6. The Relationship between Article 53(a) of the European Patent Convention and the Biomedical Sciences

6.1. The Relationship between Traditions and How it is Evolving

The EPO case law analysed in this study[1003] and the discussed legal provisions show that, at present, European patent law, belonging to the Western legal tradition, does not grant patents for inventions covering the living body of a human being, parts of the body that are not separated from it, human embryos or processes that can radically change it. As is stated in the aforementioned case law and discussed in the legal provisions, this includes processes for cloning human beings,[1004] the use of human embryos for industrial or commercial purposes,[1005] and processes for modifying the germ line genetic identity of human beings.[1006] Given that Rule 28(1) of the EPC Implementing Rules provides a non-exhaustive list of non-patentable inventions, in the course of the advancement of the biomedical sciences and, where necessary, applying Art. 53(a) of the Convention, new points may be added to it.

In assessing the described inventions with regard to Art. 53(a) EPC, the deontological rebuttable presumption test based on the protection of human life and dignity is applied, making it possible to provide for a broad interpretation of the patent claims and the term 'commercial exploitation'. Also, unlike with animal or plant-related biotechnological inventions, when dealing with the granting of patents for the discussed inventions, the potential benefit of these inventions is not taken into consideration. Such a situation can be explained based on the status of the human being as an exceptional creature in the legal systems belonging to the Western legal tradition, of which the European patent system is one.

1003 See I.4. 'European Patent Office Case Law on Article 53(a) of the European Patent Convention'.

1004 *Edinburgh Patent* (n 23); EPC Implementing Regulations, r 28(1)(a).

1005 *Use of embryos/WARF* (n 80); *Stem Cells/WARF* (n 80); *Stem cells/CALIFORNIA* (n 81); *Culturing stem cells/TECHNION* (n 23); *Embryonic stem cells, disclaimer/ASTERIAS* (n 81); *Neurale Vorläuferzellen/BRÜSTLE* (n 81); EPC Implementing Regulations, r 28(1)(c).

1006 EPC Implementing Regulations, r 28(1)(b).

Nonetheless, when analysing the biotechnological inventions discussed above and their effects on a living organism, European patent law, despite its autonomy from other legal systems, does not function alone. Each time when deciding on the patenting of a particular invention, European patent law is also confronted with the knowledge of the biomedical sciences, based on generally accepted scientific achievements, which for some time provides models of emerging problems and their solutions, referred by T. Kuhn to as 'paradigms'.[1007] This means that, when deciding on specific inventions, the EPO is guided by the knowledge of the biomedical sciences acknowledged by the scientific community at a particular point in time, which changes over time, i.e. is supplemented, refuted, replaced by new knowledge, etc.

When analysing the relationship between law and science, S. Jasanoff stated that each of these 'traditions claim an authoritative capacity to sift evidence and derive rational and persuasive conclusions from it'.[1008] It is mentioned in this study that, according to H. J. Berman, although in the discussed tradition 'law remains strongly influenced by religion, politics, morality, and custom, it is nevertheless distinguishable from them analytically'.[1009] This means that, just as the natural sciences, even if they rely on a paradigm that exists at a particular moment in time,[1010] give weight to the information obtained through observation concerning their surroundings, so does the legal system belonging to the Western legal tradition, in accordance with its fundamental values at a particular moment in time, give weight to the facts of reality in addition to these fundamental values.[1011] Therefore, not only is the tradition of the natural sciences characterised by its exceptional use of empirical tests in order to understand the environment,[1012] but also the credibility of observers and their insights is important for decision-making in the legal system.[1013]

Based on two criteria, i.e. the fundamental inherent values and knowledge about reality, these two traditions shape the 'fundamental agree-

1007 Kuhn, *The Structure of Scientific Revolutions* (n 70) viii.
1008 Jasanoff, *Science at the Bar. Law, Science, and Technology in America* (n 72) 8.
1009 Berman, *Teisė ir revoliucija: vakarų teisės tradicijos formavimasis* (n 41) 24 (translated from Lithuanian into English by the author of this study).
1010 See '2.2. The Concept and Significance of the Biomedical Sciences as a Tradition'.
1011 See '3.3. The Situation in the Western Legal Tradition in the 21st Century'.
1012 Shils, *Tradition* (n 499) 215.
1013 Jasanoff, *Science at the Bar. Law, Science, and Technology in America* (n 72) 8.

ments'[1014] mentioned by A. MacIntyre and, over time, experience transformations in response to a changing environment.[1015] These transformations are considered to be radical changes, such as a revolution in the Western legal tradition[1016] and, in the biomedical sciences, which are part of the natural sciences, a paradigm shift.[1017] In science, this happens with the help of scientists who shift the paradigm, and in law, often with the help of the legislator.[1018] However, in the latter case, the judiciary, which is faster and more flexible than the legislator in responding to the dynamic progress of science and technology, including in the biomedical sciences, cannot be excluded.

Despite the signs of the crisis in the Western legal tradition discussed in this study,[1019] and the extremely rapid progress of the biomedical sciences since the end of the 20th century, it is difficult to confidently conclude that the present situation of at least one of the analysed traditions will lead to a revolution or an entire paradigm shift in the near future. However, to a certain extent, these traditions change both internally and externally, affecting each other in different areas, one of which is the assessment of the patentability of inventions in the European patent system on the basis of Art. 53(a) EPC.

The EPO Divisions, when analysing the compliance of the commercial exploitation of inventions with *ordre public* and/or morality, must take into account the knowledge of the biomedical sciences, their reliability and their limitations, which may have implications for the granting of a patent. Based on the utilitarian theories that justify the existence of a patent system, decisions to carry out, suspend or otherwise change the strategy of a research programme may depend on the possibilities of receiving a patent in the field of biomedical sciences. The trends in the relationship between these two discussed traditions are illustrated not only by the decisions of the EPO Divisions analysed in this study, but also by the sparse case law of the CJEU.

As discussed in this research, based on Art. 53(a) EPC, the case law of the EPO and legal doctrine, the European patent system can reasonably be

1014 MacIntyre, *Whose Justice, Which Rationality?* (n 500) 12.
1015 Jasanoff, *Science at the Bar. Law, Science, and Technology in America* (n 72) 8.
1016 Berman, *Teisė ir revoliucija: vakarų teisės tradicijos formavimasis* (n 41) 15.
1017 Kuhn, *The Structure of Scientific Revolutions* (n 70) 92.
1018 Jasanoff, *Science at the Bar. Law, Science, and Technology in America* (n 72) 8-9.
1019 See '3.3. The Situation in the Western Legal Tradition in the 21st Century'.

regarded as autonomous from other legal orders.[1020] However, due to the identical provisions in the Convention, the EPC Implementing Regulations and the Biotechnology Directive regarding the patentability of biotechnological inventions, not only the case law of the EPO but also the case law of the CJEU can be considered as an appropriate illustration of the relationship between European patent law, which is a part of the Western legal tradition, and the biomedical sciences – a relationship which affects the decisions of the EPO Divisions on the granting of patents. It is in connection with the above-mentioned inventions involving a living human body, or processes that are likely to drastically modify or even create one, that changes in the European patent system and the biomedical sciences are the most significant. These are therefore analysed in this part of the study.

The *Use of embryos/WARF* decision in 2008 demonstrates a highly cautious approach by the EPO Enlarged Board of Appeal with regard to the patenting of inventions requiring the use of human embryos. As already discussed, in this case, the EPO Enlarged Board of Appeal stated that an invention whose creation requires the use of human embryos, i.e. the destruction of them, cannot be patented even if that is not covered by the patent claims.[1021] This decision can be distinguished from previous decisions of the EPO Divisions by its broad evaluation of the commercial exploitation of an invention with regard to *ordre public* and/or morality.

In this case, the EPO Enlarged Board of Appeal stated that Rule 28(c) of the EPC Implementing Regulations did not give the term 'human embryo' a narrow meaning and that, each time, according to the circumstances, the category could be redefined.[1022] However, no definition of the discussed term was provided in this decision. Still, in the case in question, when evaluating the commercial exploitation of an invention for the production of which human embryos are destroyed with regard to Art. 53(a) of the Convention, the field of the assessment of the patent application was expanded, and the term 'commercial exploitation' was understood broadly as covering both aspects of the creation of the invention and its development.[1023]

1020 See 'Introduction' and '1.2. The Relationship between Article 53(a) of the European Patent Convention and the Biotechnology Directive'.

1021 See '1.4.1. Tests for Application of Article 53(a) of the European Patent Convention' and '1.4.2. The Standards for Applying Article 53(a) of the European Patent Convention'; *Use of embryos/WARF* (n 80), para 22.

1022 *Use of embryos/WARF* (n 80), paras 27 and 33 (since 1 July 2017: EPC Implementing Regulations, r 28(1)(c)).

1023 ibid para 22.

This means that, in the *Use of embryos/WARF* case, the evaluation of the patent application involved looking at both the future and the past, by incorporating into the term 'commercial exploitation' the steps necessary for the creation of the invention but not directly included in the patent application.

The above decision shows that, when analysing inventions using human embryos, the risks arising from scientific development in the Western legal tradition are interpreted broadly by the EPO. This could be associated with the importance of human rights, life and dignity in the legal systems belonging to the Western legal tradition[1024] discussed in this study, and the fact that the knowledge of the biomedical sciences is not sufficient to define the category 'human embryo'. Unable to rely firmly on the scientific knowledge, but in order to protect the afore-mentioned values as much as possible, the European patent system takes the position that, based on Art. 53(a) EPC, objects whose creation requires the use of human embryos, even at a very early stage, are not considered to be eligible to become economic goods, and thus cannot be granted a patent.

The aforementioned interpretation of Art. 53(a) of the Convention, giving the term 'commercial exploitation' an exceptionally broad meaning, also reveals a derogation from Art. 84 and Art. 69 EPC, the former of which states that patent claims 'define the matter for which protection is sought'[1025] while the latter establishes that '[t]he extent of the protection conferred by a European patent or a European patent application shall be determined by the claims'.[1026] This means that, in assessing the patentability of an invention in accordance with Art. 52 and Art. 53 EPC, it is necessary to analyse precisely the patent claims of the application. However, in the *Use of embryos/WARF* case, the EPO Enlarged Board of Appeal deviated from the above-mentioned provisions of the EPC by incorporating activities not covered by the patent claims of the application into the commercial exploitation of the invention.

Also, in this case, it was stated that, after the filing of a patent application, the emergence of technologies enabling the extraction of stem cells by other methods (for example, without destroying the human embryo) is of no importance to the patentability of the invention discussed in the application

1024 See '3.2. The Concept of the Western Legal Tradition in the 21st Century'.
1025 EPC, Art. 84.
1026 ibid, Art. 69(1).

already filed.[1027] The *Use of embryos/WARF* decision shows that, due to innovations in the biomedical sciences, the EPO Board of Appeal is not inclined to depart from one of the fundamental principles of the patent law, i.e. the evaluation of the compliance of an invention with regard to the patentability criteria at the date of the filing of the application or at the priority date.[1028] According to the Board, a decision other than the latter would lead to legal uncertainty and the risk of harming a third party which has found a way to implement the invention that does not pose any threat to human beings.[1029]

Although not having to comply with the EPO case law, in the *Oliver Brüstle v Greenpeace e.V.* judgment of 2011,[1030] the CJEU continued the broad position established in the *Use of embryos/WARF* case with regard to inventions relating to the use of human embryos. In this case, the Court provided for a broad definition of the category 'human embryo'. The main criterion for determining whether a particular object is to be considered a human embryo is the fact of whether the process of human development begins with that object (for example, a fertilised human ovum).[1031] Therefore, in the *Oliver Brüstle v. Greenpeace e.V.* decision, these objects were regarded as a 'human embryo': (1) each human ovum from the stage of fertilisation; (2) a non-fertilised human ovum into which the cell nucleus from a mature human cell has been transplanted; (3) a non-fertilised human ovum whose division and further development have been stimulated by parthenogenesis.[1032]

Also in the *Oliver Brüstle v. Greenpeace e.V.* case, the CJEU stated that the question whether a stem cell obtained from a human embryo in the blastocyst stage constitutes a 'human embryo' within the meaning of Art. 6(2)(c) of the Biotech Directive must be determined by the national court 'in the light of scientific developments'[1033]. The position of the Court was based on the fact that the EU legislator 'intended to exclude any possibility of patentability where respect for human dignity could thereby be affected'.[1034] Thus, in the decision in question, like in the *Use of embry-*

1027 *Use of embryos/WARF* (n 80), para 34.
1028 EPC, Art. 54(2)-(3).
1029 *Use of embryos/WARF* (n 80), para 33.
1030 *Oliver Brüstle v Greenpeace eV* (n 90).
1031 ibid paras 35-36.
1032 ibid para 38.
1033 ibid.
1034 ibid 34.

os/WARF case, there is an obvious aim to respect life and human dignity as fundamental values in the Western legal tradition.

Subsequently, in 2014, in the *International Stem Cells Corporation* judgment, the CJEU responded to one of the questions that had already been analysed in the *Oliver Brüstle v Greenpeace e.V.* case.[1035] The Court of Justice needed to answer the question whether the term 'human embryo' includes unfertilised human ova that are induced to split and develop by parthenogenesis.[1036] In this case, the CJEU analysed and followed the same criterion for the status of the human embryo as in the previous case, *Oliver Brüstle v. Greenpeace e.V.*, which is that the object to be patented must be 'capable of commencing the process of development of a human'[1037] and concluded that this criterion refers to 'inherent capacity of developing into a human being'[1038].

However, in spite of the same subject-matter being in question, in the *International Stem Cells Corporation* case, the CJEU changed its judgment regarding the status as a 'human embryo' of an unfertilised human cell which by way of parthenogenesis is forced to multiply and develop. In *Oliver Brüstle v. Greenpeace e.V.*, the CJEU had established that 'it is for the referring court to ascertain, in the light of scientific developments, whether a stem cell obtained from a human embryo at the blastocyst stage constitutes a 'human embryo' within the meaning of Article 6(2)(c) of the Directive'.[1039] Consistently, according to the 'current scientific knowledge',[1040] when assessing the same object, i.e. an unfertilised human ovum which is forced to split and develop by parthenogenesis, the Court of Justice changed its interpretation from that in *Oliver Brüstle v Greenpeace e.V.*, and stated that an unfertilised human ovum which is forced to split and develop by parthenogenesis does not fall under the term 'human embryo', 'if, in the

1035 In the *Oliver Brüstle v Greenpeace eV* case, one part of the first question submitted to the Court was whether the term 'human embryo' in Art. 6 also applies to such organisms: 'unfertilised human ova whose division and further development have been stimulated by parthenogenesis' (*Oliver Brüstle v Greenpeace eV* (n 90), para 23).

1036 *International Stem Cell Corporation v Comptroller General of Patents, Designs and Trade Marks* (n 90), para 20.

1037 ibid para 27.

1038 ibid para 28.

1039 *Oliver Brüstle v Greenpeace eV* (n 90), para 38.

1040 *International Stem Cell Corporation v Comptroller General of Patents, Designs and Trade Marks* (n 90), para 33.

light of current scientific knowledge, that ovum does not, in itself, have the inherent capacity of developing into a human being'[1041].

Also, despite the rigorous position set out in the *Use of embryos/WARF* case that the progress of science and technology[1042] and the emergence of a way of not performing actions that prevent the granting of a patent after the patent application is filed do not change the evaluation of the conformity of an invention with regard to *ordre public* and/or morality, in certain cases, new scientific knowledge may still affect decisions on the conferral of an exclusive right to a particular invention. In particular, in the *Human pluripotent progenitor stem cells/PROGENITOR LABS* case, the EPO Board of Appeal, in the light of *International Stem Cell Corporation* case of the CJEU and scientific data from 2003, which showed that the use of pluripotent human cells obtained by parthenogenesis does not constitute the use of human embryos, decided on its own initiative to submit the evaluation of the commercial exploitation of an invention on the basis of Art. 53(a) EPC to the EPO Examining Division for a reassessment.[1043]

At first glance, such a change may appear to be in conflict with the *Use of embryos/WARF* case, but there is a difference between the latter and the *Human pluripotent progenitor stem cells/PROGENITOR LABS* case. The first one examined the impact of new technologies preventing actions precluding the grant of a patent, which emerged after the patent application was filed, on the decision of the EPO to grant a patent. In this case, the EPO's acceptance to evaluate the patentability of an invention with regard to Art. 53(a) EPC, or any other article, by taking into consideration a completely new technology would mean a divergence from the principle of evaluation of an invention based on the date of the patent application or priority. In contrast, in the *Human pluripotent progenitor stem cells/PRO-*

1041 *International Stem Cell Corporation v Comptroller General of Patents, Designs and Trade Marks* (n 90), para 38. However, according to the *International Stem Cell Corporation v Comptroller General of Patents, Designs and Trade Marks* decision, additional genetic manipulation may help parthenote to develop into a human being (ibid para 18).

1042 *Use of embryos/WARF* (n 80), para 34.

1043 *Human pluripotent progenitor stem cells/PROGENITOR LABS* (n 81), paras 2, 3 and 5. See also *In vitro differentiated cardiomyocytes/AXIOGENESIS* (n 81) and *Human hepatocytes/OREGON UNIVERSITY* (n 81) where the Board of Appeal, based on the revised interpretation of r 28(c) (currently r 28(1)(c)) of the Implementing Regulations in view of scientific knowledge, set the decisions under appeal aside and acknowledged that the biotechnological inventions in question cannot be excluded from patentability based on Art. 53(a) EPC.

GENITOR LABS case, only the assessment of the same process discussed in the patent claims from the position of the biomedical sciences has changed, but the moment of time of this assessment, i.e. the date of the filing of the patent application, has remained the same. Therefore, a re-evaluation of the commercial exploitation of the same invention in the light of newly acquired knowledge which was available at the time of filing the patent application or at the priority date should be considered appropriate.

The above-discussed *Use of embryos/WARF* decision shows that European patent law strictly evaluates inventions whose patenting may have a negative impact on the fundamental values of the Western legal tradition. Moreover, the above-indicated decision demonstrates that the patent system is not prone to respond to progress in the biomedical sciences where such response would lead to a departure from the provisions and principles that are important to European patent law – for example, the date of evaluation of the patentability of an invention at the time of filing an application or the priority date. On the other hand, when interpreting the scope of an invention broadly, as in the *Use of embryos/WARF* decision, if the newly discovered scientific knowledge does not alter the subject-matter of the invention, and in those cases where the patenting of a new invention is being decided on, the said scientific progress is taken into account by the European patent system.

The decisions in the *Human pluripotent progenitor stem cells/PROGENITOR LABS* and the *Oliver Brüstle v. Greenpeace e.V.* and *International Stem Cells Corporation* cases, analysing the possibility of the same object being a 'human embryo', show that the biomedical sciences, as a part of the scientific tradition, can influence European patent law. Of course, such a change in the assessment of a particular object requires consensus in a particular field of science.[1044] The discussed case law of the Court of Justice has shown that the patent system belonging to the Western legal tradition does not intend to abandon the principles of deontological ethics and the fundamental principles of the evaluation of a patent application, but changing scientific knowledge may lead to a review of whether a particular subject-matter can still be attributed to the fundamental values protected by the patent system in question.

1044 *International Stem Cell Corporation v Comptroller General of Patents, Designs and Trade Marks* (n 90), para 33.

Meanwhile, in the absence of a clear consensus in science on the nature and status of specific objects, as well as without having any scientific progress that, for example, challenges the concept of the category 'human embryo', the European patent system and the EU legal order,[1045] both belonging to the Western legal tradition and governing aspects of the patenting of inventions, evaluate the patentability of the inventions presented to them very rigorously, by applying the rebuttable presumption test based on deontological philosophy. Such a rigorous position remains until scientific progress undermines their presumption, which is the basis for assessing the patentability of controversial subject-matter with regard to Art. 53(a) EPC. In such cases, the European patent system, belonging to the Western legal tradition, by not granting patents for inventions in the field of biomedical sciences, affects the development and growth of knowledge in this field of science.

Based on all the above-discussed case law of the EPO Boards of Appeal and the CJEU, it is clear that the two traditions, i.e. the European patent system and the biomedical sciences, are affecting each other. The European patent system, which belongs to the Western legal tradition and does not have sufficiently solid knowledge in the field of biomedical sciences, uses a rebuttable presumption test based on deontological philosophy to protect the current fundamental values. This approach of the European patent system is extremely broad, since, in case of uncertainties in the biomedical sciences, it gives priority to legal norms or to important but highly abstract values such as human dignity. Failure of the European patent system to grant patents and thereby commercialise the available results may reduce the activity in the biomedical sciences and obstruct its development, resulting in a slower emergence of new scientific knowledge. At the same time, the emergence of new knowledge enabling a different perception of such categories as 'human embryo' as patentable subject-matter may result in changes in the European patent system that could lead to the application of Rule 29(2) of the EPC Implementing Regulations, which would increase the possibility of patenting more inventions and commercialising them.

All this leads to the conclusion that the European patent system, which is a part of the Western legal tradition, and the biomedical sciences, as a tradition, when addressing the issue of the patenting of biotechnological inventions in the context of Art. 53(a) EPC, influence each other. In this regard, it is important to look for categories allowing a better understand-

1045 See 'Introduction'.

ing of the interaction between these two traditions and the trends in their development.

6.2. The Concept of 'Co-Production' in the Context of Article 53(a) of the European Patent Convention

In the scholarly literature, it is indicated that in the economic, sociological and political sciences, there is a lack of terminology helping to explain the irregular and uneven process by which scientific and technological development is intertwined with social norms and hierarchical structures.[1046] Despite the difficulties in describing the relationship between the social order and science and technology, their influence on each other is inevitable. For example, it is difficult for environmentalists to find an ecosystem which is intact or unexplored by human activity, and for social scientists to find human organisations whose structure and functions are not affected by scientific and technological progress.[1047]

According to S. Jasanoff, 'society cannot function without knowledge any more than knowledge can exist without appropriate social supports'.[1048] This means that the relationship between science and society cannot be understood as taking place in only one direction.[1049] In this situation, the category which, in the context of this study, is considered to be appropriate for describing the relationship between the law and the natural sciences as

1046 Jasanoff, 'The Idiom of Co-Production' in Sheila Jasanoff (n 4). See also Stephen Hilgartner, Clark Miller and Rob Hagendijk, 'Introduction' in Stephen Hilgartner, Clark Miller and Rob Hagendijk (eds) *Science and Democracy. Making knowledge and making power in the biosciences and beyond* (Routledge 2015) 1-14; Mariachiara Tallacchini, 'To bind or not to bind?' in Stephen Hilgartner, Clark Miller and Rob Hagendijk (eds), *Science and Democracy. Making knowledge and making power in the biosciences and beyond* (Routledge 2015) 156-175.

1047 Sheila Jasanoff, 'Ordering knowledge, ordering society' in Sheila Jasanoff, *States of Knowledge. The co-production of science and social order* (Routledge 2004) 13-45, 13.

1048 Jasanoff, 'The Idiom of Co-Production' in Sheila Jasanoff (n 4) 2-3.

1049 David E Winickoff, 'Biology denatured. The public-private lives of lively things' in Stephen Hilgartner, Clark Miller and Rob Hagendijk (eds), *Science and Democracy. Making knowledge and making power in the biosciences and beyond* (Routledge 2015) 15-32, 16.

well as between the Western legal tradition and the biomedical sciences is 'co-production' as proposed by S. Jasanoff.[1050]

According to S. Jasanoff, co-production is shorthand for 'the proposition that the ways in which we know and represent the world (both nature and society) are inseparable from the ways in which we choose to live'.[1051] Viewed from the perspective of co-production, 'science and law, innovation and regulation, knowledge and policy processes do not develop separately, but co-evolve through explicit negotiations, institutional hybridization, migration of concepts, contamination and overlap of meanings'.[1052] This means that the proper functioning of the legal system as a social order requires knowledge about the surrounding environment provided by the natural sciences, whereas for the natural sciences, which aim to deepen and broaden knowledge about the world, legal regulation is important; by laying down certain requirements for research activities, legal regulation can both facilitate and complicate research in this field of science. Taking this into consideration, it is possible to agree with S. Jasanoff that 'the realities of human experience emerge as the joint achievements of scientific, technical and social enterprise: society and science, in a word, are *co-produced*, each underwriting the other's existence'.[1053] Thus, the relationship between the legal order and the natural sciences manifests itself as an interaction in which these two spheres influence each other.

One example of co-production is the history of the establishment and operation of the Intergovernmental Panel on Climate Change, which reveals the interplay between the natural and the social order. Such a connection between the areas of the identified realities is illustrated by the fact that the formal scientifically identified environmental hazards led to the creation of a new global body for cooperation, which in turn has proved to be essential to substantiate the legitimacy and credibility of scientific statements about global environmental threats.[1054] The above example shows that knowledge of the natural sciences can be the basis for certain changes

1050 Jasanoff, 'The Idiom of Co-Production' in Sheila Jasanoff (n 4); Sheila Jasanoff, 'Ordering knowledge, ordering society' (n 1047) 13-45.
1051 Jasanoff, 'The Idiom of Co-Production' in Sheila Jasanoff (n 4) 2.
1052 Tallacchini, 'To bind or not to bind?' (n 1046) 169.
1053 Jasanoff, 'Ordering knowledge, ordering society' (n 1047) 17.
1054 Clark A Miller, 'Climate science and global political order' in Sheila Jasanoff (ed), *States of Knowledge. The co-production of science and social order* (Routledge 2004) 46-66, 64.

in the social order, whereas the latter may contribute to the emergence, justification or changing of that scientific knowledge.

Apart from the idea of the interaction between the legal and natural orders discussed above, the category of 'co-production' is also important, because it allows analysis of the production of order without giving preference to any of the aforementioned areas of reality.[1055] Such a position allows one to abandon the deterministic view of both the legal order and the natural sciences,[1056] so that neither of these areas is accepted as something given, objectively and indisputably describing social or natural phenomena.

In the above context, the category 'tradition' used in this work seems to be appropriate. As discussed in this study, the natural sciences can be perceived as a phenomenon encompassing both cumulative and non-cumulative development. Therefore, in both normal science and scientific revolutions, the attitude of the scientific community is important for understanding the environment and its processes, which are often shaped by the existing tradition[1057] and do not always objectively reflect reality. Similarly, the current point of view of a particular legal order, such as the Western legal tradition discussed in this work, may change over time and therefore should not be regarded as eternal and absolutely indisputable.[1058] For this reason, the available scientific knowledge about the surrounding environment is not always objective and indisputable, and the view of the legal tradition regarding the values that matter to it should not be considered as unchanging. Such a refusal of determinism makes it easier to accept that the European patent system and the biomedical sciences can interact with each other in the context of Art. 53(a) EPC and thus influence and change one another.

The idea of co-production as appropriate in the context of the Convention is also supported by other authors, indicating that the discussed category is relevant for describing the relationship between European patent law as a social order and biomedical sciences as part of the natural sciences.[1059] Scholarly literature suggests that in the case of inventions related

1055 S Jasanoff explains why it is not possible to give preference to any of these areas (Jasanoff, 'Ordering knowledge, ordering society' (n 1047) 19-20).

1056 ibid 20.

1057 See '2.2. The Concept and Significance of the Biomedical Sciences as a Tradition'.

1058 See '3.2. The Concept of the Western Legal Tradition in the 21st Century'.

1059 Salter, 'Patents and morality: governing human embryonic stem cell science in Europe' (n 102); Parthasarathy, 'Co-producing knowledge and political legitimacy. Comparing life form patent controversies in Europe and the United States' (n

to the patenting of human embryonic stem cells in the European patent system, co-production provides two important insights. Firstly, it emphasises that knowledge and social order develop together, which means that shifts in basic social and moral considerations also change the knowledge which was considered to be significant for these decisions.[1060] Secondly, co-production highlights the process of creation, in which through the interaction between European policy and patent officials as well as scientists and activists, over time, a legal-moral order for biotechnological patents has been co-produced.[1061]

All of the above suggests that the biomedical sciences and European patent law influence each other in the context of Art. 53(a) of the Convention, and not just as one area influencing the other in one direction, i.e. when only the knowledge of the natural sciences influences legal regulation or, conversely, only the legal framework regulates biomedical sciences. As biotechnological inventions pose challenges to European patent law, the latter can also shape the development of the biomedical sciences when deciding on the legal protection of biotechnological objects or processes. This leads to the conclusion that there is an ongoing co-production between the biomedical sciences and European patent law, which is analysed in the context of Art. 53 EPC in the following part of this work.

6.3. Trends in the Interaction between European Patent Law and the Biomedical Sciences

As discussed in this study, co-production, emphasising the interaction between European patent law, as part of the Western legal tradition, and biomedical sciences, as a tradition, in the context of Art. 53(a) EPC, is considered a category capable of characterising the relationship between these traditions and the trends in its development. The above-mentioned aspects are particularly evident in the case law of the EPO Divisions and the CJEU when deciding on the patentability of biotechnological inventions.

---

17) 75 (applies to the analysis of the patenting of inventions related to human embryonic stem cells).

1060 Parthasarathy, 'Co-producing knowledge and political legitimacy. Comparing life form patent controversies in Europe and the United States' (n 17) 75.

1061 ibid.

Following the case law of the EPO Divisions, it was stated[1062] that, in assessing the commercial exploitation of biotechnological inventions in accordance with Art. 53(a) EPC, this case law contains arguments based on two ethical theories which, according to the scholarly literature, are also significant in other branches and sub-branches of the law regulating the biomedical sciences.[1063] These theories are (1) utilitarianism and (2) deontology.

The utilitarian approach is characterised by the weighing of benefits and negative consequences, which is employed when the commercial exploitation of an invention, regardless of its benefits, may have negative impact on the environment or may lead to suffering of animals, resulting in a fairly large debate in European society. This point of view is illustrated by Rule 28(1)(d) of the EPC Implementing Regulations, which provides for the weighing test according to which animal suffering is weighed against the substantial medical benefit to human beings and animals.[1064] In cases where it is not possible to apply the above-discussed test, the one established in the *Onco-mouse/HARVARD*[1065] case and analysed in the *Plant cells/PLANT GENETIC SYSTEMS*[1066] case can be applied, allowing the weighing of not only animal suffering but also environmental damage against the potential benefits for humankind and animals. Judging from the EPO case law, such a test for the assessment of the benefits and damage of the commercial exploitation of an invention is appropriate in cases where issues relating to the evaluation of the commercial exploitation of inventions involving animals or plants with regard to *ordre public* and/or morality are raised.[1067] In this case, the narrow concept of commercial exploitation is applied, meaning that in particular the invention described in the patent claims is assessed under Art. 53(a) of the Convention.[1068]

The Office's decisions based on deontological ethics with regard to the interpretation and application of Art. 53(a) EPC can be divided into two

1062 See '1.4. European Patent Office Case Law on Article 53(a) of the European Patent Convention'.

1063 See e.g. Resnik, 'DNA Patents and Human Dignity' (n 986) 152-165; Brownsword, 'Ethical Pluralism, and the Regulation of Modern Biotechnologies' (n 255) 48-50.

1064 As mentioned in this study, this rule can apply to both genetically modified and non-modified animals (*Leland Stanford/Modified Animals* (n 45), pt 8; before 13 December 2007: EPC Implementing Regulations, r 23d(d)).

1065 *Onco-Mouse* (n 80), para 5.

1066 *Plant cells/PLANT GENETIC SYSTEMS* (n 22), para 18.8.

1067 See '1.4.1. Tests for Application of Article 53(a) of the European Patent Convention'.

1068 See '1.4.3. The Concept and Scope of the Term 'Commercial Exploitation"'.

groups. The first involves decisions on inventions for which patents are considered to be entirely unacceptable, while the second encompasses decisions on inventions for which, from the point of view of this branch of philosophy, the granting of patents is acceptable.

The first approach is applied in cases where the commercial exploitation of an invention may violate the values of the Western legal tradition, for which, in principle, compromises are impossible. This means that the benefits of the commercial exploitation of an invention cannot outweigh the negative aspects.[1069] Usually, from the perspective of the Western legal tradition, these values are human life and dignity. Such a position of the European patent system is clearly reflected in the *Stem Cells/WARF* case, in which the EPO Board of Appeal had doubts as to whether, when analysing the commercial exploitation of an invention that includes human life with regard to *ordre public* and/or morality, it would be ethically appropriate to make a decision by weighing up the potential benefits against the potential damage from the exploitation of a technology.[1070]

Based on the case law of the Office, the approach under consideration includes cases where the subject-matter of a patented invention can be identified as a living human organism or a process which causes harm and is capable of endangering human dignity and/or life. In this case, Rules 28(1)(a), (b), (c) and 29(1) of the EPC Implementing Regulations, which relate to the rebuttable presumption test,[1071] or, in the absence of the aforementioned provisions, Art. 53(a) of the Convention, are applied. Also, in such situations, the concept of 'commercial exploitation' is interpreted broadly by including not only the potential commercial exploitation of an invention described in the patent claims, but also the steps for its creation and development.[1072]

The second of the two above-mentioned groups, in which Rule 29(2) of the EPC Implementing Regulations is interpreted and applied, is illustrated by the *Breast and Ovarian Cancer/UNIVERSITY OF UTAH* case.[1073] In this case, the opponents to the granting of a patent based on Art. 53(a) of the Convention stated that the applicant had not provided any evidence of

1069 See '1.4.1. Tests for Application of Article 53(a) of the European Patent Convention'.
1070 *Stem Cells/WARF* (n 80), para 55.
1071 For more information, see '1.4. European Patent Office Case Law on Article 53(a) of the European Patent Convention'.
1072 See '1.4.3. The Concept and Scope of the Term 'Commercial Exploitation''.
1073 For more information, see '1.4. European Patent Office Case Law on Article 53(a) of the European Patent Convention'.

informed consent obtained from the donors of the cells.[1074] Notwithstanding the fact that in the present case the Board accepted the view that the requirement for consent of a donor was fundamental in medical research, it stated that the Convention did not contain any norm requiring the patent applicant to submit a consent form or a benefit-sharing agreement.[1075] The EPO Board of Appeal found that the EPC did not impose an obligation to analyse the actions taken before and after the granting of a patent.[1076] Therefore, in assessing the commercial exploitation of the invention, it did not go beyond the scope of the filed patent application and did not examine the appropriateness of the consent of a donor.

Although, from the standpoint of the Western legal tradition discussed in this research, human rights are an important part of each legal system within this tradition, the case law of the EPO Divisions shows that the Office understands the limited nature of patent law and uses this approach to apply and interpret both Art. 53(a) EPC and other related legal provisions. Therefore, in assessing the commercial exploitation of an invention on the basis of Rule 29(2) of the EPC Implementing Regulations, the scope of the effect of European patent law is rather narrow: it is considered that patent law does not have to deal with the creation, development and later exploitation of a particular invention. Even recognising the importance of human rights, but being unable to ensure and control all aspects of their protection, the European patent system, as a part of the Western legal tradition, leaves it to national or EU institutions, which, within the area of their competence, must ensure that these rights are given adequate protection. Therefore, if an invention covered by the claims of a patent application falls within the said rule, no further tests are needed to assess the commercial exploitation of an invention with regard to *ordre public* and/or morality. This means that, as in the situation where the utilitarian weighing test is applied, the concept 'commercial exploitation' is construed narrowly in this case, because the provision in question explicitly states that the granting of patents for such inventions in the European patent system is acceptable.

However, such separation between these approaches should not be considered as completely immutable. Although the Western legal tradition gives particular importance to certain values, of which human life and dignity are the most prominent in the 21st century, the legal systems belonging to

1074 *Breast and Ovarian Cancer/UNIVERSITY OF UTAH* (n 22), para 47.
1075 ibid para 48-49.
1076 ibid para 48.

this tradition not only rely on the above-mentioned values when making decisions, but also take into account the facts of reality and its changes. For this reason, in the European patent system, the cases in which any one of the above-mentioned approaches is invoked in the decision-making process are not exhaustive, and their application may change in the light of scientific and technological advancement. This means that knowledge stemming from the biomedical sciences about the surrounding environment, its objects and ongoing processes will influence the decisions of European patent law, belonging to the Western legal tradition.

As discussed in this study,[1077] the natural sciences, including the biomedical sciences, can be perceived as a phenomenon embracing both cumulative and non-cumulative development. This reveals the existence of tradition and innovation alongside each other in these fields of science. Despite the existing aspiration in the natural sciences, including the biomedical sciences, to present the most accurate and realistic knowledge through cumulative development, the knowledge may radically change over time. Also, the natural sciences, including the biomedical sciences, can be influenced by the scientific community and the decisions of its dominant views on the surrounding environment and its processes.

Although patents form only a very small part of the whole regulation on science and technology, it is likely that the granting or rejecting of this exclusive right may affect the decisions of the scientific community on further research in the field of biomedical sciences. The scholarly literature concurs that there is a causal link between the granting of patents and the development of innovations in the field of biomedical sciences.[1078] Therefore, a refusal to grant an exclusive right to an invention may lead

1077 See '2.2. The Concept and Significance of the Biomedical Sciences as a Tradition'.

1078 van Zimmeren, 'Towards a New Patent Paradigm in the Biomedical Sector? Facilitating Access, Open Innovation and Social Responsibility in Patent Law in the US, Europe and Japan' (n 523) 201 citing J.E. Bessen & M.J. Meurer (2008), Patent Failure: How Judges, Bureaucrats, and Lawyers Put Innovators at Risk, Princeton University Press, at pp. 89 and 106–9, 112–118; P. Belleflamme (2008), 'How Efficient is the Patent System? A General Appraisal and an Application to the Pharmaceutical Sector', in: A. Gosseries, A. Marciano & A. Strowel (eds), Intellectual Property and Theories of Justice, New York, Palgrave MacMillan, 210-229, at pp. 219–20; W.M. Cohen et al. (2001), 'R&D spillovers, patents and the incentives to innovate in Japan and the United States', 31 Res. Pol'y, 1349–67; A. Arora, A. Fosfuri & A. Gambardella (2001), Markets for Technology: The Economics of Innovation and Corporate Strategy, Cambridge, MIT Press; R.C. Levin et al. (1987), 'Appropriating the returns from industrial research and development', 3 Brookings Papers on

to lower investment in further research in this field, which means slower development of the biomedical sciences.

All the above discussed in this study shows that the European patent system, as part of the Western legal tradition, and biomedical sciences, as a tradition, are reacting to each other in the context of Art. 53(a) of the Convention. This interaction can be compared to the 'co-production' proposed by S. Jasanoff and discussed in this research,[1079] which can be observed in certain decisions of the EPO and the CJEU.

The case law of the above-mentioned institutions regarding the evaluation of the patentability of biotechnological inventions on the grounds of *ordre public* and/or morality cannot fully illustrate the co-production process and reflect all the discussed approaches used to interpret and apply Art. 53(a) EPC as well as the related EPC Implementing Regulations. However, the way the European patent system reacts when new knowledge emerges explaining the processes or subject-matter to which patent law has applied a rigorous deontological approach based on Rules 28(1) and 29(1) of the EPC Implementing Regulations[1080] is illustrated by the EPO *Use of embryos/WARF*[1081] and *Human pluripotent progenitor stem cells/PROGENITOR LABS*[1082] cases as well as the CJEU *Oliver Brüstle v Greenpeace e.V.*[1083] case together with the *International Stem Cell Corporation*[1084] case.

The analysis and comparison of the decisions in *Oliver Brüstle v Greenpeace e.V.* and *International Stem Cell Corporation* show how gaining more knowledge on the inability of non-fertilised human cells to multiply and develop into a complete human body after they are stimulated by parthenogenesis clarified that such an object cannot be equated to a human embryo. The elimination of certain subject-matter from the scope of the category 'human embryo' based on the latest knowledge of biomedical sciences

---

Economic Activity, 783-831 and E. Mansfield (1986), 'Patents and Innovation: An Empirical Study', 32 Management Science, 173–81.

1079 See '6.2. The Concept of 'Co-Production' in the Context of Article 53(a) of the European Patent Convention'.

1080 These provisions were applied in the EPO case law. The CJEU, in the *Oliver Brüstle v Greenpeace eV* (n 90) and *International Stem Cell Corporation v Comptroller General of Patents, Designs and Trade Marks* (n 90) cases, applied Art. 5(1) and Art. 6(2)(c) (Biotech Directive, Articles 5(1) and 6(2)(c)).

1081 *Use of embryos/WARF* (n 80).

1082 *Human pluripotent progenitor stem cells/PROGENITOR LABS* (n 81).

1083 *Oliver Brüstle v Greenpeace eV* (n 90).

1084 *International Stem Cell Corporation v Comptroller General of Patents, Designs and Trade Marks* (n 90).

allows European patent law to cease applying the deontological perspective, which establishes that the human body in its various stages of formation and development is not patentable, and the tests, standards and broad interpretation of the term 'commercial exploitation' related to it. The latter change essentially means that an unfertilised human cell, which is induced by parthenogenesis to multiply and develop, can be regarded as an element isolated from the human body. Thus, with regard to the latter, presumably, it becomes possible to apply Rule 29(2) of the EPC Implementing Regulations, which establishes what is patentable. For this reason, the possibility of obtaining a patent encompassing an unfertilised human ovum which is induced to multiply and develop by way of parthenogenesis increases.

Similarly, the EPO Board of Appeal, on the basis of the *International Stem Cell Corporation* case, changed its approach to an invention and in the *Human pluripotent progenitor stem cells/PROGENITOR LABS* case, after approving a patent application, granted this exclusive right.[1085] Thus, the above-discussed decision of the CJEU opened up a broader scope for patenting of inventions which, according to Art. 53(a) EPC and Rule 28(c)[1086] of the EPC Implementing Regulations, were not eligible for such a grant. The change visible in the *Oliver Brüstle v Greenpeace e.V.* and *International Stem Cell Corporation* cases as well as in the *Human pluripotent progenitor stem cells/PROGENITOR LABS* decision allow to consider the possible trends of the interaction between European patent law, as a part of the Western legal tradition, and biomedical science, as a tradition, in the context of Art. 53(a) EPC. These trends determine the interpretation and application of Art. 53(a) and the EPC Implementing Rules related to it.

The above-discussed case law of the EPO and the Court of Justice reveals the changes in the interpretation and application of Art. 53(a) of the Convention that may result from the interaction between European patent law and the biomedical sciences, where the commercial exploitation of an invention is evaluated from the point of view of deontological ethics. As discussed earlier, this philosophy is employed when assessing two types of inventions: (1) inventions which include elements isolated from the human

1085 According to the publicly available data, the patent application (No. 06808713.9) analysed in *Human pluripotent progenitor stem cells/PROGENITOR LABS* (n 81) was also satisfied (Patent No. EP1974032, 'Method for identifying a modulator of a cell signalling') and the patent was granted (European Patent Office, European patent register <https://register.epo.org/advancedSearch?lng=en&clnrefer=yes> accessed 30 May 2023).

1086 Since 1 July 2017: EPC Implementing Regulations, r 28(1)(c).

body and (2) inventions which include a living human organism in its various stages of development. In the first case, the granting of a patent in the European patent system is feasible; in the second, it is not possible to obtain this exclusive right. In both cases, the decision to assign an invention to one of these two objects depends on the knowledge of the biomedical sciences.

In cases where normal scientific knowledge is sufficient to describe an object of an invention, it easily falls into one of the two above-mentioned categories. In the cases discussed in this study, in which biotechnological inventions involving elements isolated from the human body were analysed, there were no major doubts as to what the patent claims encompass, and therefore patents were granted in accordance with Rule 29(2) of the EPC Implementing Regulations. However, according to the case law of the Office, in certain situations an invention and its technical aspects may be sufficiently clear from the point of view of a particular field of science, but may nevertheless, based on Art. 53(a) EPC and the EPC Implementing Regulations related to it, be recognised as unpatentable because they fall under the exceptions. These cases are illustrated by the decision of the EPO Board of Appeal of 24 January 2013,[1087] in which the technical aspects of a non-biotechnological invention were quite clear, but because of the fact that the subject-matter of the patent claims included a human being, based on Art. 53(a) EPC and Rule 29(1) of the EPC Implementing Regulations,[1088] the patent application was rejected.

However, not all investigations in the field of biomedical sciences can be considered as 'normal science': the existing knowledge of the biomedical sciences cannot always fully explain the inventions for which patents are sought under the European patent system. In the absence of a possibility to perform a comprehensive analysis of inventions that fall into one of the two types, based on the knowledge of the prevailing scientific paradigm, the European patent system treats such inventions with caution. Such a deficiency in the knowledge of the biomedical sciences can lead to a broad interpretation of the categories important in the Western legal tradition, such as 'human embryo', or, when applying and interpreting Art. 53(a) EPC, essential to European patent law, such as 'commercial exploitation'.

1087 This decision does not have a header: *no headword,* Decision of 24 January 2013, Case No. T 0149/11 (n 54).

1088 The decision mentions r 28 and r 29 of the EPC Implementing Rules, but according to the content of the invention, it can be concluded that r 29(1) is most appropriate in the present case (ibid para 2.6).

The most prominent example of such a situation is the *Use of embryos/WARF* decision,[1089] in which the knowledge concerning human embryos provided by the biomedical sciences and its uncertainties, as well as the importance of human life and dignity in the Western legal tradition, led to a broad interpretation of the patent application. As a result, in assessing the commercial exploitation of the invention with regard to *ordre public* and/or morality, not only the patent claims were analysed, but also aspects that are beyond the scope of the application in question and include the creation of the invention. This shows that the limitations of knowledge in the biomedical sciences can lead to the rejection of a patent application because, in case of a doubt concerning the subject-matter of an invention in question, such as the status of a human embryo, this encourages assigning the latter to a living human organism.

European patent law also affects the development of the biomedical sciences. Despite all the controversies on the impact of patents on innovation in different fields of science and technology, the positive impact of these exclusive rights on innovation in the sphere of biomedical sciences is recognised. Therefore, it is to be considered that European patent law, by issuing these intellectual property rights, has a positive effect on the further development of the biomedical sciences and the emergence of new knowledge, whereas by rejecting a patent application, such as in the *Use of embryos/WARF* case, it hampers progress in this field of science.

On the other hand, the rejection of a patent application does not take away the opportunity to perform even controversial research, and, under favourable regulation, the emergence of new scientific knowledge remains possible. Even in the absence of a patent, but with continuing research, it may also be possible that a change in attitude with regard to inventions comprising a living human body will occur in the European patent system. In addition, the situation in question can encourage participants in a specific field of science to find new solutions that can produce alternative inventions and promote new knowledge in science.[1090] All the above actions can help in overcoming the crisis of the prevailing scientific paradigm, which in this study manifests itself in uncertainty surrounding the assessment of the commercial exploitation of an invention with regard to Art. 53(a) EPC,

1089 *Use of embryos/WARF* (n 80).

1090 It is claimed that the stem cell industry is moving towards using stem cells without destroying human embryos (Enrico Bonadio, 'Patents and Morality in Europe' (n 269) 167).

by offering a solution which falls within the scope of 'normal science' or a solution allowing for the emergence of a new paradigm of science. This may encourage the European patent system to shift from a deontological point of view, strictly indicating the non-patentable subject-matter,[1091] to an approach, based on the same branch of ethics, determining when the granting of a patent can be considered acceptable.[1092]

When assessing the commercial exploitation of an invention under Art. 53(a) EPC from the utilitarian perspective, the changes in the interaction between European patent law and the biomedical sciences are not as significant as in the case of the deontological point of view. In the EPO case law, a weighing test based on utilitarianism[1093] is selected in situations where an invention described in the patent claims concerns animals, plants or processes related to them. The analysis of the EPO case law reveals that, in fulfilling the requirement of the above-mentioned subject-matter of a patent, the granting of this exclusive right is governed by two criteria: likely benefit and damage.

Decisions of the Office reveal that, in the case of inventions encompassing animals in their claims, the benefit is associated with the curing of or research into human diseases, for example, cancer. In the case of this benefit, the harm, i.e. animal suffering,[1094] can be tolerated and the patent is granted. However, suffering of animals is unacceptable when the invention performs a less important, albeit useful, function, for example, treating hair loss. In such cases, the suffering is considered to be more significant than the potential benefits.[1095]

1091 EPC Implementing Regulations, r 28(1)(a), (b) and (c).

1092 ibid r 29(2).

1093 This can be: (1) the test indicated in r 28(1)(d) of the EPC Implementing Regulations, which is applied by weighing the suffering of animals against substantial medical benefit to man or animal, or (2) a test arising from the EPO case law requiring the suffering of animals and potential risks to the environment to be weighed against the arguments regarding the benefit this patent could bring to humanity as a whole (see e.g. *Transgenic animals/HARVARD* (n 80), paras 6.1 and 10.1).

1094 Animal suffering, as a potential damage, is analysed in almost all the decisions of the EPO case law: *Gene trap/ARTEMIS* (n 81); *Non-invasive localization/LELAND STANFORD* (n 81).

1095 Jasanoff, *Designs on Nature: Science and Democracy in Europe and the United States* (n 83) 219. See also Bagley, 'Patent First, Ask Questions Later: Morality and Biotechnology in Patent Law' (n 92) 521; Bently and Sherman, *Intellectual Property Law* (n 270) 455-456.

In cases where, according to Art. 53(a) of the Convention, the patenting of plant-related inventions is being decided on, the development of plants with higher nutritional value that can help to overcome the shortage of food in the world[1096] and the creation of herbicide-resistant plants and seeds[1097] can be regarded as the benefits. In the case of the application of the weighing test based on utilitarianism for these inventions, the harm is regarded as such situations where the commercial exploitation of an invention can seriously harm the environment,[1098] cause negative consequences for farmers in developing countries,[1099] or reduce the number of plant species in the world.[1100]

In the above-discussed cases, it is precisely the result of the weighing of the two criteria, i.e. the benefit and harm, which determines whether a patent is granted for a particular invention in the European patent system. The content of these criteria is determined with the help of the knowledge of the biomedical sciences; therefore, their completeness and validity will be relevant for the granting a patent for a particular invention. In the case of the weighing test, in order to reject an application for a patent covering plants or processes related to them, there must be 'an actual damage and/or disadvantage',[1101] whereas for inventions encompassing animals or processes related to them, both harm and benefit must reach the level of 'likelihood'.[1102]

Based on the case law on the application of the weighing test, it can be assumed that, in order to reject a patent application, the opponents will try to provide the most comprehensive knowledge of the biomedical sciences about the harm caused by the commercial exploitation of an invention, while the applicants will emphasise the knowledge revealing its benefits. This can also encourage the creation of the least harmful possible inventions. In order to perform the above-mentioned activities, research in the field of biomedical sciences is needed. Thus, in the case of a weighing test, both the grant of a patent and the rejection of its application can have

1096 *Lubrizol Genetics Inc.* (n 84), para 9.1.4.
1097 European Patent No. 0242236, 'Plant cells resistant to glutamine synthetase inhibitors, made by genetic engineering', application submitted on 21 January 1987.
1098 *Plant cells/PLANT GENETIC SYSTEMS* (n 22), para 18.5.
1099 *Lubrizol Genetics Inc.* (n 84), para 9.1.3.
1100 ibid.
1101 *Plant cells/PLANT GENETIC SYSTEMS* (n 22), para 18.8.
1102 E.g. *Transgenic animals/HARVARD* (n 80), para 9.7; *Non-invasive localization/LELAND STANFORD* (n 81), para 22.

a positive effect on the development of the biomedical sciences and the emergence of new knowledge, which can subsequently lead to a change in the approach of European patent law to the surrounding environment and the processes taking place therein, and also with regard to the assessment of new biotechnological inventions.

In the light of everything discussed above, it can be concluded that, due to the interaction between European patent law, as a part of the Western legal tradition, and the biomedical sciences, as a tradition, changes in the evaluation of the commercial exploitation of an invention with regard to Art. 53(a) EPC are possible in both of these traditions. The approach of the European patent system to the patenting of specific inventions on the basis of this provision can be changed by new biomedical knowledge about the surrounding environment, allowing assessment in a different way of the impact of the commercial exploitation of a certain invention on the values important for the Western legal tradition. Meanwhile, for the development of the biomedical sciences, whose purpose is to deepen and expand knowledge about the world, legal regulation, which, by establishing certain requirements for scientific activities, can both facilitate and complicate the research in this field of science, is important. Although, as discussed in this study, patent law constitutes only a small part of the regulatory framework of science and technology, granting or rejecting under Art. 53(a) EPC these exclusive rights for certain inventions in the field of biomedical sciences may nevertheless affect the research priorities in this sphere of science. This will influence the further development of this field of science and the emergence of new knowledge which can subsequently be used by European patent law for the evaluation of biotechnological inventions on the basis of this provision.

6.4. Preliminary Conclusion

The EPO case law with regard to the application and interpretation of Art. 53(a) EPC reveals that the European patent system, as a part of the Western legal tradition, and biomedical sciences, as a tradition, affect each other in the context of the aforementioned provision of the Convention. This interaction between these traditions can be referred to as 'co-production', which is influenced by: (1) the values protected by the Western legal tradition that are affected by the commercial exploitation of an invention; and (2) the completeness and reliability of the knowledge of the biomedical

sciences invoked for the analysis of the content of an invention. As a result of this interaction between European patent law, as a part of the Western legal tradition, and biomedical sciences, as a tradition, when assessing the commercial exploitation of inventions on the basis of *ordre public* and/or morality, changes in both of these traditions are possible.

The approach of the European patent system with regard to the patenting of specific inventions in the context of Art. 53(a) EPC may change due to new knowledge of the biomedical sciences concerning the surrounding environment, which allows a different evaluation of the impact of the commercial exploitation of an invention on the values that are important to the Western legal tradition. Meanwhile, for the development of the biomedical sciences, whose purpose is to deepen and expand knowledge about the world, legal regulation, being able to set certain requirements for scientific activity, which can both facilitate and hamper research in this field of science, is important. Although patent law constitutes only a small part of the regulatory framework of science and technology, in the context of this study, the granting or rejection of patents on the basis of Art. 53(a) EPC in relation to inventions in the field of biomedical sciences may in particular influence the further development of this field of science and the emergence of new knowledge in it.