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Biotechnology and Intellectual Property: The Limits of Animal Patentability in the European Union

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Abstract: The study considers the possibility of patenting animal breeds as objects of intellectual property, taking into account the legislation and law enforcement practices of the European Union. It presents a retrospective analysis and detailed interpretation of the conventional and directive provisions related to the patent protection of animal breeds, and characterizes the differences between the latter and the microbiological process. It was observed that the position of the European Patent Office on this issue was not always unanimous, which was manifested in the contradictory interpretation of the relevant, not perfectly formulated, legislative norms. It was analyzed under what conditions the current position of the EU manifests itself in the fact that an animal breed, as a product of an exclusively biological process, cannot be subject to patent protection. In addition, the concepts of "biological" and "technical processes" were interpreted as additional criteria for patentability concerning living organisms. Attention was also paid to the ethical component of biotechnological inventions and the still problematic aspects of animal breeding as possible results of biotechnological activity were emphasized.

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1. Introduction

The breed of animals is a specific object of intellectual property law. The legislation of the European Union (hereinafter referred to as EU) pays little attention to its protection. Patenting is an important aspect of the legal protection of animal breeds as an object of intellectual property because it is thanks to it that it is possible to implement an effective mechanism of legal protection of property and personal non-property rights of their owners.

It is relevant to consider the issue of patent protection of animal breeds in the EU in the context of the EU's unified policy in the field of intellectual property, which provides for the formation of a unified harmonized system of protection of intellectual property rights within this organization. The European Patent Convention of October 5, 1973 (also known as the Convention on the Grant of European Patents, hereinafter referred to as EPC)[1] forms the legal basis of the internal policy of the EU in the field of patent protection of the different objects of intellectual property rights, including animal breeds. Although the EU as a subject of international relations is not its signatory, all EU member states are parties to this convention, which is also the legal basis for issuing European patents. The next core legal document in this area is Directive 98/44/EC on the legal protection of biotechnological inventions (hereinafter referred to as the Directive),[2] adopted by the European Parliament and the Council of the European Union on July 6, 1998. It is already directly part of the legal framework of the EU, as it was adopted by its structural bodies. When considering the issue of patenting animal breeds as an object of intellectual property rights in the EU, it is necessary to focus on these acts, since any EU Directive must be transposed to the legislation of member states, and European patents are issued precisely on the basis of the Convention.

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1 Convention on the Grant of European Patents (European Patent Convention) of 5 October 1973 as revised by the Act revising Article 63 EPC of 17 December 1991 and the Act revising the EPC of 29 November 2000. The new text of the Convention adopted by the Administrative Council of the European Patent Organisation by decision of 28 June 2001 (see: OJ EPO 2001, Special edition No. 4, p. 55) has become an integral part of the Revision Act of 29 November 2000 under Article 3(2), second sentence, of that Act.

2 Directive 98/44/EC of the European Parliament and of the Council of 6 July 1998 on the legal protection of biotechnological inventions (O.J.E.C. L213, 30 July 1998), 13–21 (ES, DA, DE, EL, EN, FR, IT, NL, PT, FI, SV), accessed June 21, 2024, https://eur-lex.europa.eu/eli/dir/1998/44/oj.

The purpose of the study is to determine the regulatory and legal provisions and practical principles of patent protection of animal breeds as an object of intellectual property law within the EU as well as the demarcation of concepts related to animal breeds in the context of their patent protection. It is also aimed at revealing the main criteria that either prevent or enable patent protection.

The goal of the article will be achieved through the following: an analysis of the legal and practical criteria that determine the patentability of animal breeds in the EU; determination of the evolution of the position of the EU's regulatory and law enforcement authorities regarding the patenting of animal breeds; examination of the criteria that distinguish an animal breed from other patentable objects similar to an animal breed.

In addition to the introduction, the paper consists of a literature review and methodology, results and discussion, conclusions, and bibliographic references.

2. Literature Review

It is worth pointing out that the number of studies in the area of the patenting of animal breeds as an object of intellectual property law is small. Those researchers who have touched on this issue revealed only certain aspects of it and, for the most part, have done that through the prism of patent protection of genetically modified animals. Moreover, the vast majority of existing scientific works in this field were written by representatives of the American legal school.

Robert Kambic, for example, attempted to answer the question of whether genetically modified animals should be patentable, taking the US case law into account. The researcher eventually concluded that recognizing genetically modified animals as patentable by the United States Patent and Trademark Office is the right decision.[3] Rebecca Dresser, researching the legal and ethical aspects of animal patenting, considered both its positive and negative aspects. She also focused on genetically modified animals as potentially patentable subjects and noted that despite the societal benefits

[3] Robert B. Kambic, "Hindering The Progress Of Science: The Use Of The Patent System To Regulate Research On Genetically Altered Animals," *Fordham Urban Law Journal* 16, no. 3 (1988): 444, accessed June 21, 2024, https://ir.lawnet.fordham.edu/ulj/vol16/iss3/3/.

of new life forms, the arguments against patenting were overwhelming.[4] Elizabeth Jozwiak emphasized the need for patent protection of transgenic animals, as this brings many advantages in the field of pharmaceuticals, agriculture, and medicine.[5] David L. Meeker, focusing on the patenting of animal genetics and processes, based on DNA-changes in the pork industry, highlighted the need to improve the procedure for protecting intellectual property rights in this area, in particular through patents.[6] Max F. Rothschild and Lawrence R. Schaeffer researched the patenting of genetic innovations in animal breeding as well. They also directed their attention specifically to the genetic modifications of animals and how various advances in genetic engineering can be patented. However, mainly the American market was taken into account.[7] The extensive work of Michelangelo Temmerman concerned the rights of animal breeders, including through the lens of patent protection. This author concentrated on patenting animals and other living organisms, considering the aspect of bioethics. He stated that in the European Union, as well as in Canada, animal breeds are excluded from patentable objects,[8] but the legal nature of such an exclusion and the existing practice on this matter were not investigated.

European authors also touched on the issue of patenting in animal breeding, emphasizing the need to protect technical inventions in this field.[9]

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4 Rebecca S. Dresser, "Ethical and Legal Issues in Patenting New Animal Life," *Jurimetrics* 28, no. 4 (1988): 399–435, accessed June 21, 2024, https://www.researchgate.net/publication/11698480_Ethical_and_legal_issues_in_patenting_new_animal_life.

5 Elizabeth T. Jozwiak, "Worms, Mice, Cows and Pigs: The Importance of Animal Patents in Developing Countries," *Northwestern Journal of International Law & Business* 14, no. 3 (1994): 620–41, accessed June 21, 2024, https://scholarlycommons.law.northwestern.edu/njilb/vol14/iss3/32/.

6 David L. Meeker, "Patenting Animal Genetics and DNA-Based Processes: Implications for the Pork Industry," *The Professional Animal Scientist* 11, no. 1 (1996): 35–40, accessed June 21, 2024, https://www.sciencedirect.com/science/article/pii/S1080744615325481.

7 Lawrence R. Schaeffer, "Dairy Cattle Test Day Models: A Case Study," in *Intellectual Property Rights in Animal Breeding and Genetics*, eds. Max F. Rothschild and Scott Newman (Oxford, U.K.: CABI Publishing, 2002), 233–46.

8 Michelangelo Temmerman, "Animal Breeders' Rights?" (Working Paper No 2011/24, Swiss national centre of competence in research, May 2011), 1–26, June 21, 2024, http://surl.li/ddfknv.

9 Morten Tvedt, "Patent Protection in the Field of Animal Breeding," *Acta Agriculturae Scandinavica* 57, no. 3 (2007): 105–20, https://doi.org/10.1080/09064700701878554.

Individual authors investigated genetic techniques in livestock breeding, pointing out the significant increase in the techniques applied in genetic industries, which causes the establishment of an agricultural bioeconomy.[10]

Therefore, all authors highlighted the need to introduce patent protection in the field of biotechnology, however, they did not disclose the issue of patent protection of the animal breed as one of the possible results of the development of the genetic industry. That is why this aspect should be studied in detail.

3. Methodology

Achieving the stated goal of the research required an analysis of EU regulations (Convention, Directive) that relate to patent protection of intellectual property rights, including animal breeds, laws of individual EU member states in this area, decisions of the European Patent Office regarding patent applications on animal breeds and other similar objects, as well as other law enforcement acts of this body (in particular, decisions of the Boards of Appeal). It is normative legal acts and acts of application of legal norms that form the basis of the empirical material that is crucial for this study.

The general philosophical method of dialectics was aimed at a holistic understanding of the normative principles of regulation of patent protection of animal breeds as objects of intellectual property law. This method enabled the authors to apply the main rules of materialist dialectics, in particular in the part related to the accumulation of multi-sectoral legal norms in the field of animal breeding and biotechnology. The concretization of the general content of the special legal regulation regarding the breeding of animals was provided by the logical method of defining the concept through the identification of its essential features.

Logical methods of analysis and synthesis were repeatedly used throughout the study. In particular, doctrinal approaches to defining the basic categories of the conceptual apparatus, EU legislative acts, judicial practice in the field of patenting of biotechnology objects, animal breeds, and plant varieties were analyzed. With the help of the synthesis, the general

[10] David Gibbs et al., "Genetic Techniques for Livestock Breeding: Restructuring Institutional Relationships in Agriculture," *Geoforum* 40, no. 6 (2009): 1041–9, accessed June 21, 2024, https://www.sciencedirect.com/science/article/abs/pii/S0016718509000992.

state of regulatory support for the patenting of animal breeds was assessed, and distinctive points in some aspects of this policy were singled out.

The historical-legal special method made it possible to study the background of the modern mechanism of legal regulation of patenting of animal breeds in the EU, in particular, to focus on the evolution of the views of the legislative and law-enforcement bodies of the EU regarding this issue. The formal-legal method became the basis for clarification of the content of legal norms that mediate relations regarding the breeding of animals as an object of intellectual property law. The hermeneutic method was used in the interpretation of different legal sources, and their connection with each other.

The comparative legal method was aimed at characterizing the patent protection of animal breeds both at the EU level and at the level of neighboring member states, as well as comparing the approaches of the EPO to the interpretation of normative provisions in the field of the possibility of patenting animal breeds at different stages. The analogy method helped to apply similar provisions that refer to the patenting of plant varieties to animal breeds as well.

The tasks formulated at the beginning of the research paper determined the choice of the aforementioned methods, which eventually helped to achieve the set tasks.

4. Legal Regulation of the Issue and Its Evolution

At first glance, EU legal regulation in the field of patenting of animal breeds looks quite unambiguous. EPC in its Article 53(b) excludes from patent protection plant and animal varieties or essentially biological processes for the production of plants or animals, with the caveat that this provision does not apply to microbiological processes or their products.[11] The Directive in its Article 4 (part 1) also provides that animal breeds, as well as essentially biological processes for the production of plants or animals, cannot be patented, adding in part 3 of this Article that inventions relating to a microbiological or some technical process or a product obtained using such

[11] EPC Article 53 amended by the Act revising the European Patent Convention of 29 November 2000.

processes may nevertheless be patented.[12] Part 2 of Article 2 indicates that a process of plant or animal production is essentially biological if it consists entirely of natural phenomena such as cross-breeding or selection.[13] An interpretation of Article 3 (part 1) of the Directive, namely: "(…) inventions which are new, which involve an inventive step and which are susceptible of industrial application shall be patentable even if they concern a product consisting of or containing biological material or a process using which biological material is produced, processed or used"[14] allows us to state that a certain invention that meets all the criteria for patentability (novelty, inventive step, and industrial applicability) can relate to an animal, but not be limited to it. In this case, it can be patented even if it concerns a product that includes biological material or a process by which this biological material is produced or used. The analysis of the provisions mentioned above makes it clear that the Directive does not consider the breed of animals separately as a possible object of patenting. Even if the patent concerns an animal breed, it should not be limited to it (a caveat that a patent can protect inventions related to animals, if the technical possibility of such an invention is not limited to a certain type of animal is provided by the Article 4 (part 2)).[15] That is, even if a new breed of animal was bred in the process of genetic modification, it cannot be patented, although genetic modification itself is a biotechnological process (it means that this process can be patented, but not the animal as such); for example, a dog breeder cannot apply for patent protection for a new breed.

The norm that can be interpreted in favor of patent protection of animal breeds is Part 2 of Article 3 of the Directive, which states that biological material isolated from the natural environment or produced by a technical process can be the subject of an invention, even if it previously occurred in nature.[16] These provisions, provided they are interpreted in favor of the patentability of the animal breed itself, still provide scope for a wide interpretation and can be easily used to justify the expediency and legality of patenting a given object. The main condition is the meeting of

12 Directive 98/44/EC.
13 Ibid.
14 Ibid.
15 Ibid.
16 Ibid.

patentability criteria, the involvement of the microbiological, i.e. technical, stage in the creation of the animal breed, as well as the non-limitation of the patent exclusively to the animal breed itself. Even the new breed of dogs, mentioned in the example above, can satisfy these conditions.

Concerning these provisions, patents related to animal breeding were issued, especially methods of selecting animals before and after crossing. Examples include a method for identifying cows with mastitis by bulk genotyping of tank milk (EP2597159A1),[17] as well as DNA markers for meat tenderness (EP1358356A1).[18]

In these patents there is no requirement for the animal breeds themselves. However, depending on the wording of the formula, according to opponents of the issuance of such patents, such patents can be used to control further breeding if the animals in subsequent generations have the genetic characteristics described in the patent. Thus, this type of patent can interfere with traditional animal breeding and be used, for example, to prevent or prohibit farmers from further breeding of animals, in particular, dairy cows (which were discussed in the patents mentioned above).[19]

Interpretation of Article 53(b) of the EPC was repeatedly carried out by the Boards of Appeal (hereinafter referred to as BoA) of the European Patent Office (hereinafter referred to as EPO; the highest judicial body whose task is the uniform application of the provisions of the EPC) in the process of law enforcement. In the T19/90 case, it was held that the exception to patentability under Article 53(b) applies to certain categories of animals but not to animals as such.[20] Obviously, in this context, we are talking about the exclusion from patentability of animal breeds created using an exclusively biological process. However, the EPC and Directive mention animal breeds in general as one of the exclusion options. This was done to

17 Michael Georges, Gregoire Blard, and Wouter Coppieters, "Method for Identifying Cows with Mastitis by Bulk Genotyping of Tank Milk," EU Patent, EP2597159A1, November 28, 2011, accessed June 21, 2024, https://patents.google.com/patent/EP2597159A1/en.

18 William John Barendse, "DNA Markers for Meat Tenderness," EU Patent, EP1358356A1, February 8, 2002, accessed June 21, 2024, https://patents.google.com/patent/EP1358356A1/en.

19 Christoph Then and Ruth Tippe, "European Patents on Plants and Animals – Is the Patent Industry Taking Control of Our Food?," No Patents on Seeds!, 2014, accessed June 21, 2024, https://www.no-patents-on-seeds.org/en/node/285.

20 Decision of Technical Board of Appeal of the European Patent Office 3.3.2 dated 3 October 1990 – T 19/90 (OJ EPO 1990), 476.

emphasize that even a certain modification of an animal, which leads to the creation of a new species, does not make it patentable.

However, the interpretation by the BoA was not unanimous. This was confirmed by two resonant and identical decisions issued in the cases of "Tomatoes II"[21] and "Broccoli II,"[22] which related to the patentability of biological products due to the description of the procedure for obtaining this product (a claim for the product by the process). Here the BoA provided the following interpretation of Article 53(b) of the EPC: "Essentially biological processes for the production of plants or animals" are subject to exclusion from patentability, but not plants and animals obtained with the help of these processes,[23] which enabled breeders to submit applications for obtaining a patent for an animal breed, which in the sense of the BoA is considered a patent for a product (even if it is made with the help of a biological process), and not for this biological process itself. This interpretation allowed the patenting of new breeds of animals, created even by crossbreeding and selection, since the object of patenting is not this process, but the product. In addition, the decision states that a product that is the result of a biological process can be patented under the following conditions:

(1) the declared animal meets other basic patentability requirements, such as novelty (Article 54 of the EPC), inventive step (Article 56 of the EPC), or industrial application (Article 57 of the EPC);[24]
(2) the application contains appropriate language to sufficiently define the claimed product, which in certain situations can be achieved by formulating a product-by-process claim, and;
(3) the patent does not claim a plant variety as such, which is also excluded by Article 53(b).[25]

21 Decision of the Enlarged Board of Appeal of the European Patent Office dated 25 March 2015 – G 2/12 (OJ EPO 2016), A27.
22 Ibid., A28.
23 Ibid.
24 Convention on the Grant of European Patents (European Patent Convention).
25 Decision of the Enlarged Board of Appeal of the European Patent Office dated 25 March 2015 – G 2/12 & G 2/13 (OJ EPO 2016).

This decision refers to varieties of plants, however, by analogy of law, we can apply similar provisions to breeds of animals. Consequently, the last (third) condition indicates that the patentable product should not have the name "breed of animals."

Since then, more than 5,000 patent applications for the breed have been submitted to the EPO, and 3,800 patents have been issued, 120 of which were related to normal selection processes. This state of affairs caused heated discussions and criticism from the public. More than 40 written claims have been submitted on this issue, including from public and governmental institutions (e.g. Austrian Patent Office, Danish Government, EU Commission), plant breeders' associations (e.g. German Plant Breeders' Association, Euroseeds), NGOs, and experts in the field of law.[26]

In response to such an outcry, on July 1, 2017, the BoA supplemented Implementing Regulations to the Convention on the Grant of European Patents by Rule 28(2). It expressed a position already contrary to the previous precedent practice, namely: according to Article 53(b), European patents are not granted in respect of plants or animals exclusively obtained by means of an essentially biological process.[27] The higher legal force of this provision is indicated by Article 164(2) of the EPC, according to which, in case of inconsistency between two opposite standards of the EPO, the norms of the EPC (or additions to the EPC) prevail.[28]

Interestingly, the BoA also noted that "the interpretation given to this legal provision can never be taken as set in stone, as its meaning may change or evolve over time." With this statement, the BoA recognizes the variability of the presented legal positions and indicates the possibility of future evolution of the legislation on this issue.[29]

In its decision G 3/19 "Pepper" of May 14, 2020, the BoA, referring already to the Implementing Regulation and its new rule 28(2), stated that

[26] Kline Moore and Robert Frederickson, "Strong Roots: Comparative Analysis of Patent Protection for Plants and Animals," IPWatchdog, August 5, 2020, accessed June 21, 2024, https://ipwatchdog.com/2020/08/05/strong-roots-comparative-analysis-patent-protection-animals-plants/id=123649/.

[27] Amended by a decision of the Administrative Council CA/D 6/17 of 29 June 2017 (OJ EPO 2017, A56), which entered into force on July 1, 2017.

[28] Convention on the Grant of European Patents (European Patent Convention).

[29] Decision of the Administrative Council of 29 June 2017 amending Rules 27 and 28 of the Implementing Regulations to the European Patent Convention, CA/D 6/17 (OJ EPO 2017, A56).

European patents will no longer be granted to plants and animals if they are obtained exclusively by mean of an essentially biological process (such as breeding or crossing). However, this new dynamic interpretation is not retroactive to patents or patent applications issued or filed before the effective date of rule 28(2) (7 January 2017). Such patents or applications are still subject to the previous, more applicant-friendly interpretation.[30] It means that, for example, a new dog breed, obtained by conventional crossing and subsequent selection, cannot be patented under any circumstances.

It is worth emphasizing that this decision did not apply to microorganisms and cells, as well as plants and animals obtained by microbiological processes (for example, gene transfer), since the EPC, as well as the Directive, do not exclude the latter from patentability. Thus, they are patentable, provided that the invention is not limited to an animal breed itself and that there are no ethical exceptions to its patenting.[31] An example worth mentioning here is the genetically modified oncomouse, created by researchers at Harvard Medical School in the early 1980s by introducing an oncogene into the animal's body, which provoked the growth of tumors. This was done for further cancer research. This patent was considered from the beginning to be granted to an animal produced by a microbiological process,[32] but the position on the justification of its grant has long been ambiguous. In the case T 19/90, the BoA emphasized that since the tumor is a product of a microbiological process, the exceptions outlined in Article 53(b) do not apply to it when assessing patentability, however, the presence of genetic manipulations, namely the introduction of an activated oncogene, gives grounds for applying Article 53(a) – exclusion from patentability in case the invention is in conflict with the principles of morality.[33]

The final opinion regarding the patenting of the oncomouse was expressed by the EPO in 2004. The EPO decided that the oncomouse does not

30 Opinion of the Enlarged Board of Appeal dated 14 May 2020 – G 3/19 (OJ EPO 2020, A119).

31 "Patentability of Plants and Animals at the European Patent Office – the Decision G 3/19 'Pepper,'" Kailuweit & Uhlemann, June 13, 2020, accessed June 21, 2024, https://ku-patent.de/en/ekk-patentability-of-plants-and-animals-at-the-european-patent-office-the-decision-g-3-19-pepper/.

32 Decision of Technical Board of Appeal of the European Patent Office dated 3 October 1990 – T 19/90 (OJ EPO 1990).

33 Ibid.

fall under the prohibition of Article 53(b), since it is not an animal breed, but the result of genetic manipulation.[34] There is no breeding and selection involved in obtaining it. Thus, genetic modification of biological material enables its patent protection, however, it is not the animal as such or its new breed that is subject to protection, but rather the genetically modified organism as one of the manifestations of the microbiological process, that is fully correlated with the provisions of the EPC and the Directive, which allow the patenting of such objects.

It is worth noting that none of the EU member states, at the level of their national legislation, refers to the breeds of animals as objects that can be subject to patent protection. For example, animal breeds are also not subject to patenting according to Article 3 of the National Patent Act of the Netherlands.[35] In the Section 2a of German Patent Act it is clearly stated that patents are not granted for "plant and animal varieties and essentially biological processes for the production of plants and animals and the plants and animals produced exclusively by such processes."[36] An identical provision is illustrated in Section 4 of the Patent Act of the Czech Republic.[37] However, in the Czech Republic there is a separate legal regulation and protection regarding animal breeds. Law on the legal protection of New Varieties of Plants and Breeds of Animals refers to the breed as a separate independent object of intellectual property law, the law enforcement document for which is a certificate.[38] Almost identical legal legislation regarding animal breeds developed in Bulgaria. According to the Law on the Protection of New Plant Varieties and Animal Breeds the certificate is also a law enforcement document, besides, it is issued by the patent office of

34 Decision of Technical Board of Appeal of the European Patent Office 3.3.8 dated 6 July 2004 – T 315/03 – 3.3.8 (OJ EPO 2005), 246.

35 National Patent Act 1995 of Netherlands (Kingdom Act of December 15, 1994, Containing Rules Regarding Patents, status as of June 1, 2023), WIPO Lex No. NL111, as amended.

36 Patent Act as published on 16 December 1980 (Federal Law Gazette 1981 I, p. 1), as last amended by Article 1 of the Act of 30 August 2021 (Federal Law Gazette I, p. 4074).

37 Czech Republic Patent Act No. 527 of 27 November 1990 on Inventions and Rationalization Proposals, as amended by Act No. 519/1991.

38 Act No. 132/1989 Coll. of 15 November 1989, on the Protection of New Varieties of Plants and Breeds of Animal, Czech Republic, WIPO Database of Intellectual Property, accessed June 21, 2024, https://www.wipo.int/wipolex/en/legislation/details/948.

Bulgaria,[39] from which it can be concluded that the legal protection of the animal breed in Bulgaria is similar to patent protection. It is obvious that the legislation of the EU member states does not contradict the provisions of the EPC and the Directive, which meets the requirements of the EU's unified policy in this area. But it is striking at the same time that the Czech Republic and Bulgaria are the only two countries among all EU member states where specialized legal regulation about animal breeds is established, which indicates an insufficient level of legal protection of this object within the EU.

5. Essentially Biological, Microbiological, and Technical Processes

As we can observe, the key characteristics to be analyzed when assessing the patentability of an animal breed in the sense of the EPC and Directive are "exclusively essentially biological process," "microbiological process," and "technical process."

A more extensive interpretation is contained in the Guidelines for Examination in the European Patent Office (hereinafter referred to as Guidelines) dated July 1, 1978, with changes and additions as of March 2023, where a biological process is characterized as one where there is no direct technical interference with the genome of plants or animals, as suitable parental plants or animals are simply crossed and the desired offspring are selected. The exception applies even when technical means facilitate the performance of essentially biological steps. Only plants or animals produced by a technical process that alters the genetic characteristics of such plants or animals are patentable. The term "exclusively" is used here to indicate that a plant or animal that is created by a technical process or characterized by a technical intervention in the genome was not considered unpatentable, even if in addition a non-technical method (crossing or selection) is also used (Part G, chapter II, 5.4.2.).[40] The examples of subject matter, which relate to essentially biological processes (e.g. use of a (transgenic) animal for

[39] Law on the Protection of New Plant Varieties and Animal Breeds (SG No. 84/1996, as amended up to December 23, 2022), Bulgaria, WIPO Database of Intellectual Property, accessed June 21, 2024, https://www.wipo.int/wipolex/en/legislation/details/21802.

[40] Guidelines for Examination in the European Patent Office, March 2024 edition, HTML version with amendments, accessed June 21, 2024, https://www.epo.org/en/legal/guidelines-epc.

breeding, introduction of a (transgenic) gene into the genome by crossing and selection, etc.) are also provided in these Guidelines (Part G, chapter II, 5.4.2.1).[41] The presence of a non-technical method alongside a technical process is not a reason for exclusion from patentability. But again, the use of a technical process in the development of a new breed does not turn such a breed into an invention as the object of patent law. The technical process as such can be patented. In the cases G2/07[42] and G1/08,[43] it is indicated that the processes are considered biological if they are based on the sexual crossing of entire genomes and their subsequent selection.

In order to determine whether the animal was obtained exclusively by biological means, it is necessary to check whether there are changes in the hereditary characteristics of the declared organism, which is the result of a technical process. The latter, in turn, should involve more than simple crossing and selection, that is, not simply serve to ensure or facilitate the implementation of essentially biological stages of the process. Thus, transgenic plants and engineered mutants are patentable (since they are not exclusively produced by biological means), while products of conventional breeding (as, for example, a new dog breed) are not. UV-induced mutations are an example of a technical process.[44]

The prohibition of Article 53(b) of the EPC in the sense of the EPO also does not fall under the method aimed at technical steps, carried out before the step of breeding and does not include the step of breeding itself. This is noted by the EPO in its written decision regarding the patent EP 1263521 (Ovasort, Great Britain), which concerns sex selection in animals.[45]

The concept of "essentially biological process" concerning plant breeding is treated in detail in decision G 3/19 and is characterized as follows: (1) the process is not microbiological; (2) sexual crossing of entire plant

41 Ibid.

42 Decision of the Enlarged Board of Appeal of the European Patent Office dated 9 December 2010 G 1/08 (OJ EPO 2012), 206.

43 Decision of the Enlarged Board of Appeal dated 9 December 2010 G 2/07 (OJ EPO 2012), 130.

44 Guidelines for Examination in the European Patent Office, March 2024 edition, HTML version with amendments, accessed June 21, 2024, https://www.epo.org/en/legal/guidelines-epc.

45 Ian Cumming, "A Method of Sorting Cells," EU Patent, EP1263521A2, March 8, 2001, accessed June 21, 2024, https://data.epo.org/publication-server/rest/v1.0/publication-dates/20021211/patents/EP1263521NWA2/document.html.

genomes and subsequent selection of plants are included in the stages of the process. Crossbreeding or selection can be enabled or improved by a "technological step" that can be created independently as a supplement to or as part of the crossbreeding or selection process. If this "technical step" introduces a new trait into the genome or modifies an existing trait in the genome of the plant, such that the introduction or modification of the trait does not result from the mixing of the genes of the plants selected for sexual crossing, then such a process is not excluded from patentability under Article 53(b) of EPC.[46] Similar requirements apply to an essentially biological process for animal breeding.[47] Therefore, in order to be patented, a new organism should be created with the help of a technical process that modifies this organism genetically.

However, in terms of interpretation of the "biological" process, the following question remains open: whether the process is considered completely biological, if it was not possible to achieve an identical result during repeated breeding. That is, if repeated breeding, even being essentially a biological process, provoked certain genetic changes in the animal (mutagenesis), and therefore the final result was not identical? Is there a difference in whether this process occurs naturally or was directed by a man and purposefully aimed at obtaining a specific result in the form of a new breed of animals?[48] Today it is clear that such a new breed of animals is unlikely to receive patent protection within the European Union. However, taking into account the previous precedent practice, it is obvious that breeders will continue to explore the limits of Article 53(b) of the EPC and seek to expand them in their favor. One of the options for how breeders can apply for patent protection of their breeds is the wording of the claim, in which the invention is not limited to the breed of animals itself, but receives protection along with, for example, the technical process that may be involved

46 Opinion of the Enlarged Board of Appeal dated 14 May 2020 – G 3/19 (OJ EPO 2020, A119).

47 Alex B. Berger and Kerstin Galler, "Regarding the Patentability Of Plants And Animals In Europe – The G 3/19 Decision ('Pepper') Of The European Patent Office," Monaq, July 28, 2020, accessed June 21, 2024, https://www.mondaq.com/germany/patent/970084/regarding-the-patentability-of-plants-and-animals-in-europe--the-g-319-decision-pepper-of-the-european-patent-office.

48 Neil Wilkof, "More on Broccoli, Tomatoes, and the Patentability of a Plant or Animal Obtained by Means of an Essentially Biological Process," The IPKat, July 28, 2017, accessed June 21, 2024, https://ipkitten.blogspot.com/2017/07/more-on-broccoli-tomatoes-and.html.

in this case. The problem is, however, that the number of such technical processes aimed at obtaining a new breed of animals can be quite limited. Therefore, the possibilities of breeders under such conditions are limited.

6. Bioethics and Morality

Another important aspect that must be taken into account when considering the possibility of patenting an animal breed or at least an animal created with the help of microbiological or technical processes, is the issue of bioethics and morality. Article 53(a) EPC prohibits the patenting of inventions whose commercial use would be contrary to "public order" or morality.[49] In the case of the already mentioned oncomouse, the EPO ruled that the benefits of the oncomouse for further cancer research significantly outweighed moral concerns about the suffering caused to the animal.[50] However, by itself, the EPC does not clarify the meaning of the concepts of ethics and morality in the context of patenting. Moreover, it is rather difficult to identify the general criteria of the latter for states with different religious and cultural traditions.[51] Therefore, these points should be considered individually in each specific case, since the issue of bioethics in biotechnology and breeding is quite sensitive. It is impossible to ask an animal whether it has suffered from any human interference with its body, nor to measure the intensity of such suffering or any possible discomfort. In general, it should not be allowed for commercial benefits to become the only guide in matters of innovation and biotechnology.

7. Conclusion

The analysis of EU legal acts in the field of patenting of objects of intellectual property law, in particular animal breeds, as well as law enforcement practice on this issue, allows us to conclude that the provisions expressed in the EPC and the Directive are not completely unambiguous. On the one hand, animal breeds are excluded from the objects of patent protection, as

49 Convention on the Grant of European Patents (European Patent Convention).

50 "Bioethics and Patent Law: The Case of the Oncomouse," WIPO Magazine, no. 3 (2006), accessed June 21, 2024, https://www.wipo.int/wipo_magazine/en/2006/03/article_0006.html.

51 Andrii Olefir, "To the Problem of Legal Protection of Biotechnology," *A Scientist's View. Series: Theory and Practice of Intellectual Property*, no. 1 (2015): 81, accessed June 21, 2024, http://nbuv.gov.ua/UJRN/Tpiv_2015_1_10.

well as essentially biological processes for producing animals. By default, within the meaning of the EPC and the Directive, all new breeds of animals can be created with the help of such essential biological processes as breeding and selection. It is allowed to patent objects that only relate to the breed of animals, are not excluded by it and, of course, have all the necessary criteria for patentability. On the other hand, certain provisions can be interpreted in favor of patenting animal breeds or, at least, be considered contradictory. For example, the rule that biological material isolated from the natural environment or produced by a technical process can be the subject of an invention, even if it previously occurred in nature, made it possible to issue patents in the field of animal breeding (although not for the animal breed itself).

An important stage in the formation of precedent practice regarding the patenting of animal breeds was the adoption of the "Tomatoes II" and "Broccoli II" decisions, in which the BoA subjected Article 53(b) to an interpretation according to which essentially biological processes for the production of animals, but not animals created with the help of these processes, were considered unpatentable. It certainly became a resonant statement and required an adequate response from the EPO, which resulted in the consolidation of the provision according to which European patents are not granted in respect of plants or animals obtained exclusively by means of an essentially biological process. In the future, BoA decisions were already based on this norm. The adjective "exclusively" is extremely important, which is used to outline the fact that, provided that a certain technical component or microbiological process is involved, the animal may be subject to patent protection.

When considering the prospects for patenting animal breeds, it is worth taking into account and distinguishing the following categories: "microbiological process," "essentially biological process," and "technical process." A microbiological process is an independent patentable object, as are animals obtained as a result of its application (for example, the oncomouse). However, such animals are still not a new breed. The biological process is characterized by the absence of direct technical intervention in the animal's genome, suitable chosen parent animals are simply crossed and selected. Finally, the technical process must exceed simple crossing and selection, and not only serve to ensure or facilitate the implementation of the biological

stages of the process, but also introduce a new trait into the genome or modify an existing trait in the genome (an example of a technical process is UV-induced mutations).

We found out that an animal breed as such cannot be an object of patenting if its derivation does not require the involvement of microbiological or technical processes. The application of the latter in relation to an animal involves its genetic modification, and in such a case the modified animal may be subject to patenting as a product (invention in general). The breeding of a new breed of animals concerns exclusively biological processes, such as crossing and selection. Still, the question of what to do with one-time or subsequent repeated breeding, in the process of which unforeseen genetic changes took place, which led to the appearance of a completely new breed of animals, remains unsolved. That is, although the process was supposed to be exclusively biological, significant changes at the microbiological level were involved. We hope that an answer to this question will soon be found by law enforcement agencies or a direct answer will be given at the level of the law, in particular at the EU level.

The practical significance of unambiguous regulatory wording and uniform enforcement is to prevent the issuance of patents for animal breeds in some cases and the refusal to issue them in other cases, as was the case until 2017. In addition, the same legal position on patenting at the EU level will lead to identical legal regulation of this issue by its member states, which generally corresponds to the principles that govern the functioning of the EU. Reforming the EU legislation in this area in the direction of the unification of legal regulation would contribute to the elimination of disagreements and ambiguous wording.

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