Conclusion

Taking into account the objective and tasks of this study, the following conclusions are reached:

1. When making decisions on the patenting of biotechnological inventions under Art. 53(a) EPC and the related provisions of the EPC Implementing Regulations, the EPO applies tests based on one of the prevailing Western ethical theories: utilitarianism or deontology. The weighing test based on the first approach is most often used in deciding on the patentability of inventions involving animals, whereas the rebuttable presumption test based on the second is used in deciding on inventions encompassing the human body at various stages of its formation and development or the isolated elements of it. For inventions concerning plants, both tests based on the above-mentioned ethical approaches can be applied. The sparse EPO case law reveals that, when using the weighing test to assess the commercial exploitation of an invention, the unacceptability standard is usually applied and, in the case of the rebuttable presumption test, the standard of abhorrence is used. In the first group of cases, a narrower interpretation of the term 'commercial exploitation', which includes the concept of the invention described in the patent claims, is more likely, whereas in the second case, the term may be broader, covering the steps for the creation of the invention. When the EPO chooses the applicable tests, standards or definition of the term 'commercial exploitation' in assessing a biotechnological invention, available knowledge of the biomedical sciences is of paramount importance for a proper evaluation.
2. The natural sciences, including the biomedical sciences, can be perceived as a phenomenon involving both cumulative and non-cumulative development. Both in the time of 'normal science' and in the moment of scientific revolutions, knowledge about the environment and the processes taking place in it are influenced by the attitude of the scientific community, which is often formed by the existing tradition and does not always objectively reflect reality. For this reason, European patent law may be more cautious about the knowledge provided by the natural sciences, including the biomedical sciences, and may make decisions only after conducting a more critical assessment of the surrounding

environment and the knowledge about it, which can lead to weaker influence of natural sciences on the decisions of the EPO.

3. After the great upheavals in the first half of the 20th century, the modern Western legal tradition can be characterised as emphasising the value of a human being and the protection of his/her rights, based on deontological ethics. Still, in making decisions that do not adversely affect a human being, as well as in situations where different human rights compete with one another or with other non-human objects in the world, or where the consequences of decisions play a key role, utilitarianism becomes important. The dynamics of the utilisation of the discussed ethical theories for decision-making depends on the relationship between the legal system belonging to the Western legal tradition, which is based on its main principles and values, and other areas of reality, such as the biomedical sciences, which provide knowledge.
4. The perception of the concepts '*ordre public*' and 'morality' as well as their relationship in the EPO case law and in the Western legal tradition are similar:
   a) In the greater part of the EPO case law, morality and *ordre public* are treated as a single ground for opposing the granting of a patent on the basis of Art. 53(a) EPC. There are only a few decisions of the Office that distinguish between these categories, with morality relating to non-legal social norms that are recognised in a particular society, and *ordre public* referring to the legal norms that are fundamental to the existence and proper functioning of a particular society.
   b) In legal positivism and legal realism, morality is perceived as non-legal norms of conduct accepted by a society or the individual's inner beliefs that influence the development, interpretation and application of legal norms, whereas from a natural law point of view, morality, regardless of its relative nature, can be identified with the legal system itself or can be the basis for its assessment. Nevertheless, even in paradigms that seek to make a strict distinction between morality and law, there are situations where it is difficult to do so, and these two categories may coincide. Meanwhile, *ordre public*, despite the fact that in the Western legal tradition it is first and foremost identified with legal norms and principles that are of fundamental importance for the existence and proper functioning of a particular society, its members and the surrounding environment, due to its ability to evolve and adapt to changing conditions, can accept arguments of a non-legal nature and coincide with moral provisions.

All this reveals that, both in the EPO case law and in the Western legal tradition in general, *ordre public*, which in all cases is identified with the legal norms and principles, and morality, which is equated to non-legal standards of conduct, can be difficult concepts to distinguish from each other.

5. Despite the controversies regarding the efficiency of the patent system, in scholarly literature it is agreed that patents ensure economic returns and encourage the development of innovations in the field of biomedical sciences. This means that failure to grant a patent for an invention in this field of science based on Art. 53(a) EPC reduces the possibility of commercialisation of an invention, and in turn the potential economic advantage of the patent holder. In view of this, there is a likelihood that research on the objects or related processes that are deemed not patentable with regard to *ordre public* and/or morality, as well as the creation of inventions based on these objects or processes, will receive less investment. This will lead to slower progress in the field of biomedical sciences on certain issues and will not encourage the growth of knowledge about the surrounding environment, its objects and the ongoing processes.
6. When decisions on the patentability of biotechnological inventions are being made, the European patent system, being part of the Western legal tradition, and the biomedical sciences, as a tradition, are affecting each other in the context of Art. 53(a) EPC. This interaction is influenced by: (1) the values protected by the Western legal tradition that might be affected by the commercial exploitation of an invention; and (2) the completeness and reliability of the knowledge provided by the biomedical sciences which is used by the EPO to analyse the commercial exploitation of a particular invention. The European patent system's approach with regard to the patenting of specific inventions on the basis of Art. 53(a) EPC is shaped by the knowledge about the surrounding environment provided by the biomedical sciences, which can depend on the attitude of the scientific community. This knowledge allows understanding of the invention, determination of the relationship of the invention with the values protected by the Western legal tradition, and evaluation of the potential effect of its commercial exploitation on the aforementioned values. Such an evaluation based on the knowledge of the biomedical sciences with regard to Art. 53(a) EPC can either lead to the granting of a patent or the rejection of a patent application. The granting of a patent will signal that, from the position of the knowledge

of biomedical sciences available at a given moment, the commercial exploitation of an invention is in line with the values protected by the Western legal tradition. This will encourage further development of the biomedical sciences and promote the emergence of knowledge which will later be used to evaluate the commercial exploitation of new inventions with regard to Art. 53(a) EPC. The rejection of a patent application based on the aforementioned article will signal that the commercial exploitation of an invention, in view of the knowledge of the biomedical sciences available at a given moment, is not in line with the values protected by the Western legal tradition. In this case, the research regarding certain questions might not continue, or a search will take place for alternative inventions which would allow the same problem to be solved but would be patentable under Art. 53(a) EPC. Although the effect of the granting of a patent or the rejection of an application under Art. 53(a) EPC will not be identical, in both cases there will be a certain impact on the development of this field of science leading to the creation of potentially patentable inventions – either follow-on inventions or disruptive inventions – in the European patent system. Upon the filing of a patent application, the commercial exploitation of these new inventions will be assessed under Art. 53(a) EPC, based on the available knowledge of the biomedical sciences, with regard to the values protected by the Western legal tradition. The result of such an assessment, which will manifest in the granting of a patent or the rejection of an application, will continue to affect the development of the biomedical sciences, which in the future will provide new challenges to European patent law in relation to deciding on the granting of patents for biotechnological inventions.