they form a single inventive concept.

□ *Analysis*

✓ The other claimed inventions, i. e.,

- method for controlling the growth of undesired vegetation
- method of selecting plants

were considered not to be linked by the above mentioned DNA sequences, to the first group of inventions.



□ **Analysis**

2. Examination of the clarity and completeness of disclosure – first group of inventions



- ✓ The first group of inventions considered to fulfill the unity criterion was examined from the point of view of clarity and completeness of disclosure, and there have been ascertained the following:

1. The claims for DNA molecule - not defined by appropriate technical features → could not be accepted as filed.

□ **Analysis**

2. The claims for host cell, plant seed and propagating material, could not be accepted because of:



- lack of:
 - information about morphological and biochemical features of the claimed biological material,
 - information about proposed taxonomic description thereof,
 - a preparation method thereof;

- the applicant's failure to file the Deposit Certificate for biological material (Art. 18).

□ **Conclusions:**

✓ The Office issued the first substantive examination notification and the applicant was notified:

- that the patent application lacks unity and that divisional applications may be filed;

- to file an amended set of claims that are in agreement with the legal provisions and that do not exceed the initially filing, for the first group of inventions that fulfill the unity criterion.





- ✓ The applicant filed an amended set of claims.

□ *Claims (New set of claims)*

- An isolated DNA molecule, encoding a protein having protoporphyrinogen oxidase activity, comprising an amino acid sequence selected from the group consisting of SEQ ID No. 2 or SEQ ID No. 4 and from the group consisting of SEQ ID No. 6 or SEQ ID No. 8, including DNA molecules which are selected homologues and hybrids thereof.
- A chimeric gene comprising a promoter operably linked to the said DNA molecule encoding a protein having protoporphyrinogen oxidase activity.
- A recombinant vector comprising said chimeric gene, wherein said vector is capable of being stably transformed into a host cell.
- A plant comprising the said DNA molecule, wherein this DNA molecule is expressed in said plant and confers upon said plant tolerance to a herbicide which inhibits naturally occurring protox activity.



✓ The new set of claims has fulfilled the provisions of Art.18 (clarity and completeness of disclosure) and Art. 19 (unity).

✓ The documentary search for the new set of claims was performed in the Databases of the Romanian Patent Office:

- *Common Soft* (comprises information about all the published and non-published Romanian Patent Applications, and about the Romanian Granted Patents), and
- *RoPatent Search* (comprises all published Romanian Patent Applications and the Romanian Granted Patents);
- the results of the ISR were also taken into consideration.



✓ The amended set of claims was accepted as it fulfills the novelty, inventive step and industrial applicability criteria, and the application was granted patent **RO120003 B1**.



✓ The applicant has filed two divisional applications for:

- a method for controlling the growth of undesired vegetation,

and


- a method of selecting plants, plant cells, plant tissues and seeds and transgenic progeny thereof having protoporphyrinogen activity,

presently pending.



➤ Romanian Patent **RO120003 B1** has encountered no opposition within the legal term set forth by the Law.

Conclusions:

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- *The presentation has intended to illustrate an example of substantive examination procedure, at the Romanian Patent Office, of a typical patent application in the field of biotechnology;*
 - *The biotechnological patent applications are examined according to the Romanian Patent Law to which, in 2002, there was transposed the Directive 98/44/EC and which was harmonized with EPC;*
 - *Aims of the harmonization:*
 - *to enable an applicant to benefit by an increased predictability about the level of protection that he might benefit by;*
 - *to assure a proper competition balance in the biotechnological field.*

Thank you for your attention!



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