

BIOTECHNOLOGICAL INVENTIONS IN THE UK – CASE STUDIES

Introduction

The article is intended to analyse legal regulations concerning inventions in the biotechnological field in the UK. First of all, it will focus on the impact of international legislations on the UK regulations. Secondly, it will examine general requirements for granting a biotechnological patent which involve a novelty, an inventive-step and an industrial application.¹ Further, it will analyse a patentable subject matter having regard to the exclusions laid down by respective regulations, i.e. animal varieties, plant varieties, biological processes for the production. It takes into account the moral issues that may accompany and arise in relation to the methods of obtaining biotechnological inventions. The express connection between patent law and morality is not a new idea. The U.K. Patents Act of 1883, for example, gave the comptroller a right to refuse the grant of a patent the use of which would be „*contrary to law or morality*”.²

The first experiences of the UK in the application of patent law

The United Kingdom has a longstanding experience in application of patent law, including biotechnology inventions. One of the first patents that have been granted referred to a technological process for producing stained glass. Glassmaker, John Utynam requested the exclusive rights to prepare, produce and manufacture it using a process which he claimed to have invented. On 3rd of April 1449 King Henry VI of England issued an imperial order

* Wyższa Szkoła Finansów i Zarządzania w Białymstoku.

¹ The Patents Act 1977, s. 1(1)

² Patents, Designs and Trade Marks Act, 1883, s. 86

granting a twenty years monopoly to the producer.³ The desire to improve the quality of human life led to the development of biotechnology field, the corollary of which is an extension of patent law related to this field. Biotechnology refers to the exploitation and manipulation of organisms and genetic material for the development of useful technologies and products. In the United Kingdom the first patent for a biotechnological process was granted in 1787 for a yeast like composition for use in baking (Patent No. GB 178701625). In recent years the impact on the development of patent law in the United Kingdom has been influenced by the international law (in particular, the European Patent Convention) and the policy and law of the European Union (The Directive 98/44/EC). Biotechnological inventions in the United Kingdom are patentable under the European Patent Convention.

Legal protection of biotechnological inventions

European patent applications and patents concerning biotechnological inventions are to be interpreted in accordance with the provisions of Rules 26 to 29 of the European Patent Convention. Directive 98/44/EC of 6 July 1998 on the legal protection of biotechnological inventions constitutes a supplementary act for the purpose of interpretation. Judgments of the Court of Justice of the European Union on the interpretation of EU Directive 98/44/EC are not binding on the European Patent Office, but are to be considered as persuasive resources.⁴

The Directive was originally proposed in 1988 and approved 10 years later after ethical debate concerning the patentability of living matter. The Directive includes provisions specifying what is excluded from patentability for reasons of morality, which involves methods of cloning human beings, and the use of human embryos for commercial and industrial purposes. It also specifies that inventions based on an element isolated from the human body, or otherwise produced by means of a technical process, including gene sequences or partial gene sequences, are not excluded from patentability, however, an indication of function is required.⁵

³ Cf. M. L. F. Nascimento, E. D. Zanotto, *On the first patents, key inventions and research manuscripts about glass science & technology*, World Patent Information (2016), p. 1; M. L. F. Nascimento, *The First Patents and the Rise of Glass Technology*, Recent Innovations in Chemical Engineering, 2016, Vol. 9, No. 1, p. 1; A. Gomme. *Early British Patent Grants*, Nature 119 (1927), p. 494.

⁴ https://www.epo.org/law-practice/legal-texts/html/guidelines/e/g_ii_5_2.htm, access 10.02.2021 r.

⁵ *Ibidem*.

The Directive 98/44/EC⁶ on the legal protection of biotechnological inventions has had an impact on the development of the UK patent law concerning biotechnological inventions since it was implemented by The Patents Regulations 2000⁷, The Patent (Amendment) Rules 2001⁸ and The Patents and Plant Variety Rights (Compulsory Licensing) Regulations 2002⁹. The first regulation came into force on 28 July 2000 and implemented the provisions of Articles 1 to 11 of the Directive 98/44/EC. It involves the requirements that have to be fulfilled to grant a biotechnological patent. The second regulation came into force on 6 July 2001 and implemented Articles 13 and 14 of the Directive, which relate to the deposit, access and re-deposit of biological material. The third regulation implemented Article 12 of the Directive on 1 March 2002 and is associated with mandatory cross-licensing agreements concerning patents and plant breeders' rights which do not have direct impact on pre-grant matters.¹⁰

The Directive 98/44/EC underlines that a role of biotechnological inventions increases, especially in the industry sector. There has been a consistent need to harmonise a patent law on biotechnology throughout the European Community as the Member States tended to interpret biotechnology law in a different manner.¹¹ The European Patent Office basically approved the approach to biotechnological matters shaped by the Directive, even that it was not required to do so. The Directive aims to clarify a patentable subject matter. As an example, it validated a patentability of inventions regarding biological material which had a direct effect on the UK legislation.¹² The United Kingdom as a party of the TRIPS agreement shall approve a patent in all field of technology if it meets specific criteria.¹³

The Patent Regulations 2000 as an implementation of the Directive supplemented the Patents Act 1977¹⁴ with a new definition of biotechnological invention which resulted in permitting for granting a patent in the biotechno-

⁶ Directive 98/44/EC of The European Parliament and of The Council of 6 July 1998 on the legal protection of biotechnological inventions, Official Journal of the European Communities, L 213/13.

⁷ The Patents Regulations 2000, SI 2000/2037.

⁸ The Patent (Amendment) Rules 2001, SI 2001/1412.

⁹ The Patents and Plant Variety Rights (Compulsory Licensing) Regulations 2002, SI 2002/247.

¹⁰ Examination Guidelines for Patent Applications relating to Biotechnological Inventions in the UK Intellectual Property Office (September 2007), p. 6.

¹¹ Directive 98/44/EC of The European Parliament and of The Council of 6 July 1998 on the legal protection of biotechnological inventions, ..., *op. cit.*, p. 9.

¹² Sch. A2 to the Patents Act 1977.

¹³ The Agreement on Trade Related Aspects of Intellectual Property Rights (TRIPS) 1994, art. 7.

¹⁴ Patents Act 1977 (c.37).

logical field. A biotechnological invention means “an invention which concerns a product consisting of or containing biological material or a process by means of which biological material is produced, processed or used”¹⁵. A biological material in the above definition is regarded as “any material containing genetic information and capable of reproducing itself or being reproduced in a biological system”¹⁶.

Criteria for patenting biotechnological inventions

The biotechnological invention to be patented requires meeting the following criteria: a novelty, an inventive step and an industrial application.¹⁷ It is believed that most of biotechnological inventions will be examined under above conditions.¹⁸

In regard to a novelty requirement¹⁹ the UK’s Intellectual Property Office has established a practice which can be seen, e.g. in the *Howard Florey Application* which concerned the cDNA encoding human H-2 relaxin. It was assumed that a natural substance in question had been unknown until it was isolated, thus a novelty of that patent had to be identified, even if such substance had existed in nature in the past.²⁰

The example of an application which was refused by the Patent Office, as it did not meet a novelty requirement under the section 2(3) of the Patents Act 1977 for granting a patent was *Asahi Kasei Kogyo KK’s Application*.²¹ The patent described a human tissue necrosis factor polypeptide which was produced by using genetic engineering methods. It was believed that it might be helpful for treatment of human tumours. The application was completed after the priority date, but that priority was claimed from the former application which involved a claim and a disclosure of a chemical compound. The method to produce such compound was not described. The applicant contended that a disclosure to be novel must be enabling which means that a method showing how an invention works must be included in it. The case came before the House of Lords where it was found that a patent was not anticipated. It was

¹⁵ Patents Act 1977, s. 130 (1).

¹⁶ *Ibidem*.

¹⁷ *Ibidem* s. 1 (1).

¹⁸ Examination Guidelines for Patent Applications relating to Biotechnological Inventions in the UK Intellectual Property Office (September 2007), p. 7.

¹⁹ The Patents Act 1977, s. 1(1)(a).

²⁰ *Howard Florey Institute’s Application / Relaxin OJEPO 1995, 388 (V0008/94)*.

²¹ *Asahi Kasei Kogyo KK’s Application [1991] RPC 485*.

emphasized that a disclosure must be enabling and that a patent in question was not made available to the public in the situation when the information disclosed the existence of a patent, but did not provide the information how to obtain the product. Lord Oliver concluded that in other cases a man skilled in the art could produce the product knowing only the formula of its composition, as it would be clear for such person how to prepare it.²²

The second requirement for granting a patent involves an inventive-step.²³ It is believed that it may take place if an invention is not obvious to a person skilled in the art.²⁴ The test which is applied to biotechnological patents by examiners does not significantly differ from a test for any other type of invention. The House of Lords dealt with that in the case *Biogen Inc v Medeva Plc*.²⁵ The Biogen's patent concerned production of antigens of hepatitis B virus using genetic engineering methods. It was believed that it might be useful in diagnosing the illness and in producing vaccines against it. In fact, it was thought that Biogen method had mere chance for a success. Biogen had claimed a priority in the application and further argued that Medeva infringed their patent when the latter proposed to market the vaccine in question which also used genetic engineering techniques. The defendants wanted a refusal of a patent as, in their view, the Biogen's patent was not an invention, as it was known and obvious at the priority date and at the date of application. In addition, they questioned the patent, as the description and the material to support the invention were not sufficiently described. The plaintiff admitted partially emphasizing that although it was obvious at the date of application, it was not on the 22th of December 1978 when a priority for the patent was claimed in the UK. The House of Lord held that Biogen's patent involved one method of producing the antigens, therefore a monopoly for all the methods of producing could not be granted, as it would dissuade the competition in the particular biotechnological field. Finally, Biogen's patent could not be given priority and was found invalid and insufficient, as it claimed all methods of making the product using recombinant technology, but disclosed only one. The Court took the view that whatever invention is made for the first time, it is a contribution to the existing knowledge. It might be a new idea of using well-known methods that no one had considered before. In this case "*the inventive idea*

²² Asahi Kasei Kogyo KK's Application [1991] RPC 485.

²³ The Patents Act 1977, s. 1(1)(b).

²⁴ *Ibidem*, s. 3.

²⁵ *Biogen Inc v Medeva Plc* 1997 RPC 1.

would be the way of achieving the goal”²⁶. It was considered that, in general, people might have a thought enabling them to achieve such goal, but particular problems could also occur, which might not allow them to do so. If a measure to solve these problems was thought up, the solution for that instead of the aim itself or the general way of attaining it would constitute an inventive step.²⁷

The third requirement of patentability, namely industrial application²⁸, was deliberated by the courts in the case *Eli Lilly and Company v Human Genome Sciences, Inc*²⁹. The key issue of the case was a validity of a patent, held by the defendant, which disclosed a gene and amino acid sequence of a novel protein called Neutrokin-a. This was found by using bioinformatics methods rather than traditional lab-based methods, therefore the HGS company was incapable of finding an actual activity of protein. However, shortly after its finding it filled a patent application to obtain a protection. The claims included descriptive information of Neutrokin’s activity and its uses, but it did not contain any data from appropriate studies (e.g. in-vitro). The information contained certain predictions based on the former knowledge about Tumour Necrosis Factor family which Neutrokin was a member. The claimant claimed for revocation of patent discerning that predictions made by the HGS company were speculative and an application was prepared without a knowledge about identity of receptors, the actual activity of protein, its function and possible diseases that it could treat. It was questioned if a person skilled in the art could perform an invention, as the patent was not, in claimants’ view, completely disclosed. These factors contributed to negation that the patent had met the requirements of industrial application, which the court further upheld. The judge Kitchen J. mentioned in his judgement the case of Patent Comptroller concerning an invention for a protein that involved the use of bioinformatics methods, in which the officer examined a capability of industrial application of an invention by applying a test of “*specific, substantial and credible utility*”. He concluded that industrial application could not be constituted if an invention is used as an instrument to perform further research.³⁰

²⁶ Biogen Inc v Medeva Plc 1997 RPC 1.

²⁷ Ibidem.

²⁸ The Patents Act 1977, s. 1(1)(c).

²⁹ Eli Lilly and Company v Human Genome Sciences, Inc [2008] EWCH 1903.

³⁰ Eli Lilly and Company v Human Genome Sciences, Inc [2008] EWCH 1903.

Categories of inventions excluded from the subject of patentability

The provisions laid down in the Patent Act 1977 have established the categories of inventions excluded from a subject matter of patentability, i.e. “*animal variety*” and “*plant variety*”.³¹ One of the reasons why “*animal variety*” was excluded from patentability was a belief that it ought to be regarded as “*not an appropriate subject matter*”³². The meaning of “*animal variety*” was clarified in a *Harvard / Oncomouse* case³³ which concerned a genetically modified mouse produced by the Harvard University. A human cancer gene called “*oncogene*” was inserted into a genome of an animal, a non-human mammal. The modification was made to make a mouse vulnerable to cancer. It was presumed that it would lead to the growth of cancer strains which might be particularly useful in clinical trials (for example in the evaluation of anti-cancer drugs). In the US the patent was granted. The Examining Division of European Patent Office initially rejected the application, as it was interpreted that animals were excluded under the provisions of Article 53 (b) of the European Patent Convention. It came before the Technical Boards of Appeal (TBA) which refused the former view of the Division stating that narrow construction of exclusion should have been applied and sent the issue back to the Examining Division for reassessment. The TBA, analysing the meaning of a term “*animal variety*” realized that a term was not coherent throughout the parties of the European Patent Convention. The problem was a result of language differences. As the official languages were English, German and French it was not required to indicate which meaning had to be respected. The German term meaning “*species*” was the widest in the taxonomy and was therefore used by the TBA as a criterion in the *Oncomouse* case. It was ruled that a term in question ought to be interpreted as meaning species or a sub-unit of species and as *Oncomouse* was a genus, it did not cover the animal in the case. It has to be mentioned that genus is taxonomically above the species. As a result of that, the TBA settled on that a subject matter of the case was not covered by the Article 53 (b) of the European Patent Convention. Conclusively, the patent was granted by the European Patent Office. At a later time, the modified *Oncomouse* patent (which was bounded to transgenic rodents containing an additional cancer gene) was upheld by the Opposition Division.³⁴ The deci-

³¹ Patents Act 1977 Schedule A2, s. 3.

³² *Harvard / Oncomouse* [1989] OJEPO 451; [1990] EPOR 4.

³³ *Ibidem*.

³⁴ *Harvard / Oncomouse* [2003] OJEPO 473.

sion emphasized that life-forms, especially plants and animals were not excluded from patentability in general and that the exclusion was bounded to varieties only. As the amended *Oncomouse* patent covered more than just varieties of mice, it was concluded that a patent did not fall within the exclusion of the Article 53(b).³⁵

The moral and social perspective of biotechnological inventions

One of the most important issues arised from the proceedings was whether the methods of obtaining biotechnological inventions are acceptable from a moral and social perspective. The TBA during proceedings applied an utilitarian balancing test. On the one hand, it was emphasized in the decision that a research in the cancer field was of crucial importance to humanity. On the other hand, the TBA considered suffering of animals and potential risks to the environment stemmed from research. At the end, the former view was found more appropriate in that case. The article 53(a) of the European Patent Convention sets out a rule that patents could not be granted if they are contrary to the *ordre public* (which refers to the public order and safety) and morality.³⁶ An appropriate test regarding a morality issue ought to be established. One of the proposal was: “*in light of what is now known about the public’s moral approach to the invention, what can be deduced about what its approach would have been at the effective date had it been in possession of the relevant facts?*”³⁷. In defining morality, the regulations which are the most common in Europe should be taken into consideration, therefore it is said that to some extent there was no need to be dependent only on public opinions polls.³⁸ In the United Kingdom there is a requirement to acquire essential permission if the research involves participation of animals. An applicant has to present what is a purpose of a project and go through various tests³⁹.

The same utilitarian test as in the *Oncomouse* case was applied in *Upjohn* case⁴⁰ with a different result. The latter application concerned a transgenic mouse into which a gene was introduced, such that an animal would loose its

³⁵ Harvard / *Oncomouse* [2003] OJEP0 473.

³⁶ European Patent Convention of 5 October 1973, article 53(a).

³⁷ D. Thomas, G. Richards, *The importance of the morality exception under the European Patent Convention: the Oncomouse case continues*, E.I.P.R. 2004, 26(3), p. 97-104.

³⁸ Harvard / *Oncomouse* [2003] OJEP0 473.

³⁹ The Animals (Scientific Provisions) Act 1986.

⁴⁰ *Upjohn* [1991] ECR I-1703, C-112/89.

hair. The aim of the invention was to find a potential treatment of human baldness. The European Patent Office took into account eventual benefits (an utility of animal experiment in the case of finding a cure for hair loss) and a harm endured by a mouse and decided that the latter outweighed the former, as the invention was contrary to morality, therefore unpatentable.⁴¹

The case which dealt with a morality issue in regard to plant varieties (one of the exclusion under the provision of Article 53(b)) was the *Plant Genetic Systems*⁴² case. The patent concerned genetically engineered plants, plant cells and seeds which contained a foreign gene enabling them to be resistant to a particular class of herbicide. Initially, the objection was made by Greenpeace (an international organization which aim is to protect the environment). They found a patent immoral and harmful to the environment. The Opposition Division did not apply the test used in the *Oncomouse* case. They stated that they were not capable to consider ethical matters as a patent system, in general, should focus on technical considerations.⁴³

The issue weighed up during the proceedings was whether an application in question fell within the scope of a “*plant variety*”. Greenpeace organization made an objection that an invention which was claimed was a plant variety. The Opposition Division, which examined the application stated that it concerned a wide group of plants and it did not fall within the scope of a variety, therefore a patent was acceptable. The Technical Boards of Appeal clarified that a plant variety: “*refers to any plant grouping within a single botanical taxon of the lowest known rank*”⁴⁴ which is “*characterised by at least one single transmissible characteristic distinguishing it from other plant groupings and which is sufficiently homogeneous and stable in its relevant characteristics.*”⁴⁵ It was established that plant cells did not fall under a definition of plant or a plant variety, therefore plant cells themselves were likely to be patented. The TBA held that claims in question eventually were not patentable as they encompassed a plant variety. The following issue arised from the case: as a plant variety was normally used to produce genetically engineered plants,

⁴¹ S. Conner, *Patent Ban on Baldness ‘Cure’ Mouse*, Independent (London), Feb. 2, 1992.

⁴² *Plant Genetic Systems / Glutamine synthetase inhibitors T356/93* [1993] 24 IIC 618; [1995] EPOR 357; [1995] OJEPO 545.

⁴³ *Ibidem*.

⁴⁴ *Plant Genetic Systems / Glutamine synthetase inhibitors T356/93* [1993] 24 IIC 618; [1995] EPOR 357; [1995] OJEPO 545.

⁴⁵ *Ibidem*.

the plants would not have been granted a patent, because they were often an effect of genetic engineering.⁴⁶

It has to be mentioned that the TBA clarified a meaning of “*microbiological process*” which constitutes a general qualification of an invention.⁴⁷ The term relates to a process when a new or modified products are made by using micro-organisms or their parts. It involves a development of such organisms for particular uses. It was emphasized that a process of genetic engineering itself cannot be considered microbiological. The TBA dealt also with a meaning of “*essentially biological process*”⁴⁸, in particular whether a claim was for that process. It was stated that it had to be reviewed on the ground of “*the essence of invention*”⁴⁹ considering “*the totality of human intervention*”⁵⁰ and its influence on the result. In this case a human intervention was of crucial importance as plants in question could exist as an effect of an invention process.⁵¹

Conclusions

The above examples of biotechnological inventions indicate that relevant legislations have to quickly respond to changes in the biotechnological field. They present what approach has been taken by the UK Intellectual Property Patent Office and the courts to the biotechnological inventions. European regulations, as noted in the text, had significant impact on a shape of the UK provisions. Particular requirements for granting a biotechnological patent were mentioned by giving examples of cases. A field of biotechnology has been evolving and a lot of inventions, such as modified micro-organisms, plants, animals were invented through a research in the biotechnological field. A number of morality issues have arisen from biotechnological inventions which are a subject of further legal debate. We can ascertain that legal protection of biotechnological patent occupies an important place in the intellectual property law and can be granted for specified group of inventions after fulfilling rigorous legal requirements.

⁴⁶ A. Schrell, *Are plants (still) patentable? Plant Genetic Systems (EPO Decision T356/93)*, E.I.P.R. 1996, 18(4).

⁴⁷ Patents Act 1977 Schedule A2 3(f).

⁴⁸ *Ibidem*.

⁴⁹ *Plant Genetic Systems / Glutamine synthetase inhibitors T356/93* [1993] 24 IIC 618; [1995] EPOR 357; [1995] OJEP 545.

⁵⁰ *Ibidem*.

⁵¹ *Ibidem*.

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Summary

The article analyses legal regulations regarding inventions in the biotechnological field in the UK. It focuses on the impact of international regulations on domestic regulations and on the requirements that have to be fulfilled for a biotechnological patent to be granted. On the basis of selected case studies it indicates what a scope of patentable subject matter is and what possible exclusions of patentability are. It clarifies a legal definition of biotechnological invention for the purpose of patent application. The article demonstrates how certain criteria of patentability in the biotechnological field have been interpreted by the courts in the UK. A biotechnological invention should meet selected criteria in order to be patented that involve, according to the article 52 (1) of the European Patent Convention, *inter alia*, a novelty, an inventive step and an industrial application. On the basis of selected case studies the article explains what characterizes each of these requirements, taking into account given state of facts. Under certain circumstances these requirements can be fulfilled. It indicates also which moral issues can emerge in regard to biotechnological inventions. The courts have to take into consideration if a given invention and its commercial exploitation is not contrary to morality and "*ordre public*", in accordance with the article 53 (a) of the European Patent Convention.

WYNAŁAZKI BIOTECHNOLOGICZNE W WIELKIEJ BRYTANII – STUDIUM PRZYPADKU

Streszczenie

Artykuł analizuje regulacje prawne dotyczące wynalazków z dziedziny biotechnologii w Wielkiej Brytanii. Koncentruje się na wpływie regulacji międzynarodowych na regulacje krajowe oraz na wymaganiach, jakie muszą być spełnione, aby patent biotechnologiczny mógł zostać udzielony. Na podstawie wybranych studiów przypadku wskazuje, jaki jest zakres przedmiotowy patentu i jakie są możliwe wyłączenia zdolności patentowej. Wyjaśnia definicję prawną wynalazku biotechnologicznego na potrzeby zgłoszenia patentowego. Artykuł wskazuje, jak określone kryteria zdolności patentowej w dziedzinie biotechnologii zostały zinterpretowane przez sądy w Wielkiej Brytanii. Na podstawie wybranych studiów przypadku w artykule wyjaśniono, czym charakteryzuje się każdy z tych wymogów, biorąc pod uwagę dany stan faktyczny. W pewnych okolicznościach te wymagania mogą być spełnione. Wskazuje również, jakie problemy natury moralnej mogą pojawić się w związku z wynalazkami biotechnologicznymi. Sądy muszą wziąć pod uwagę, czy dany wynalazek i jego komercyjne wykorzystanie nie jest sprzeczne z dobrymi obyczajami i porządkiem publicznym, zgodnie z art. 53 (a) Konwencji o patencie europejskim.

