THE SUMMARY OF THE DOCTORAL THESIS

"PATENT ON A BIOTECHNOLOGICAL INVENTION AND ITS PATENT QUALITY IN COMPARATIVE LEGAL ANALYSIS"

WRITTEN BY JOANNA UCHAŃSKA

UNDER THE SUPERVISION OF PROF. INP PAN, DR HAB. PAWEŁ PODRECKI

The doctoral dissertation deals with the title issues of the patentability of biotechnological inventions and the quality of those patents. The subject matter analysis was conducted in a comparative manner, i.e. with regard to Polish and European law and their jurisprudence, as well as to other selected legal orders of other countries. Structurally, the work consists of the introduction, five chapters, the summary and the bibliography. In addition, it is dichotomous: firstly, it discusses the problem of 1) the patent for a biotechnological invention, secondly, 2) the quality of the patent, and based on these two detailed analyzes, a synthetic evaluation of the patent quality for a biotechnological invention has been made.

In the essay **introduction,** the content of the individual chapters was discussed, as well as the use of research methods and the scope of the research, i.e. the normative material (especially Directive 98/44/EC of the European Parliament and of the Council on the legal protection of biotechnological inventions; The European Patent Convention of 5 October 1973 from Munich and the Law of 30 June 2000 - Industrial Property Law, and the US Code, Title 35 of the US Patent Law), administrative decisions and case law that were included in this Ph.D. thesis.

The **first** chapter of the paper entitled "Biotechnology and Patent Law - Outline the Problem" is divided into two parts. The basic notions, including biotechnology, the history of its development, and its specific variants, highlight the importance of "green" (agricultural) and "red" biotechnology (medicine and pharmacy) are quoted and discussed. In addition, this chapter presents a number of statistics on the biotechnology industry as well as on patent applications and patents granted for biotechnological inventions in the national procedure and before the European Patent Office. The second part of this chapter deals specifically with the concept of patent protection, including biotechnological inventions. The historical development of patent protection of biotechnological inventions from European and American perspective is also presented. This section also discusses the ethical problems of patenting natural products (patent on life).

In the next chapter (**second**) "Granting patent protection for biotechnological inventions", the issues of patentability of biotechnological inventions are described in the light of European and Polish jurisprudence and in the field of American jurisprudence. Patentability is discussed comprehensively from the point of view of substantive concepts as well as those of formal conditions that influence the essence of patentability of biotechnological inventions. A material place in the work has also been reserved for the patentability of genes inventions. Among the issues of substantive nature, which were particularly described, were distinguished as follows:

a. establishing the boundary between the non-patentable discovery of living matter and the patentable invention using this matter;

b. interpretation of patentability: novelty, inventive step (non-obviousness) and industrial ability (utility), especially with respect to patents on genes;

c. exclusions from patenting inventions, including due to i/ contradiction with public order and good morals (with particular reference to patent exclusions for biotechnological inventions), ii) prohibition of patenting of plant varieties, animal breeds and purely biological methods of animal and plant breeding and iii / the prohibition of patenting human or animal treatment;

d. the scope of protection of a biotechnological invention characterized by the self-reproducibility of genetic material.

This section discusses a number of issues related to the specific requirements of the patent application as having a cardinal impact on the conduct of the patentability of the invention, and the content of the patent granted. Moreover, there is compared the traditional evaluation scheme of examination of the patentability of inventions with the new paradigm of analyzing it (born in the USA, based on the case law of the German Federal Court of Justice and the Warsaw Voivodship Administrative Court). A number of remarks have been made on the importance of investigating mental processes and inventive concepts for the patentability, especially complex and pioneering inventions such as biotechnological inventions. This chapter also highlights the importance of proper disclosure of the invention by referring to the deposit of biological material. Subsequently, a major body of prior informed consent for the use of biological material (i.e. the use of i/ natural biological resources of the Earth in accordance with the Convention on Biological Diversity, done at Rio de Janerio on June 5, 1992, as well as ii/ human genetic material in accordance with the recital 26 of Directive 98/44/EC), which may have a significant impact on the correct provision of patent protection to biotechnological inventions.

In the **third** chapter entitled "The quality of a patent on biotechnology invention and its impact on exercising of patent rights" a number of patent quality issues are discussed. This concept is presented by reference to its various definitions, as well as the factors by which the quality of the patent is measured and evaluated as low or high-quality patents. On this basis, an appropriate subset of before-mentioned comments was made regarding the patentability of the biotechnological invention and subsequently a specific assessment of the quality of the patent for the biotechnology invention was made. In the light of those aspects, examples of the phenomenon of biological piracy are presented, and the impact of patent quality on the exercise of patent rights. This section covers the institutions forming the content of the patent, i.e. the absolute protection of biotechnological inventions, and the limitation of patent rights through the possibility of using a compulsory license, farmer's privilege, or research privilege. The doctrine of exhaustion of law in relation to biotechnological inventions was also addressed. Finally, non-patent restrictions on the exercise of patent rights, especially those relating to patents for gene inventions, have been analyzed. There were also comments on the patent relationship for biotechnology invention and competition law.

In the last major (**fourth**) chapter of the paper entitled "Proposals for improving the quality of patents on biotechnological inventions. Current and proposed initiatives" present various legal solutions (hard and soft ones) as well as non-legal ones (i.e. border management tools or ITs) necessary to improve the quality of granted patents for biotechnological inventions.

Instruments to optimize the model of patent protection of biotechnological inventions (*de lege ferenda*) have been distinguished by:

1) patenting the function and application of the gene:

2) new exception: biotechnological inventions for health care purposes;

3) resignation from patent protection;

4) correction of the farmer's privilege;

5) introduction of a patent court institution.

A number of interpretative concepts have been proposed, based on existing legislation, and finally from the frontier of management or finally IT science:

1) narrowing the specific absolute protection of biotechnological inventions;

2) partial or full revocation of the patent;

3) use of the rationalization institution;

4) use of prior authorization for access to biological resources and equal distribution of benefits;

5) the use of an informed consent institution for conducting research on the human biological material;

6) redefinition of patentability testing scheme; 10-Facts-Screeing-and-Transforming-Processing-tests; the use of the concept of mental steps/inventions; analyzing of creativity of inventions;

7) European Quality System/Quality Management System.

Much of this chapter is devoted to the above-mentioned patentability examination method – 10-FSTP-tests that are a systematic and internationally consistent patentability assessment scheme, as well as an assessment of its creativity (and hence the quality of the patent). In this Ph.D. thesis, efforts have been made to demonstrate that the use of additional tools and the desire to standardize patentability fosters the improvement of patent quality.

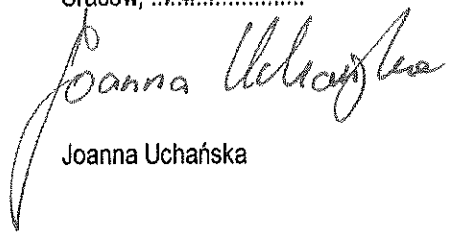
The **summary** highlighted the ambiguity of the patent situation of biotechnological inventions and a particular position among other inventions and also pointed out the opacity and the far-fetched of patent assessment in

general. The main conclusion of a multidimensional analysis of the basis of axiological patent law as well as its substantive and procedural aspects, and the functioning and operation of patent offices, is that the quality of the patent system is difficult to assess unambiguously. However, there are many low-quality patents because of the lack and complexity of uniform standards for patentability, the growing number of patent applications and the lack of reliable tools to help patent experts.

A number of relevant research methods were used in the summary of the dissertation, namely: the critical analysis of Polish and foreign sources, statistical method, case study method, experimental method, intuitive method.

The work was created in 2013/2014 and the legal status described here is valid as of December 18, 2014. The results of the survey and research conducted at the Institute of Intellectual Property Rights and the Competition Law of Max Planck in Munich, Library of the European Parliament in Brussels, Library of the Patent Office in Warsaw, Library of the Institute of Intellectual Property Law of the Jagiellonian University and Library of the Jagiellonian University in Cracow. Also familiar with the documentation of patent applications and statistics provided courtesy of the Patent Office of the Republic of Poland. Moreover, the work is also a result of participation in the international Facts-Screening-and-Transforming-Processor / Innovative Expert System project to create a unique and precise tool for uniform patent analysis.

Cracow, 16.04.2015



Joanna Uchańska