PROTECTION OF BIOTECHNOLOGICAL INVENTIONS IN SLOVENIA

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Abstract

Sufficient patent protection is, because of high investments in R&D, one of the most important factors for further development of high-technological fields, like modern biotechnology. Unfortunately patent law and practice have serious difficulties in keeping up with the rapid scientific progress in these fields. European Union (EU) has attempted to adapt present patent legislation to the current state of the art in the field of biotechnology with special legal act-The European directive on legal protection of biotechnological inventions (Directive) issued in 1998.

The comparison of patent legislation in Slovenia with those in EU shows that the possibilities for protection of biotechnological inventions in Slovenia and EU are almost the same. The protection of industrial property in Slovenia is regulated by Law on Industrial Property of 1992, which form together with several international treaties (like TRIPS Agreement, Paris Conventions, The Budapest Treaty, UPOV Conventions, etc.) signed by Slovenia, a legal frames for protection of inventions. Slovenian patent law is less restrictive than European Patent Conventions (EPC) and allows inventors to get even broader protection for their inventions than they can get in EU. Patenting of some inventions whose patentability is by EPC explicitly excluded (plant and animal varieties) is possible in Slovenia. At the moment there is a new Slovenian patent law in preparation. Its main purpose is, because of the demands for harmonisation of Slovenian legislation with EU legislation, to harmonise the text of Slovenian patent law with provisions of TRIPS Agreement, EPC and Directive. This will ensure to inventors and researchers in Slovenia the same competitive environment in regard of protection of their inventions as it have their colleagues in EU.

Introduction

Modern biotechnology[1] is one of the fastest developing scientific and technological fields on the world. Its further development is due to high investments in R&D strongly connected with proper protection of industrial property. There were several attempts, some of them also controversal,[2] to shape an appropriate legal framework for the protection of biotechnological inventions, especially inventions in the domain of the molecular biology.

European Union (EU) has harmonised and regulated this particular field of industrial property with the adoption of European directive on legal protection of biotechnological inventions[3] (Directive) on July 30 1998 which has to be implemented into the national laws of the member states to July 30, 2000.

Slovenia is one of the candidates for the accession to the EU in the first round. Both political and economic circumstances require that Slovenia harmonises its legal system with EU legal system before the accession. Fortunately, in the field of industrial property, Slovenia has already met most of the EU legislation criterium related to industrial property with its Law on Industrial Property of 1992.[4] With this Act the basis for an original and advanced system of protection of industrial property in Slovenia were made.

Slovenia as the EU member candidate has also to meet EU legislation in the field of protection of biotechnological inventions and to provide an adequate protection for them. The purpose of this paper is to elucidate state of the art of Slovenian legislation related to the protection of industrial property in relation to EU legislation.

International and national legislation framework

Slovenia was one of the founding members of the World Trade Organisation (WTO) and is therefore also a signatory of TRIPS Agreement. Despite the possibility for countries with centrally-planned economy to delay the applicability of TRIPS Agreement for four years as provided for in the paragraph 3 of Article 65 of the TRIPS Agreement, Slovenia has not decided to make use of this provision. The decision was based on the study done by Slovenian Intellectual Property Office (SIPO) which has shown that all substantive TRIPS provisions have been met already with Law on Industrial Property of 1992. [5]

Slovenia has inherited the membership in the Paris Union for the protection of industrial property from former Yugoslavia and it has been member of it since June 25, 1991. Very recently, Slovenia acceeded to the two biotechnology related treaties: The Budapest Treaty (on March 12, 1998) and UPOV Convention (on July 29, 1999).

Filing of patent applications in Slovenia is possible through national route which is regulated by Law on Industrial Property of 1992. Another possibility to file them is by using PCT registration system[6] or by »extension« of validity of European patents through the system provided by the so-called »Extension Agreement«[7] signed between Government of Slovenia and European Patent Organisation (EPO). According to this agreement at the applicant's request and on payment of the extension fee European patent applications filed before February 18, 1994 and not granted yet on February 18, 1994 or European patent applications filed on February 18, 1994 or later can be extended to Slovenia where they will have the same effects as national patent applications and patents and will enjoy substantially the same protection as patents granted by EPO for the member states of the EPO. An applicant should within three months after the grant of European patent pay a publication fee and provide a Slovenian translation of patent claims granted by EPO to SIPO.

National law and the protection of biotechnological inventions

Definition of an invention contained in Law on Industrial Property of 1992 basically matches the wording of Article 52 of European Patent Convention (EPC). Patent shall be granted for any inventions which are new and susceptible of industrial application and which involve an inventive step. Discoveries, scientific theories and similar are not considered inventions. Similar to Article 53 of EPC a protection can be denied for inventions for which their publication or use would be contrary to public order or morality and for inventions of surgical, diagnostic or therapeutic methods for treatment practised on the human or animal body. Inventions related to substances used in any of these methods can be patented. Drugs and chemical compounds are also patentable.[8] However Slovenian Law on Industrial Property allows plant and animal varieties to be protected by patent, what is not allowed by EPC.

Invention is new if it did not form part of the state of the art prior the date of filing the request for the recognition of a patent application. An invention is considered to form the state of the art if it was made available to the public by publishing, exhibition,

demonstration or use in a such way as to enable persons skilled in the art to apply it or if it is not different from the inventions earlier applied for in Slovenia or abroad (through PCT with Slovenia as designated state or through »Extension Agreement«) which were made available to public after to the filing of the patent application. Disclosure of the invention concerned by the inventor himself within the grace period of twelve months prior to the filing date is not considered as an information which form part of the state of the art.

An invention is considered to involve an inventive step if, having regard to the state of the art, it is not obvious to a person skilled in the art. Technically feasible inventions that can be applied in the industry or any other activities are considered to be industrially applicable.

An invention that involves the use of or concerns biological material which is not available to the public or can not be described in a such a manner as to enable person skilled in the art to carry out the invention, shall only be regarded as being disclosed as prescribed in Law on Industrial Property of 1992, Article 52 (2) if the microorganism[9] was deposited at an institution having a status of depository authority under Budapest Treaty or under bi- or multilateral agreement between Slovenia and other countries.[10]

In Slovenia the patent is granted at the same time as the patent application is published.[11] There is no substantial examination, but only formal in respect of formalities and excludability requirements. At any time after the grant of patent may any person oppose it by filing a suit at the court. Duration of patent is twenty years from the filling date of the application. Beside paying renewal fees, the patentee must submit to SIPO within nine years from the filing date also a document with evidence, that the patented inventions fulfil the criteria on novelty, inventive step and industrial applicability required by Law. This document can be a parallel patent granted for the identical invention by any patent office having a status of Preliminary Examination Authority according to the PCT, a positive report of any authority having before mentioned status or patent or report issued by any other patent office having a special agreement with SIPO. After a submission of the above mentioned document the granted patent is compared with it and

then acknowledged either fully or in part, as the case may be. This so called "document of evidence system" allows that the applicants can get a protection also for the inventions that are not patentible under EPO-in case that they submitt as the document of evidence a granted US patent.[12] If the document of evidence is not submitted to SIPO, the patent lapses after the tenth year of validity.

Duration of patents granted for inventions that should get before use a special approval from authorities (i.e. pharmaceutical products, agrochemicals), can be extended for the period of five years.[13]

Patentee has exclusive rights to exploit the protected invention for manufacturing, to sell the product manufactured by use of the protected invention, to dispose of the patent and to prevent exploitation of the protected invention in production or legal transactions by any third party without of his consent. The effect of the patent shall not extend to acts done in private sphere and for non-commercial purposes, acts done for experimental purposes without limitation to final purpose[14] and the extratemporaneous, individual preparation of medicines in pharmacies based on a medical prescription or acts concerning the medicines so prepared. Acts provided in 5 *ter* Article of Paris Convention and acts provided by 27 Article of Convention on International Civil Aviation are also not considered as patent infringing activities.

Patent protection shall be extend to products if the patent is granted in respect of a process and if the products are obtained directly by the said process.

Use, manufacturing and selling of the substances useful as medicine for humans and animals are not deemed to constitute infringement of a patent of invention for such substances if the corresponding patent application is filed before or on December 31, 1992 or if priority right for the said patent application is claimed before or on December 31, 1992 and the said substance shall be not manufactured by a process protected by patent.[15]

Any person who infringes a right arising out of an invention is liable for any caused damages with the general principle governing compensation for damages. In addition to damages may person whose rights has been infringed, request that the person infringing

his rights be prohibited from continuing with infringing activities. Where the said infringing act is committed against an invention concerning a process for the production of a new substance, any substance having the same composition or being the same shall, in the absence of any evidence of the contrary, be deemed to have been manufactured using the protected process. The burden of proof is upon the person producing the said substances, with due regard to his legitimate interest in safeguarding its business secrets.

If the patentee misuses the rights granted by a patent, a compulsory license for the use of the invention may be granted to another person. Misuse of granted rights takes place if the patentee, either himself or through a third party, does not work or insufficiently works a patented invention and refuses to license to other persons the right to work he protected invention or imposes unjustified conditions on him or when an invention protected by a patent can not be worked fully or partially, without use of an invention of an earlier patent, and the working of the invention is of special importance for the economy or is in the public interest with respect to meeting the social needs of health services or national defence. A competent court decides on granting of a compulsory license.

Other ways of protecting biotechnological inventions

Beside classic patents there exist in Slovenia also so called "short-term patents".[16] The duration of "short-term patents" is maximum 10 years from the date of filing of the patent application. By these patents can be protected all inventions that fulfil requirements for normal patent or new inventions susceptible to industrial application but do not involve inventive step. Processes and animal and plant varieties are excluded from the protection by "short term patents".

New plant varieties can be protected also *sui generis* through the system provided under UPOV Convention, so at the moment it is possible to obtain a double protection for new plant varieties in Slovenia.[17]

Draft of new Law on Industrial Property

There is in a preparation a new Slovenian Law on Industrial Property,[18] which does not contain some substantial changes in comparation with the old one. Changes related to the patents are of formal nature mostly just for the harmonisation of the text with the text of TRIPS Agreement and EPC. However the most important changes are the following:

- Patenting of second medical use of known substance is allowed.[19]
- Scope of patent protection is determined by the terms of the patent claims. The description and drawings shall be used to interpret the claims.[20]
- Patent application can be filed also in electronic form.
- Patent application comprising DNA, genes or fragments thereof, peptides and polypeptides have to comprise a sequence listing.[21]
- Nullification of patents is possible on the same basis as opposition before EPO.[22]
- The court can grant preliminary injunctions to prevent the further infringement of the granted rights.
- As the document of evidence shall be submitted primarily granted European patent-in case of submission of any other document of evidence will SIPO have right not to acknowledge the claims that are not in accordance with EPO patent practice.

Final harmonisation of a new Slovenian Law with Directive will be done with special legal Act. It will determinate things like:

- Definition of terms "biotechnological material", "microbiological process" and "essentially biological process"
- Criteria for patentability of biological material isolated from its natural environment
- Exclusion of 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 from patentability

- Unpatentability of different biotechnological processes like processes for cloning human beings or modifying the germ line genetic identity
- Some specifics regarding the scope of protection[23] and definitions of "breeders rights"

Differences between Slovenia and EU in regard to patent protection

The existing Slovenian patent system with filing of “document of evidence” allows to obtain much broader protection for the invention than it can be obtained under the EPC system in EU. It enables inventors to get protection also for plant and animal varieties and for DNA sequences and genes without known function. This difference between both systems which is in the favour of patentees will be eliminated by new law to ensure the harmonisation with EU.

EPC and national patent laws of EU countries define “experimental exemptions” very strictly and they do not permit trials to see weather a person can produce product commercially according to the patent or to obtain authorisation from government authority for marketing. Slovenian patent law includes so called “Bolar” provision which allows all kinds of experiments also those for commercial purposes. This is especially important for generic pharmaceutical industry which may prepare a production and obtain a marketing authorisation for generic drug from government authority before the expiration of relevant patent. EU is at the moment not in favour to include the “Bolar” provision in its legislation despite constant pressure of generic drug producers.

Conclusions

We can say from the facts written above, that the legal environment for the protection of biotechnological invention in Slovenia is almost the same as anywhere else in EU or in other EPC member states. Slovenia is a signatory of most international treaties related to protection of industrial property rights (i.e. TRIPS Agreement, Paris Convention, PCT Treaty, UPOV Convention and Budapest Treaty). The main differences from EU are the possibility for protection of plant and animal varieties by patents and

Bolar provision related to the experimental use.[24] Chemical substances and pharmaceuticals enjoy the same protection as anywhere else in EU or in US. Pharmaceuticals are eligible also for the extension of patent protection for additional five years (similar to SPC in EU).

It can be concluded that the efficient system for the protection of industrial property rights related to biotechnological invention already exist in Slovenia and it provides a solid basis for the further development of biotechnology in this area. We hope that efficient system for protection of industrial property rights will attract the foreign investors to do research work in Slovenia and also to encourage them to invest in Slovenian research and academic institutions and companies in the field of biotechnology and bio-pharmaceuticals.

References and Notes

1. *European Federation of Biotechnology, 1989:* Biotechnology is the integration of natural sciences and engineering sciences in order to achieve the application of organisms, cells, parts thereof and molecular analogues for products and services.
2. J. Straus, IIC 24, 1993, pp. 602
3. EU directive 98/44/EU
4. Uradni list RS, No.13-676/92 dated March 20,1992 and No.27-1222/93 dated May 29, 1993
5. Pretnar B. (1999) Protection of biotechnological inventions and the implementation of the Budapest Treaty in Slovenia, WIPO Regional Seminar for the Promotion of Acceptance and Implementation of the Budapest Treaty, Ljubljana, November 23-24, 1999, 1-8
6. Uradni list RS, No.19-88/93-MP dated December 3, 1993; It is possbile to extend patent applicaton to Slovenia also by using of so called “Euro-PCT route”.
7. Uradni list RS, No.15/93-MP dated June 23, 1993 and No.2-17/94-MP dated February 18, 1994. Use of this route is very popular among applicants-according to the information of SIPO (databases SI patents and EP SI Extended Applications) in the period between January 1, 1991 and March 16, 2000 in the field of biotechnology (C 12M, C12N, C12P and C 12Q) there were filed only 135 patent application using national route and 2159 using system provided by "Extension Agreement".
8. see Slovenian Law on Industrial Property of 1992, Article 121. Effective protection for drugs is available for applications that are filed after December 31, 1992, and not claiming priority prior to that date. This exception was taken from the old law and should enable the domestic pharmaceutical industry to prepare itself for the new situation.
9. Term microorganism shall be interpreted in a broad sense-similar to definition of biotechnological material as defined in Rule 28 (6) (a) of EPC legislations.
10. Official Journal of Slovenian Intellectual Property Office, I/1998 dated February 28, 1998.
11. Usually 18 month after the date of filling or the priority date. Earlier publication can be requested by applicant, but not earlier than tree month after the date of filling.
12. In case that Slovenian patent application or PCT application Slovenia as designated country contains claims for expressed sequence tags (EST’s) or single nucleotide polymorphism (SNP’s) and as the document of evidence the US patent with granted claims for these EST’s or SNP’s, the SIPO will acknowledge such claims. In the proposal of new Slovenian Law on Industrial Property as the document of evidence shall be submitted primarily granted European patent-in case of submission of

any other granted patent the SIPO will have right not to acknowledge the claims that are not in accordance with EPO patent practice.

13. see Slovenian Law on Industrial Property of 1992, Article 37 (2). This extension is equivalent to the extension granted by Supplementary Protection Certificates in EU.
14. see Slovenian Law on Industrial Property of 1992, Article 32 (2). Experiments done for the purpose of obtaining marketing approval from Health Authorities are allowed.
15. Similar provisions have also Spain, Portugal, Austria and Greece-countries where the patenting of chemical compounds and pharmaceutical formulations were not allowed prior to joining to EPC.
16. Similar to German "Gebrauchsmuster" or to American "Utility or Design Patents"
17. A double protection is permissible under 1991 ACT of UPOV Convention and under Article 27 of TRIPS Agreement.
18. Draft of new Slovenian Law on Industrial Property is available on Internet URL:http://www.sipo.mzt.si/ZIL_1801.htm
19. It is possible to obtain a patent protection for second medical use also under the present Law, but that is not explicitly cited in it.
20. Similar to the wording of Article 69 of EPC. The same way of interpretation of the scope of the protection was used by the Court also under the present Law.
21. Similar to the wording of Rule 27a of EPC.
22. Similar wording to Article 100 of EPC.
23. Like Article 8 and 9 of EU directive 98/44/EU.
24. Preparation of production of pharmaceuticals and the production of small quantities of the medicine for the purpose of obtaining marketing approval from Health Authorities is not deemed as a patent infringing act.

Povzetek

Možnost zadostne patentne zaščite je zaradi velikih vložkov v razvoj in raziskave eden ključnih pogojev za nadaljni razvoj visokotehnoloških področji, kot je na primer moderna biotehnologija. Izredno hiter znanstveni napredek na tem področju pa povzroča velike težave patentni zakonodaji in patentni praksi pri njunem prilagajanju modernim tehnologijam. Na področju biotehnologije poskuša Evropska Unija prilagoditi veljavno patentno zakonodajo sedanjemu stanju znanosti na tem področju s posebnim aktom - z Evropsko direktivo za pravno zaščito biotehnoloških izumov iz leta 1998 (Direktiva).

Primerjava slovenske patentne zakonodaje z evropsko pokaže, da so možnosti za zaščito biotehnoloških izumov v Sloveniji skoraj enake tistim v Evropi. Zaščita industrijske lastnine je v Sloveniji urejena z Zakonom o industrijski lastnini iz leta 1992. Ta skupaj z mednarodnimi sporazumi (TRIPS sporazum, Pariška konvencija, Budimpeštanski sporazum, UPOV konvencija itd), ki jih je podpisala Slovenija, tvori pravne okvire za zaščito izumov v Sloveniji. Na splošno je slovenska patentna zakonodaja manj restriktivna kot na primer Evropska patentna konvencija (EPK) in omogoča izumiteljem pridobitev precej širše patentne zaščite, kot jo dovoljuje EPK. Možna je tudi zaščita nekaterih izumov, ki jih EPK izrecno označuje kot nepatentibilne (rastlinske in živalske vrste). Trenutno je v pripravi tudi nov slovenski patentni zakon, katerega namen je, zaradi zahtev po harmonizaciji zakonodaje z Evropsko Unijo, predvsem uskladiti besedilo sedanjega zakona z besedilom TRIPS sporazuma, EPK in Direktive. To bo zagotovilo slovenskim izumiteljem in raziskovalcem enake možnosti zaščite njihovih intelektualnih stvaritev, kot jih imajo njihovi kolegi v Evropi in drugod v razvitem svetu.