

**PATENTABILITY ISSUES IN BIOTECHNOLOGY
- LAW AND PRACTICE IN EUROPE**

PRACTICE OF THE POLISH PATENT OFFICE

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The approach of the Polish Patent Office towards proceeding biotechnology inventions is presented.

In 2004 Poland joined the European Patent Organization and the European Union as well. But changes in the Polish patent law started in 2000. The Polish patent law is now harmonized with the European Patent Convention.

In the Polish patent law system there are many documents and acts which have to be taken into consideration before and during the proceeding of biological applications.

The Budapest Treaty – covers all issues concerning deposits of microorganisms. The Seed Act – the Polish legal act that regulates different aspects concerning seeds in agriculture and relates to new varieties of plants (according to the UPOV convention).

The Biotechnology Directive – a base for patenting biotechnology inventions. The Polish Industrial Property Law and executive regulations to this act.

The Transgenic Organisms' Law – regulates every aspect of working, distributing, controlling GMOs in Poland. That was an important document that has exerted influence on our approach in the biotechnology field.

The Inventors Guides (2005 and 2006) - very useful and practical publications that make our life, as examiners, and life of inventors, much easier. It includes some explanations written in a regular – not legal language. The practice and indications for applicants are shown. It is very useful for examiners to make their job more unified. The jurisdiction sustaining or reversing our decisions are shown as well.

The Polish law system, in the biotechnology field, is fully harmonized with Biotech EU Directive and EP Convention. There could be even found the equivalents of each single article.

During the last few years the approach of the Polish Patent Office towards several issues has been changed. There were several reasons, not only the joining of Poland to the EPC, but others as well. They all came and did affect our approach at about the same time. The harmonization of the law was the base.

What were the main fields of changes?

For the purposes of the meeting only two are mentioned – GMOs, antibodies. Some differences in regard to dealing with “product by process” definitions and disclosure products by their function are presented.

Some differences in the procedure in the Polish Patent Office, concerning for example – lack of unity, proceeding the complex applications, two processes – search and examination, procedure of “re-examination” and the lack of the patent court in the Polish patent law system.

There are differences in the procedure but there are also some similarities - patenting DNA polynucleotides, genes, vectors and others, proteins, for example.

The GMOs – the approach in granting of GMOs has changed. Couple of years ago we did not grant anything which was connected with GMOs – neither plants nor animals. We did not grant methods of their producing, either. The base of our position was the article stating on inventions which stand in contradiction to the public order. The results of introducing them into the natural environment can be unexpected and unpredictable – against the public order. Couple of reasons have the influence on our changes – first the harmonization of our approach with the approach according to EPC, but also opinions and very strong positions and arguments of applicants. We were at that time the one and only country in Europe not granting these things. Nevertheless, we can not forget that the public opinion in this field is very divided. And each side has its own arguments and the scientific evidences. Now – there is no problem with granting of GMOs in the Polish Patent Office, as well as methods of producing them.

Antibodies – in the past we asked for a precisely defined structure of the antibody, in practice – the sequences. No other way of disclosure were accepted. Now – there are many ways of disclosing of antibodies – structure, but others too – deposits, methods of producing and the new sufficiently disclosed antigen which is recognised by this antibody. So, there are many possibilities for the applicants to choose the best way of protection.

“Product by process” – is accepted but first we ask for the technical features which normally define this category of invention – which is the product. In practice of the Polish Patent Office there is a very strong position to require the proper technical feature to each category of invention: product – structure, chemical structure, elements, exactly shown places of modifications, methods – steps and conditions of these steps. The scope of protection is broader.

In every case we ask first to show that another disclosure is impossible and the product can not be described in other way. Then, we accept this way of disclosure of the product but under some conditions – the product must be new

and in the claim must be defined some parameters which can identify this product without any doubts. So we are very strict in this case.

Product defined by its function – we do not accept such a way of disclosure. Product must be described in the way to reproduce it and must be measurable.

If there exists **the lack of unity** of application, the application must be divided. There are no additional fees for inventions which are not linked with others.

Search and examination - there are two procedures in the Polish patent system but they are not so explicitly separated like the ones in the EPO. We do both of them together.

There are the consequences of the above. For example proceeding the complex applications.

We do not make the partial search report – there is no such possibility. But there are many other tools for dealing with such a kind of applications: no clarity of claims, no unity, no support in the description, lack of disclosure.

A special procedure there is in the Polish Industrial Property Law which is called **“re-examination”**. After the refusal by the first examiner in the Examining Department, there is a possibility for the applicant to ask for the re-examination by the second, different examiner. This second examiner re-considers the case - the application from the beginning and makes his own decision, independently.

Then, if the refusal is still confirmed, the applicant may appeal.

So the applicant has several possibilities to reach the grant. And decisions of examiners in the Examining Department are not final.

And finally, in the Polish patent system there is no **patent court**. Every decision, opposition may be the subject of consideration by the administrative court, that makes decisions formally and accordingly to the procedure. No essential discussions during this court proceedings are foreseen.

There are discussions and plans but until now there is no patent court in Poland.

According to the growing number of information and inventions as well, in the future there will be needed probably more changes in patent systems to keep pace with reality. In the field of biotechnology discussions and doubts about *patenting of Life* appear in almost every society.

Another problem that we have to face with is informatization – in the view of so many documents and information which have to be put into the public in an easy and fast way, it will be a challenge to organize them and to make them “friendly” with efficient search and examination tools.

There is another thing, maybe more practical – if there is so much information and it is expected to be much more in the future, the objection of lack of inventive step will be probably raised very often. The state of art is going to be more rich and ...dense. Even now this objection is raised often in biology, but it can be a bigger problem in the future.
By the way - can they be the real inventions?

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