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Jurgita Randakevičiūtė-Alpman

The Relationship between Law and Biomedical Sciences in the Context of Article 53(a) of the European Patent Convention

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MIPLC Munich Intellectual Property Law Center
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To my family and in memory of my father.

Acknowledgements

This book is based on a doctoral dissertation[1] submitted in pursuit of the degree of Doctor in Social Sciences (Law) at Vilnius University, Lithuania. In the Lithuanian context, this doctoral dissertation is exceptional because, according to the publicly available databases,[2] this is the first doctoral research in the field of patent law in Lithuania during the entire period of restoration of Independence of the Republic of Lithuania since 1990.[3] Although this book was later updated and slightly modified, as the doctoral dissertation was written for Vilnius University, its structure and research methods are still partly in line with Lithuanian academic standards.

I would like to extend my sincere gratitude to Prof. Dr. Josef Drexl LL.M. (UC Berkeley) for not only giving me the opportunity to pursue this project using the highest-class research facilities of the Max Planck Institute for Innovation and Competition, but also for his patience and confidence in my ability to write and complete this work. Despite the fact that he was not my doctoral dissertation supervisor, and despite his busy schedule, he provided me with insightful advice and support throughout the writing process and even during the defence of the doctoral dissertation at Vilnius University.

1 Doctoral dissertation 'The Relationship between Law and Biomedical Sciences in the Context of Article 53(a) of the European Patent Convention' (in Lithuanian: *Teisės ir biomedicinos mokslų santykis Europos patentų konvencijos 53 (a) straipsnio kontekste*) (supervisor: Prof. Dr. Jevgenij Machovenko, Vilnius University).

2 A search for dissertations in Lithuania on the topic of patent law conducted through: (1) Lithuanian Academic Electronic Library, Lithuanian Electronic Theses and Dissertations (ETD) Database <https://aleph.library.lt/F?func=option-update-lng&P_CON_LNG=ENG> accessed 30 May 2023 (search criteria: (1) Basic search: (i) (a) Word or phrase: 'išradim', (b) Field to search: 'Title' and (c) Type of document: 'Dissertations'; and (ii) (a) Word or phrase: 'patent', (b) Field to search: 'Title' and (c) Type of document: 'Dissertations'; (2) Multi-field Search: (a) Title: 'išradim', (b) Title: 'patent' and (c) Document type: 'Dissertations'; (3) Advanced search: (a) Word or phrase: 'išradim' and Field to search: 'Title', (b) Word or phrase: 'patent' and Field to search: 'Title', (c) Document type: 'Dissertations' and (d) Words adjacent?: 'No'); (2) Research Council of Lithuania, Database of dissertation defences <https://db.lmt.lt/lt/perziura/disertacijos/d-db.html> accessed 30 May 2023 (search criteria: (1) search word 'patent' in the search field and (2) search word 'išradim' in the search field).

3 On 11 March 1990, the Supreme Council of the Republic of Lithuania adopted an Act on the Restoration of the Independent State of Lithuania.

I am deeply grateful to my doctoral dissertation supervisor Prof. Dr. Jevgenij Machovenko and the members of my doctoral dissertation defence committee: Prof. Dr. Vytautas Mizaras LL.M. (Chairperson), Prof. Dr. Toma Birmontienė, Prof. Dr. Ramūnas Birštonas, Prof. Dr. Josef Drexl LL.M. (UC Berkeley), Assoc. Prof. Dr. Giedrė Lastauskienė. Further, I wish to thank my former supervisors and colleagues at the law firm, in particular Assoc. Prof. Dr. Jaunius Gumbis, Rūta Karpičiūtė, Vitoldas Kumpa, Jurgita Petkutė-Gurienė, Gediminas Ramanauskas, Rimantė Tamulytė and Vilija Vaitkutė Pavan.

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Abbreviations

Agreement on a Unified Patent Court	Agreement on a Unified Patent Court, OJ C 175, 20.6.2013, p. 1
Biotech Directive, Directive	Directive 98/44/EC of the European Parliament and of the Council of 6 July 1998 on the legal protection of biotechnological inventions, OJ, 1998 L 213, p. 13
CJEU, The Court of Justice	Court of Justice of the European Union
Declaration	Universal Declaration of Human Rights (adopted 10 December 1948) UNGA Res 217 A(III)
EEC	European Economic Community
EPC 1973	Convention on the Grant of European Patents of 5 October 1973 (European Patent Convention)
EPC, Convention	Convention on the Grant of European Patents of 5 October 1973, as revised on 17 December 1991 and on 29 November 2000 (European Patent Convention), [2001] OJ EPO 55.
EPC Implementing Regulations	12 December 2002 Implementing Regulations to the European Patent Convention, [2003] OJ EPO, p. 57
EPO, Office	European Patent Office
EPO Board(-s) of Appeal, Board(-s), EPO Divisions	European Patent Office's Enlarged Board of Appeal and Boards of Appeal
EPO case law	Case law of the European Patent Office's Opposition Division, Boards of Appeal and Enlarged Board of Appeal
EPO Opposition Division	Opposition Division of the European Patent Office
EPOrg	European Patent Organisation
EU, Union	European Union
EU Treaty	Consolidated version of the Treaty on the European Union, OJ, 2016 C 202, p. 13
Guidelines for Examination, Guidelines	Guidelines for Examination in the European Patent Office

ICCPR	International Covenant on Civil and Political Rights (adopted 16 December 1966, entered into force 23 March 1976) 999 UNTS 171
OECD	Organisation for Economic Co-operation and Development
Order of 2012	16 October 2012 Order 'On the Confirmation of the List of Study Branches Comprising Science Fields' (*Dėl mokslo krypčių patvirtinimo*). *Valstybės žinios (Official Gazette)*, 2012, No. V-1457
Order of 2019	6 February 2019 Order 'On the on the adoption of the Classifications of the Fields of Science and of the Fields of Art' (*Dėl Mokslo krypčių ir Meno krypčių klasifikatorių patvirtinimo*). *Valstybės žinios (Official Gazette)*, 2019, No. V-93
Regulation 1257/2012	Regulation (EU) No 1257/2012 of the European Parliament and of the Council of 17 December 2012 implementing enhanced cooperation in the area of the creation of unitary patent protection, OJ, 2012 L 361, p. 208
Regulation 1260/2012	Council Regulation (EU) No 1260/2012 of 17 December 2012 implementing enhanced cooperation in the area of the creation of unitary patent protection with regard to the applicable translation arrangements, OJ, 2012 L 361, p. 89
Strasbourg Convention	Convention on the Unification of Certain Points of Substantive Law on Patents for Invention of 27 November 1963 (ETS No. 047) (adopted 27 November 1963)
TRIPS Agreement	Agreement on Trade-Related Aspects of Intellectual Property Rights (Marrakesh, Morocco, 15 April 1994), Marrakesh Agreement Establishing the World Trade Organization, Annex 1C, THE LEGAL TEXTS: THE RESULTS OF THE URUGUAY ROUND OF MULTILATERAL TRADE NEGOTIATIONS 321 (1999), 1869 U.N.T.S. 299, 33 I.L.M. 1197 (1994)
Unitary Patent	European patent with unitary effect as defined in Art. 2(c) of Regulation (EU) No 1257/2012 of the European Parliament and of the Council of 17 December 2012 implementing enhanced cooperation in the area of the creation of unitary patent protection, OJ, 2012 L 361, p. 208
UPC	Unified Patent Court
U.S.	United States of America
WTO	World Trade Organization

Introduction

The problem, relevance and novelty of the research. Scientific progress has a growing influence on different fields of reality, including law.[4] For this reason, judges, when resolving disputes, and legislators, when drafting new legislation, need to consider not only strictly legal issues, but also those that are closely related to the various branches of science and technology, and regulate objects or processes comprehensible to only a small circle of specialists in a particular field.

For a long time, it was possible to perform the aforementioned actions by way of employing existing legal regulation and established legal categories. However, as scientific and technological progress makes situations increasingly complex, the question arises as to whether the ability of the contemporary legal system to respond to this advancement can be considered sufficient.[5] One of the legal areas more and more challenged by scientific progress is patent law.[6] Despite the fact that patent law covers a narrow part of the legal rules relating to scientific research and new technologies, due to the potential economic benefits that patents are able to provide – thus

4 See e.g. Sheila Jasanoff, 'The Idiom of co-production' in Sheila Jasanoff (ed), *States of Knowledge. The co-production of science and social order* (Routledge 2004) 1-12, 2; Johannes Somsen, *Regulating Modern Biotechnology in a Global Risk Society: Challenges for Science, Law and Society* (Amsterdam University Press 2005) 8; Oliver Mills, *Biotechnological Inventions: Moral Restraints and Patent Law* (Ashgate 2010) 1-2; Thérèse Murphy and Gearóid Ó Cuinn, 'Works in Progress: New Technologies and the European Court of Human Rights' (2010) 10 Human Rights Law Review 601; Carlos María Romeo Casabona, 'Criminal Policy and Legislative Techniques in Criminal Law on Biotechnology' (2011) 82 Revue internationale de droit penal 83, 83; Alex Faulkner, Bettina Lange and Christopher Lawless, 'Introduction: Material Worlds: Intersections of Law, Science, Technology and Society' (2012) 39 Journal of Law and Society 1, 1-2.

5 See e.g. Roger Brownsword, 'Lost in Translation: Legality, Regulatory Margins, and Technological Management' (2011) 26 Berkeley Technology Law Journal 1322, 1325. See also Jens Kersten, *Das Klonen von Menschen. Eine verfassungs-, europa- und völkerrechtliche Kritik* (Mohr Siebeck 2004) 30.

6 See e.g. Mills, *Biotechnological Inventions: Moral Restraints and Patent Law* (n 4) 2; Åsa Hellstadius, *A Quest for Clarity: Reconstructing Standards for the Patent Law Morality Exclusion* (Stockholm University 2015) 54.

incentivising the creation of new inventions or the improvement of existing inventions – it is considered to have a significant impact on innovation.[7]

According to international agreements and the provisions of certain national patent laws, patents cannot be granted in respect of inventions whose exploitation is not in accordance with *ordre public* or morality.[8] The European Patent Convention (the 'EPC' or 'Convention')[9] is not an exception, as its Article 53(a) stipulates that patents are not to be granted for inventions the commercial exploitation of which would be contrary to

7 See e.g. Paul Braendli, 'The Future of the European Patent System' (1995) 26 International Review of Intellectual Property and Competition Law 813, 820; Dominique Guellec and Bruno van Pottelsberghe de la Potterie, *The Economics of the European Patent System* (OUP 2007) 66-74; Hellstadius, *A Quest for Clarity: Reconstructing Standards for the Patent Law Morality Exclusion* (n 6) 81.

8 See e.g. Agreement on Trade-Related Aspects of Intellectual Property Rights (Marrakesh, Morocco, 15 April 1994), Marrakesh Agreement Establishing the World Trade Organization, Annex 1C, THE LEGAL TEXTS: THE RESULTS OF THE URUGUAY ROUND OF MULTILATERAL TRADE NEGOTIATIONS 321 (1999), 1869 U.N.T.S. 299, 33 I.L.M. 1197 (1994) (TRIPS Agreement), Art. 27 para 2: 'Members may exclude from patentability inventions, the prevention within their territory of the commercial exploitation of which is necessary to protect *ordre public* or morality, including to protect human, animal or plant life or health or to avoid serious prejudice to the environment, provided that such exclusion is not made merely because the exploitation is prohibited by their law.'; the German Patent Act as published on 16 December 1980 (*Patentgesetz*) (Federal Law Gazette 1981 I p. 1), as last amended by Article 4 of the Act of 8 October 2017 (Federal Law Gazette I p. 3546), s 2 sub-s (1): 'No patents shall be granted for inventions the commercial exploitation of which would be contrary to "ordre public" or morality; such exploitation shall not be deemed to be so contrary merely because it is prohibited by law or regulation' (in German: '*Für Erfindungen, deren gewerbliche Verwertung gegen die öffentliche Ordnung oder die guten Sitten verstoßen würde, werden keine Patente erteilt; ein solcher Verstoß kann nicht allein aus der Tatsache hergeleitet werden, dass die Verwertung durch Gesetz oder Verwaltungsvorschrift verboten ist*'); Patent Law of the Republic of Lithuania (*Lietuvos Respublikos patentų įstatymas*). *Valstybės žinios (Official Gazette)*, 1994, No. 8-120, art 5 pt 1 point 3: 'Patents shall not be granted for: […] 3) inventions the commercial exploitation of which would be contrary to public interest, principles of morality and humanity. Decisions not to grant patents may not be taken on the sole ground that the use of such inventions is prohibited by law or regulation' (in Lithuanian: '*1. Patentai neišduodami:* [...] *3) išradimams, kurių komercinis panaudojimas prieštarautų visuomenės interesams, moralės ir humaniškumo principams. Sprendimai neišduoti patentų negali būti priimami vien dėl to, kad naudoti tokius išradimus draudžiama pagal įstatymus ar kitus teisės aktus*').

9 Convention on the Grant of European Patents of 5 October 1973, as revised on 17 December 1991 and on 29 November 2000 (European Patent Convention), [2001] OJ EPO 55: <http://www.epo.org/law-practice/legal-texts/epc.html> accessed 30 May 2023 (EPC).

ordre public[10] or morality.[11] This means that, even if all patentability requirements[12] set out in Art. 52(1) EPC are fulfilled, a patent may still not be granted if an invention falls under the exception of Art. 53(a) EPC. The exception in question is particularly relevant for biotechnological inventions, the patentability of which, compared to other scientific and technological inventions, is frequently disputed on the basis of the aforementioned provision,[13] and which form the bulk of the case law of the European Patent Office (the 'EPO' or 'Office') on the interpretation and application of the provision of the Convention analysed in this study.

Although currently there are not many decisions taken by the EPO regarding the legal protection of inventions under Art. 53(a) EPC, the existing ones differ among themselves, as there is no consensus on the content of the categories 'morality' and '*ordre public*' and their relationship, as well as on the standards and tests that would be suitable for assessing the commercial exploitation of inventions in accordance of this provision of the Convention.[14] Also, due to the rapid development of science and technology, the knowledge which these fields provide for assessing the commercial exploitation of inventions is rapidly changing. Therefore, the content of Art. 53(a) EPC is unclear, and the interpretation and application of this provision to inventions, in particular those in the field of biotechnology, are unclear and difficult to predict.

All this is a *problem*, because the protection of legitimate expectations, legal certainty and legal security is not guaranteed for those whose interests are affected by the granting of patents for biotechnological inventions. This situation adversely affects the competitiveness of business and research organisations, the development of their activities, as well as the public's access to the results of scientific progress, which can be crucial for the health and well-being of individuals. This reduces not only support for granting exclusive rights to specific inventions, but also confidence in the

10 This term in each of the three official languages of the European Patent Convention is used as follows: (1) *ordre public* (in the English text); (2) *gute Sitten* (in the German text); (3) *ordre public* (in the French text) (EPC).

11 EPC, Art. 53(a).

12 ibid Art. 52(1): 'patents shall be granted for any inventions, provided that they are new, involve an inventive step and are susceptible of industrial application'.

13 Justine Pila and Paul Torremans, *European Intellectual Property Law* (OUP 2016) 156-157.

14 For more details see '1.4. European Patent Office Case Law on Article 53(a) of the European Patent Convention'.

benefits of the entire patent system and its transparency in the eyes of those who create, develop and use inventions.

In this context, it is not surprising that the patenting of biotechnological inventions has sparked much debate all around the world. However, the controversy in the European patent system is considered to be the most prominent.[15] Non-governmental organisations and individual activists, including environmentalists, patients, animal rights defenders and scientists,[16] have become involved in this process, and protests or other forms of unrest have occurred.[17]

The search for the solution to this problem is complicated by the wording of the aforementioned EPC provision, which reveals the position of the European patent system[18] in relation to the national legal systems. The second part of the sentence of Art. 53(a) EPC states that '[commercial] exploitation shall not be deemed to be so contrary merely because it is prohibited by law or regulation in some or all of the Contracting States'.[19] This provision indicates, that, according to Art. 53(a) EPC, the granting or refusal of a European patent does not depend on the national legal systems of the Contracting States (also the 'Member States') of the European Patent Organisation (the 'EPOrg'),[20] because a prohibition in one or more legal systems of the Member States is not a sufficient precondition to regard the commercial exploitation of an invention as being against *ordre public*

15 Larissa Gruszow, 'Types of invention in the field of genetic engineering, arising in the practice of the European Patent Office' in Sigrid Sterckx (ed) *Biotechnology, Patents and Morality* (2nd edn, Ashgate Publishing 2000) 207-216, 207.

16 Shobita Parthasarathy and Alexis Walker, 'Observing the Patent System in Social and Political Perspective: A Case Study of Europe' in Ruth L Okediji and Margo A Bagley (eds), *Patent Law in Global Perspective* (OUP 2014) 321-343, 332.

17 See e.g. Sonja Schubert, 'Europe halts decisions on stem-cell patents' (2005) 435 Nature 720, 720-721; Quirin Schiermeier, 'Germany challenges human stem cell patent awarded 'by mistake'' (2000) 404 Nature 3, 3; Shobita Parthasarathy, 'Co-producing knowledge and political legitimacy. Comparing life form patent controversies in Europe and the United States' in Stephen Hilgartner, Clark Miller and Rob Hagendijk (eds) *Science and Democracy. Making knowledge and making power in the biosciences and beyond* (Routledge 2015) 74-93, 80.

18 In this study, the term 'European patent system' is used to describe the system established on the basis of the EPC.

19 EPC, Art. 53(a).

20 Derk Visser, *The Annotated European Patent Convention 1973* (H Tel Publisher BV 2006) 61.

and/or morality.[21] This position is also confirmed by the case law of the Boards of Appeal of the European Patent Office (the 'EPO Board(-s) of Appeal', 'Board(-s)' or 'EPO Divisions'), which indicates that '[t]he content of national legislation does not form part of the legal order established by the EPC and is thus irrelevant to the issue of how the EPC should be interpreted'.[22] Hence, the fact that, according to the legal rules of the Contracting States, an exploitation of an invention is allowed or prohibited is not *per se* a sufficient criterion for the granting of exclusive rights in an invention under Art. 53(a) EPC.

All of these considerations allow agreement with a widely recognised position in legal doctrine that, at least for now, the European patent system, built on the basis of the EPC, is an autonomous legal order,[23] formally

21 Deryck Beyleveld and Roger Brownsword, *Mice, Morality and Patents: The Oncomouse Application and Article 53(a) of the European Patent Convention* (Intellectual Property Institute 1993) 74.

22 Board of Appeal (European Patent Office), *Breast and Ovarian Cancer/UNIVERSITY OF UTAH,* Decision of 27 September 2007, Case No. T 1213/05, EP:BA:2007:T121305.20070927, para 55. EPO's Board of Appeal also stated that 'The second half-sentence of Art. 53(a) EPC contains the qualification "that the exploitation shall not be deemed to be so contrary merely because it is prohibited by law or regulation in some or all of the Contracting States". This qualification makes clear that the assessment of whether or not a particular subject-matter is to be considered contrary to either "ordre public" or morality is not dependent upon any national laws or regulations. Conversely and by the same token, the Board is of the opinion that a particular subject-matter shall not automatically be regarded as complying with the requirements of Art. 53(a) EPC merely because its exploitation is permitted in some or all of the Contracting States. Thus, approval or disapproval of the exploitation by national law(s) or regulation(s) does not constitute per se a sufficient criterion for the purposes of examination under Art. 53(a) EPC.' (Board of Appeal (European Patent Office), *Plant cells/PLANT GENETIC SYSTEMS*, Decision of 21 February 1995, Case No. T 0356/93, EP:BA:1995:T035693.19950221, para 7).

23 European Patent Office, Information about the European Patent Convention <https://www.epo.org/law-practice/legal-texts.html> accessed 30 May 2023 ('The European Patent Convention provides an autonomous legal system for the granting of European patents via a single, harmonised procedure before the EPO.'). See also *Breast and Ovarian Cancer/UNIVERSITY OF UTAH* (n 22), para 55; Opposition Division (European Patent Office), *Edinburgh Patent*, Decision of 21 July 2003, Application No. 94913174.2, para 2.5.2, 19-20; Ingrid Schneider, 'Governing the patent system in Europe: the EPO's supranational autonomy and its need for a regulatory perspective' (2009) 36 Science and Public Policy 619, 619; Jens Hemmingsen Schovsbo, Thomas Riis and Clement Salung Petersen, 'The Unified Patent Court: Pros and Cons of Specialization – Is There a Light at the End of the Tunnel (Vision)?' (2015) 46 International Review of Intellectual Property and Competition Law 271, 272; Board of Appeal (European Patent Office), *Culturing stem cells/TECHNION*, Decision of

independent of its Contracting States' national legal systems. Also, as will be demonstrated in this research, it is independent from the legal order of the European Union (the 'Union' or 'EU'), including its institutions: the European Parliament and the Court of Justice of the European Union (the 'CJEU' or 'Court of Justice').[24] This distinguishes the European patent system from other major patent systems of the world, e.g. the patent system of the United States of America (the 'U.S.'). While the activities of the United States Patent and Trademark Office are regulated by the U.S. Congress and federal court system, the politics and operations of the EPOrg depend on the EPO and its Administrative Council comprised of representatives of the Contracting States.[25] Thus, currently, the EPOrg has significant power to shape the patent policy, as well as to define the 'European public interest, and the meaning of Europe itself'.[26] Hence, when assessing the possibility of granting a European patent for a particular invention under Art. 53(a) EPC, the determination of the content and the application of the said legal norm in this legal system should take place autonomously.

On the other hand, the Opposition Division of the European Patent Office (the 'EPO Opposition Division') has indicated in its case law that the concepts '*ordre public*' and 'morality' have to be evaluated 'primarily by looking at laws or regulations which are common to most of the European countries'.[27] The desire for unity is also reflected in the fact that,

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4 February 2014, Case No. T 2221/10, ECLI:EP:BA:2014:T222110.20140204, para 38. However, legal literature indicates that, under international public law, the structure and the situation of the EPOrg provide the circumstances for autonomy of the legal system of this institution. Despite that, the system in question is not completely 'impermeable' because, according to Art. 125 EPC, 'in the absence of procedural provisions in this Convention, the European Patent Office shall take into account the principles of procedural law generally recognised in the Contracting States'. Case law of the EPO Boards of Appeal also indicates that in certain cases the EPOrg Contracting States' nationally recognised principles may be consulted (Agnieszka Kupzok, 'Human rights in the case law of EPO Boards of Appeal' in Christophe Geiger (ed), *Research Handbook on Human Rights and Intellectual Property Rights* (Edward Elgar 2015) 311–326, 313-314).

24 For more on the relationship between the European patent system and the EU legal order, see '1.2. The Relationship between Article 53(a) of the European Patent Convention and the Biotechnology Directive'.

25 Parthasarathy and Walker, 'Observing the Patent System in Social and Political Perspective: A Case Study of Europe' (n 16) 330.

26 ibid.

27 Opposition Division (European Patent Office), *Onco-mouse/HARVARD*, Decision of 7 November 2001, [2003] OJ EPO 473, Application No. 85304490.7, para 9.3.

although the Agreement on Trade-Related Aspects of Intellectual Property Rights (the 'TRIPS Agreement') does not bind the Convention and is not directly applicable to it,[28] the TRIPS Agreement may still be taken into account, as all the members of the EPOrg have joined this agreement[29] and it 'gives a clear indication of current trends'.[30] This position not only fails to meet the above-discussed autonomy,[31] but may be also regarded as being difficult to implement due to the fact that it is complicated to find agreement among the 39 Member States[32] on the interpretation and application of Art. 53(a) of the Convention. However, the pursuit in the case law of the EPO Opposition Division to respect the national laws of the EPO Member States in the interpretation and application of Art. 53(a) EPC reflects a process with a long tradition,[33] which is older than the EU and its predecessor the European Economic Community (the 'EEC')[34] and aims

28 *Case Law of the Boards of Appeal of the European Patent Office* (10th edn, European Patent Office, Legal Research Service of the Boards of Appeal 2022) 893.

29 Marta Díaz Pozo, *Patenting Genes. The Requirement of Industrial Application* (Edward Elgar 2017) 41. The terms '*ordre public*' and 'morality' used in Art. 27(2) of the TRIPS Agreement, on the proposal by the European Community, were 'borrowed' from Art. 53(a) EPC, which is analysed in this study (see Nuno Pires de Carvalho, *The TRIPS Regime of Patent Rights* (3rd edn, Kluwer Law International 2010) 297).

30 *Case Law of the Boards of Appeal of the European Patent Office* (n 28) 893.

31 Even next to the indication in the publication of the EPO Boards of Appeal that it is possible to take the TRIPS Agreement into consideration, it is also emphasised that 'The European Patent Organisation as an international organisation has an internal legal system of its own, the EPC. The boards of appeal of the EPO have the task of ensuring compliance with the autonomous legal system established by the EPC and are bound by the provisions of the EPC alone (Art. 23(3) EPC).' (ibid 892).

32 The Contracting States of the European Patent Convention are: Albania, Austria, Belgium, Bulgaria, Croatia, Cyprus, the Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Liechtenstein, Lithuania, Luxembourg, Macedonia, Malta, Monaco, Montenegro, the Netherlands, Norway, Poland, Portugal, Romania, San Marino, Serbia, Slovakia, Slovenia, Spain, Sweden, Switzerland, Turkey, and the United Kingdom (European Patent Office, List of member states sorted according to the date of accession <https://www.epo.org/about-us/foundation/member-states/date.html> accessed 30 May 2023).

33 Reto M Hilty and others, 'The Unitary Patent Package: Twelve Reasons for Concern' <http://pubman.mpdl.mpg.de/pubman/item/escidoc:1621166:13/component/escidoc:2052742/MPI-IP_Twelve-Reasons_2012-10-17.pdf> accessed 30 May 2023.

34 Jan Brinkhof and Ansgar Ohly, 'Towards a Unified Patent Court in Europe' in Justine Pila and Ansgar Ohly (eds), *The Europeanization of Intellectual Property Law* (OUP 2013) 199, 199-200.

to create a unitary patent system in Europe.[35] This explains why, despite its autonomy, the European patent system seeks to provide an interpretation of Art. 53(a) EPC which would not fundamentally oppose the patent laws of the majority of the EPOrg Member States or their prevailing attitudes. Thus, in assessing the commercial exploitation of inventions on the basis of the provisions of the Convention, even in the autonomous European patent system, there exists a certain aspiration for a 'unified standard'.[36]

In this context, in order to clarify the interpretation and application of Art. 53(a) of the Convention with regard to granting legal protection to biotechnological inventions, it is *first of all* necessary to search for a basis on which the EPO could rely and which would allow maintaining of the previously discussed autonomy of European patent law in relation to the other legal systems, and, at least to a certain extent, ensure that the EPO Member States preserve a common approach with regard to the patenting of the said inventions.

Since the interpretation and application of the terms 'morality' and '*ordre public*' used in Art. 53(a) EPC are heavily influenced by religious, philosophical and cultural beliefs[37] or customs,[38] the author of this book believes that relying on a tradition, which is generally perceived as 'a phenomenon that shapes our everyday behaviour, regardless of which culture and time we are in'[39] and which is close and common to the majority of the EPO Member States, may contribute to the understanding on how to interpret and apply the aforementioned provision of the Convention. As indicated by J. G. A. Pocock, tradition is a basic feature of a society which is the

35 The pursuit of unity in the legal framework for European patents can be seen from the start of its creation (see Aisling McMahon, 'An Institutional Examination of the Implications of the Unitary Patent Package for the Morality Provisions: a Fragmented Future too Far?' (2017) 48 International Review of Intellectual Property and Competition Law 42, 47-48). A Unitary Patent package created after many unsuccessful attempts and even covering only part of the EPOrg Member States of the EU can also be seen as an illustration of this partnership.

36 Tine Sommer, *Can Law Make Life (too) Simple?: From Gene Patents to the Patenting of Environmentally Sound Technologies* (DJOF Publishing 2013) 199.

37 '*Ordre public*' and 'morality' are open concepts, which each country can apply and interpret depending on their cultural, social, religious and political beliefs (Daniel Gervais, *The TRIPS Agreement, Drafting History and Analysis* (3rd edn, Sweet&Maxwell 2008) 46).

38 Sven JR Bostyn, 'Biotech Patents and the Future of Scientific Research' in Pieter JD Drenth and Johannes JF Schroots (eds), *Critical topics in science and scholarship: Biennial Yearbook ALLEA 2004* (2004) 29-48, 43.

39 Jurga Jonutytė, *Tradicijos sąvokos kaita* (Vilniaus universitetas 2011) 7.

transmission of a formed behaviour or lifestyle to those who are starting or developing their social dependence.[40] Therefore, turning back to tradition, and analysing its origins and development, can provide the means for dealing with contemporary deficiencies, or for explaining the reasons behind the formation of the current situation.

More concretely, this foundation could be the Western legal tradition, which, like every legal tradition, is characterised by its own unique legal institutions, values and concepts passed on from generation to generation.[41] This choice is not intended to suggest that the Western legal tradition is the only or the best legal tradition in the world. The selection of this legal tradition for this analysis does not mean that this tradition, as pointed out by H. P. Glenn, has not suffered famine, injustice, plague, absolutism, inhumanity and other negative phenomena which, unfortunately, may occur again in the future.[42] The Western legal tradition has been chosen for this study:

1. due to its proximity to the EPOrg: the origins of this organisation lie in the states which, since ancient times, have been regarded as being part of the Western legal tradition.[43] Moreover, currently, the majority of the EPOrg Member States belong precisely to this tradition.[44]
2. due to the fact that in patent grant disputes based on Art. 53(a) EPC, parties assess the latter provision of the EPC from the perspective of

40 John GA Pocock, *Political Thought and History. Essays on Theory and Method* (Cambridge University Press 2009) 187.

41 Harold J Berman, *Teisė ir revoliucija: vakarų teisės tradicijos formavimasis* (Pradai 1999) 15.

42 H Patrick Glenn, *Legal Traditions of the World* (4th edn, OUP 2009) 16.

43 Belgium, France, Germany Luxembourg, the Netherlands, Switzerland and the United Kingdom were the first to join the European Patent Organisation on 7 October 1977 (European Patent Office, Member states of the European Patent Organisation <https://www.epo.org/about-us/foundation/member-states.html> accessed 30 May 2023). The aforementioned states are classified as part of the Western legal tradition since ancient times (see e.g. David B Goldman, *Globalisation and the Western Legal Tradition: Recurring Patterns of Law and Authority* (Cambridge University Press 2008) 4).

44 The Contracting States of the European Patent Convention are: Albania, Austria, Belgium, Bulgaria, Croatia, Cyprus, the Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Liechtenstein, Lithuania, Luxembourg, Macedonia, Malta, Monaco, Montenegro, the Netherlands, Norway, Poland, Portugal, Romania, San Marino, Serbia, Slovakia, Slovenia, Spain, Sweden, Switzerland, Turkey, and the United Kingdom (List of member states sorted according to the date of accession (n 32)).

'Western society'.[45] Additionally, the EPO Board of Appeal has indicated that Art. 53(a) EPC should be interpreted in the light of 'the culture inherent in European society and civilisation',[46] which can be regarded as part of the Western legal tradition.

3. due to the recent encouragement of regional discussions in the sphere of legal scholarship concerning different areas of law, including patent law.[47]
4. given that, despite the attempts to harmonise national and regional patent systems and the similarities among the main patent systems in the world, it is argued that, due to the events in Europe related to the Second World War, the European patent system is characterised by a unique history and a distinct political and social context that plays a key role in shaping its policies and practice.[48] Additionally, in comparison with other patent systems of developing countries, currently, those of industrialised countries, including in Europe, are characterised by different needs, issues and ways of solving them that are reflected in the legal framework.[49]

This study is based on the concept and features of the Western legal tradition articulated by H. J. Berman in his influential and widely recognised[50] work 'Law and Revolution: The Formation of the Western Legal Tradition'[51].

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45 See e.g. Opposition Division (European Patent Office), *Leland Stanford/Modified Animals*, Decision of 16 August 2001, Application No. 88312222.8, pt 8: 'unethical in Western society'.

46 *Plant cells/PLANT GENETIC SYSTEMS* (n 22), para 6.

47 E.g. E Richard Gold, 'Patents and human rights: a heterodox analysis' (2013) 41 Global Health and the Law 185, 193; Geertrui Van Overwalle, 'Gene Patents and Human Rights' in Paul LC Torremans (ed), *Intellectual Property Law and Human Rights* (4th edn, Wolters Kluwer 2020) 1019-1062, 1023.

48 Parthasarathy and Walker, 'Observing the Patent System in Social and Political Perspective: A Case Study of Europe' (n 16) 321-343. Also in the context of human rights, see Van Overwalle, 'Gene Patents and Human Rights' (n 47) 1023.

49 Differences in the needs and attitudes of industrialised Western and developing countries with regard to the regulation of intellectual property, including patent, protection have been discussed in scholarly literature (e.g. Ruth L Gana, 'Prospects For Developing Countries Under the TRIPs Agreement' (1996) 29 Vanderbilt Law Review 735, 746-756; Alexander Peukert, 'Intellectual Property and development – narratives and their empirical validity' (2017) 20 The Journal of World Intellectual Property 2).

50 See Robin Bradley Kar, 'Western Legal Prehistory: Reconstructing the Hidden Origins of Western Law and Civilization' 5 (2012) Illinois Public Law and Legal Theory Research Papers Series 1499, 1516.

When analysing the issues of the patenting of inventions from the perspective of Art. 53(a) EPC, it should be noted that this provision was not relevant until the late 80s of the 20th century.[52] The surge of activity concerning the application of this legal provision, which was referred to as 'the fossil of patent law', occurred approximately between 1980 and 1990 and is associated with the progress of the biomedical sciences.[53] Currently, even after many years since the beginning of a more active application of this EPC provision, the inventions whose commercial exploitation is most frequently evaluated on the basis of Art. 53(a) EPC with regard to *ordre public* and morality are the biotechnological ones.[54] This inevitably requires the knowledge provided by the biomedical sciences.

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51 Berman, *Teisė ir revoliucija: vakarų teisės tradicijos formavimasis* (n 41) 15-27.

52 Ingrid Schneider, 'Exclusions and Exceptions to Patent Eligibility Revisited: Examining the Political Functions of the 'Discovery' and 'Ordre Public' Clauses in the European Patent Convention and the Arenas of Negotiation' in Iñigo de Miguel Beriain and Carlos María Romeo Casabona (eds), *Synbio and Human Health* (Springer Dordrecht 2014) 145-173, 146; Parthasarathy, 'Co-producing knowledge and political legitimacy. Comparing life form patent controversies in Europe and the United States' (n 17) 74.

53 Hellstadius, *A Quest for Clarity: Reconstructing Standards for the Patent Law Morality Exclusion* (n 6) 25 citing according to Karnell Gunnar, 'En genteknologiskt vitaliserad patenträttsfossil? – Förbudet mot patentering av "Uppfinning vars utnyttjande skulle strida mot goda seder eller allmän ordning"', NIR 2/1990, 179-193.

54 Performing a search in the EPO Board of Appeal Decisions database based on the criteria: (1) EPC Art.: '53 (a)'; (2) decision types: 'all'; (3) language of proceedings: all three official EPO languages, i.e. 'English, German, French', 54 results are found, only four of which are not related to biotechnology: (1) Board of Appeal (European Patent Office), *Euthanasia Compositions/MICHIGAN STATE UNIV*, Decision of 11 May 2005, Case No. T 0866/01, EP:BA:2005:T086601.20050511; Application No. 92902903.1, published as No. WO9211009; the patent claims defined a pharmaceutical composition: a solution for the euthanasia of lower mammals; (2) Board of Appeal (European Patent Office), *no headword*, Decision of 25 November 2010, Case No. T 0385/09, EP:BA:2010:T038509.20101125; Application No. 00946559.2, published as No. WO0110197; the patent contained claims for a method of cooling animals such as cows in which a liquid reduced to a fine spray is applied to the animals and air is blown over the wetted animals; (3) Board of Appeal (European Patent Office), *no headword*, Decision of 24 January 2013, Case No. T 0149/11, EP:BA:2013:T014911.20130124; Application No. 97202226.3, published as No. EP0819381; the patent contained claims for a method and device for processing a slaughtered animal or part thereof in a slaughterhouse; (4) Board of Appeal (European Patent Office), *Procédé et système de transport collectif*, Decision of 21 September 2017, Case No. T 0369/13, ECLI:EP:BA:2017:T036913.20170921; Application No. 10181612.2, published as No. EP2267669A1; the patent claims encompassed a process and system of public transport where people are sharing individual vehicles

Taking this into consideration, the *second important aspect* of this research is that, in the interpretation and application of Art. 53(a) of the Convention, European patent law, as a part of the Western legal tradition, does not act in isolation, but rather together with the biomedical sciences, which, by providing European patent law with the knowledge necessary for the assessment of the commercial exploitation of biotechnological inventions, can influence decisions in this field of law and determine its further development. Therefore, the biomedical sciences are relevant for the interpretation and application of Art. 53(a) EPC and are thus considered to be an important element of this study.

Also in this case, not only is European patent law affected by the biomedical sciences, but it can also influence the development of this field of science. Economic arguments, together with those of property theory stemming from natural law,[55] are considered to be one of the main reasons for the creation of this system.[56] Each patent system, including the one analysed in this research, has a strong economic function: the grant of a patent means that its holder may gain economic benefit during the period of validity of the patent by having an exclusive right to prohibit third parties from using patented technology,[57] which is one of the factors driving this person or other stakeholders to further develop innovations. Thus, such an exclusive right is based on one of the objectives of patent law, i.e. the promotion of scientific and technological progress,[58] as is reflected in other international legal acts.[59]

(European Patent Office, Law & practice. Search in the Boards of Appeal decisions database <https://www.epo.org/law-practice/case-law-appeals/advanced-search.html> accessed 30 May 2023).

55 See Wendy Lim, 'Towards Developing a Natural Law Jurisprudence in the U.S. Patent System' (2003) 19 Santa Clara High Technology Law Journal 561; Peter S Menell, 'Intellectual Property: General Theories' <http://www.sfu.ca/~allen/intellectual.pdf> accessed 30 May 2023.

56 See Bronwyn H Hall and Dietmar Harhoff, 'Recent Research on the Economics of Patents' (2012) 4 Annual Review of Economics 541; Joseph Straus, '*Ordre public* and morality issues in patent eligibility' in Toshiko Takenaka (ed), *Intellectual Property in Common Law and Civil Law* (Edward Elgar 2013) 19-49, 19.

57 Donal O'Connell, *Harvesting External Innovation: Managing External Relationships and Intellectual Property* (Routlege 2016) 43.

58 Kamperman Sanders A and others, 'Final Report of the Expert Group on Patent Law in the Field of Development and Importance of Biotechnology and Gene Technology' (Directorate General Internal Market, Industry, Entrepreneurship and SMEs (DG GROW) 2016) <https://cris.maastrichtuniversity.nl/ws/portalfiles/portal/4753322/Report_of_Biotech_Expert_Group.pdf> accessed 30 May 2023, 163.

While the positive impact of patents on innovation is assessed differently in different areas of technology and industry, in economics for many years there has been a consensus that patents particularly encourage innovation in biotechnology and pharmaceuticals,[60] both of which fall under the category of biomedical sciences.[61] The importance of patents in the aforementioned fields of biomedical sciences is also reflected in the EPO statistics: according to publicly available data, in the last years, biotechnological and pharmaceutical inventions have been in the top ten most patented areas of technology.[62]

Also, despite the fact that the Guidelines for Examination in the European Patent Office (the 'Guidelines for Examination' or 'Guidelines') explicitly state that the EPO does not take into account the economic effects of the granting or non-granting of patents,[63] in reality this aspect is important for patent holders and users as well as for the general public. This is evident from the use of Art. 53(a) EPC as a means of blocking the patenting of biotechnological inventions,[64] which, depending on national legislation, may not restrict but rather reduce the interest in research in a particular field of biomedical sciences. This situation shows that, due to the aforementioned economic function of patents, the decisions made by the EPO may influence the development of the biomedical sciences.

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59 TRIPS Agreement, preamble.

60 Hall and Harhoff, 'Recent Research on the Economics of Patents' (n 56); Ashish Arora, Marco Ceccagnoli and Wesley M Cohen, 'R&D and the patent premium' (2008) 26 International Journal of Industrial Organization 1153; Edwin Mansfield, 'Patents and Innovation: An Empirical Study' (1986) 32 Management Science 173, 174 and 180; Roberto Mazzoleni and Richard R Nelson, 'Economic Theories about the Benefits and Costs of Patents' (1998) 32 Journal of Economic Issues 1031, 1038; Somsen, *Regulating Modern Biotechnology in a Global Risk Society: Challenges for Science, Law and Society* (n 4) 17.

61 See '2.1. The Concept and Position of the Biomedical Sciences in the 21st Century'.

62 European Patent Office, Patent Index (2019, 2020, 2021, 2022) <https://www.epo.org/about-us/annual-reports-statistics/statistics.html> accessed 30 May 2023.

63 European Patent Office, Guidelines for Examination in the European Patent Office, March 2023, pt G-II, 4.1.3. <https://new.epo.org/en/legal/guidelines-epc/2023/index.html> accessed 30 May 2023 (Guidelines for Examination or Guidelines). However, within the theory of patent law there is a unanimous agreement on the importance of the economic function of patents (see Hall and Harhoff, 'Recent Research on the Economics of Patents' (n 56)).

64 Sigrid Sterckx, 'European patent law and biotechnological inventions' in Sigrid Sterckx (ed) *Biotechnology, Patents and Morality* (2nd edn, Ashgate Publishing 2000) 1-112, 11.

Based on the fact that: (1) in the last more than 30 years of the existence of the European patent system, when dealing with patenting of inventions in the field of biomedical sciences, problems related to *ordre public* and/or morality, compared to the inventions from other areas of science and technology, have been the most actively analysed, and (2) the importance of patent granting to the development of the biomedical sciences is widely recognised, it can be concluded that the interpretation and application of Art. 53(a) EPC to biotechnological inventions is a topical issue affecting not only legal but also economic and biomedical science progress-related processes in Europe.

The above discussion suggests that European patent law can influence the progress of the biomedical sciences, and the knowledge acquired in the development of the latter field of science may be used in patent law when analysing the issues of granting legal protection to inventions, including those cases where the provision of the Convention investigated in this study is applicable. This allows a reciprocal link to be presumed between European patent law and the biomedical sciences in cases where Art. 53(a) EPC is interpreted and applied. It is precisely the peculiarities[65] of this relationship that may lead to a decision to grant a patent for a particular biotechnological or other invention in the field of biomedical sciences on the basis of the provision at hand.

In view of the discussed aim of European patent law to reconcile its autonomy with the commonality of the Member States of the EPOrg, as well as the dynamic development of the biomedical sciences and their ability to present radically new or even difficult-to-understand knowledge alongside the inventions, it can be stated that the applicability and interpretation of Art. 53(a) EPC, which is based on *ordre public* and morality, depend on a variety of factors. These include: the autonomy of the European patent system and the aim of coherence among the EPOrg Contracting States, the content of the invention and its novelty, the comprehensiveness and reliability of the knowledge of the biomedical sciences concerning the subject-matter of an invention, and so on. It is therefore questionable whether it is possible to find a definitive interpretation and

65 In this study, the word 'peculiarity' is used with the meaning of a feature that is typical or only belongs to one particular person, thing, place, etc. (see 'Peculiarity', *Oxford Learner's Dictionaries* <https://www.oxfordlearnersdictionaries.com/definition/english/peculiarity?q=peculiarity> accessed 30 May 2023; 'Peculiarity', *Cambridge Dictionary* <https://dictionary.cambridge.org/dictionary/english/peculiarity> accessed 30 May 2023).

application of the analysed provision of the Convention which would be appropriate in all cases.

In this context, it seems that the clarification of the relationship between European patent law and the biomedical sciences, as well as the identification of its peculiarities when deciding on the grant of protection for biotechnological or other inventions in the field of biomedical sciences on the basis of Art. 53(a) EPC, would make it possible to predict the trends in the application and interpretation of the aforementioned provision. All this could better protect legitimate expectations and provide more legal certainty and assurance to those for whom the grant of these patents is crucial.

The novelty of this study lies not only in the fact that it is based on the first doctoral legal research in the field of patent law in Lithuania[66] during the entire period of the restoration of Independence of the Republic of Lithuania.[67] This characteristic is also evident from the fact that this study is not limited to a single branch of law, i.e. patent law, but an important part of it is devoted to a complex analysis of Art. 53(a) EPC from the perspective of general legal theory,[68] history of law and philosophy of law.

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66 A search for dissertations in Lithuania on the topic of patent law conducted through: (1) Lithuanian Academic Electronic Library, Lithuanian Electronic Theses and Dissertations (ETD) Database <https://aleph.library.lt/F?func=option-update-lng&P_CON_LNG=ENG> accessed 30 May 2023 (search criteria: (1) Basic search: (i) (a) Word or phrase: 'išradim', (b) Field to search: 'Title' and (c) Type of document: 'Dissertations'; and (ii) (a) Word or phrase: 'patent', (b) Field to search: 'Title' and (c) Type of document: 'Dissertations'; (2) Multi-field Search: (a) Title: 'išradim', (b) Title: 'patent' and (c) Document type: 'Dissertations'; (3) Advanced search: (a) Word or phrase: 'išradim' and Field to search: 'Title', (b) Word or phrase: 'patent' and Field to search: 'Title', (c) Document type: 'Dissertations' and (d) Words adjacent?: 'No'); (2) Research Council of Lithuania, Database of dissertation defences <https://db.lmt.lt/lt/perziura/disertacijos/d-db.html> accessed 30 May 2023 (search criteria: (1) search word 'patent' in the search field and (2) search word 'išradim' in the search field).

67 On 11 March 1990, the Supreme Council of the Republic of Lithuania adopted an Act on the Restoration of the Independent State of Lithuania.

68 Egidijus Kūris, 'Grynoji teisės teorija, teisės sistema ir vertybės: normatyvizmo paradigmos iššūkis' in Hans Kelsen *Grynoji teisės teorija* (Eugrimas 2002) 11-41, 24: 'In trying to construct a general concept of law, the theory of law (from the point at which it separated from political and morality philosophy) took three directions: modified doctrines of Natural law, legal positivism (the product of which is analytical jurisprudence) and sociology of law (including legal realism)' (translated from Lithuanian into English by the author of this study). According to E Kūris, this is a simplified view.

In addition, the natural sciences (also referred to as 'science' in this study), including the biomedical sciences, are perceived as a tradition in this research.[69] This approach means that this study supports the position that not only law but also the natural sciences, including the biomedical sciences, can develop and change gradually (i.e. cumulatively), meaning that revolutions are not always necessary in this field and that the fundamental agreement on the essential questions within the scientific community plays an important role.[70] It is precisely by using the concept of biomedical sciences as a tradition that this research aims to analyse their relationship with the European patent legal system, in particular with Art. 53(a) EPC, which in this study is regarded as a part of the Western legal tradition.

Viewing biomedical sciences as a tradition allows them to be understood differently from the early 17th century perspective that science is based on facts determined by observation.[71] Unlike according to the early 17th century perspective, science is not considered as something given, i.e. a realm of reality which provides us with undisputed and objective knowledge about our surrounding environment at all times. This study highlights a certain subjectivity of science and its inability to continuously present society with extensive knowledge about all issues of concern.[72] This is so because the perception of the processes happening in reality is influenced by the individual perspective of an observer, which is often shaped by a particular 'scientific paradigm'.[73] With the help of this perspective, it becomes easier to

69 The term 'tradition' (in Latin *traditio*: a teaching, a saying handed down from earlier times) means the preservation and passing on of customs, rituals, imagery, symbols from generation to generation (Valerija Vaitkevičiūtė (ed), 'Tradicija', *Tarptautinių žodžių žodynas* (2000) vol 2, 603).

70 Thomas S Kuhn, *The Structure of Scientific Revolutions* (University Chicago Press 1970) 94. See also I Bernard Cohen, *Revolution in Science* (Harvard University Press 1985) xvi.

71 Alan F Chalmers, *Kas yra mokslas?* (Apostrofa 2005) 24.

72 See e.g. Sheila Jasanoff, *Science at the Bar. Law, Science, and Technology in America* (Harvard University Publishing 1997) 7 citing Marc Galanter, 'Predators and Parasites: Lawyer-Bashing and Civil Justice' Georgia Law Review 28 (1994), 633-681. A traditional perspective to natural science: Robin Feldman, 'Historic Perspectives on Law & Science' (2009) Stanford Technology Law Review 1 <https://repository.uchastings.edu/cgi/viewcontent.cgi?article=1156&context=faculty_scholarship> accessed 30 May 2023.

73 According to T Kuhn, a scientific paradigm can be regarded as the 'universally recognized scientific achievements that, for a time, provide model problems and solutions for a community of researchers' (Kuhn, *The Structure of Scientific Revolutions* (n 70) viii).

identify the trends in the development of the relationship between the biomedical sciences and European patent law, which can help in interpreting and applying Art. 53(a) EPC.

The *object* of this research is the relationship between European patent law, as a part of the Western legal tradition, and the biomedical sciences, as a tradition, when decisions based on Art. 53(a) EPC are taken on the patentability of biotechnological inventions. It should be noted that this research does not analyse cases referred to in Art. 138 EPC, when European patents are revoked by the competent authorities of a Member State in accordance with Art. 53(a) of the Convention.[74] In addition, this study does not analyse the legal framework governing research in the field of biomedical sciences, other activities in this field of sciences, or objects created to protect the health of individuals and the general public, to ensure the safety of food and the environment, etc.

The *objective* of this research is to reveal the relationship between European patent law, as a part of the Western legal tradition, and the biomedical sciences, as a tradition, when decisions on the grant of European patents for biotechnological inventions are taken based on Art. 53(a) EPC, and to assess the significance of this relationship for the granting of legal protection for these inventions in the European patent system.

Taking into consideration this objective, the *research questions* of this study are the following:

1. How do European patent law and the biomedical sciences interact?
2. What does this relationship between European patent law and the biomedical sciences mean for the decision-making on the protection of biotechnological inventions under Art. 53(a) EPC?

In order to answer these research questions, interdisciplinary research on the relationship between European patent law and the biomedical sciences in the realm of the morality and *ordre public*-based exception of Art. 53(a) EPC was undertaken. This included the following steps:

1. Analysis of the case law of the European Patent Office's Opposition Division, Boards of Appeal and Enlarged Board of Appeal (the 'EPO case law') concerning the grant of patents to biotechnological inventions under Art. 53(a) EPC and identification of the existing tests, standards

74 EPC, Art. 138.

and relevant categories used in the interpretation and application of the aforementioned provision.[75]

2. Analysis of the concept of biomedical sciences as a tradition and identification of the significance of this concept for the relationship between European patent law and the biomedical sciences.
3. Analysis of the concept of the Western legal tradition and identification of its main characteristics.
4. Analysis of the concepts of *ordre public* and morality as well as their interrelationship in the Western legal tradition and in the EPO case law.
5. Analysis of the economic implications of the application of Art. 53(a) EPC and their influence on scientific and technological progress.
6. Identification of the peculiarities of the relationship between European patent law, as a part of the Western legal tradition, and the biomedical sciences, as a tradition, in the context of Art. 53(a) EPC, and assessment of the influence of this relationship on the legal protection of biotechnological inventions in the European patent system.

Research methods. First, a *linguistic method of research* was used in this study. With the help of this method, the author analysed categories essential to this research, e.g. 'morality', '*ordre public*', 'Western legal tradition', 'biomedical sciences', 'biotechnology', etc., as well as provided their definitions and identified their meanings.

Furthermore, the method of *doctrinal legal research* which accommodates the legal research methods mentioned below[76] was highly important throughout this study.

Using the *analytical legal research method*, Art. 53(a) EPC was divided into its components ('*ordre public*', 'morality', 'commercial exploitation'), in order to be able to analyse them individually as well as the relationship between any two of them (for example, the relationship between '*ordre public*' and 'morality').

In addition to the relevant categories mentioned above, the decisions of the EPO Boards of Appeal and EPO Enlarged Board of Appeal on the patentability of biotechnological inventions in relation to Art. 53(a) EPC found in the publicly accessible EPO case law database were also subject

75 In addition, one decision of the EPO Examining Division was also analysed (Examining Division (European Patent Office), *Harvard/Onco-Mouse*, Decision of 14 July 1989 [1989] OJ EPO 451, Application No. 85304490.7).

76 See P Ishwara Bhat, *Idea and Methods of Legal Research* (OUP 2020) 150-151, 155-161.

to the *analytical legal research method* in this study. These decisions were selected according to the following search criteria: (1) EPC article – '53(a)'; (2) decision types – 'all'; (3) all three official EPO languages, i.e. 'English, German, French', were selected under the criterion 'language of proceedings'.[77]

During this search, 54 decisions in English, German and French of the EPO Boards of Appeal and EPO Enlarged Board of Appeal were found, of which four decisions did not belong to the field of biomedical sciences,[78] 14 decisions in German and French coincided with those found in English,[79]

77 European Patent Office, Law & practice. Search in the Boards of Appeal decisions database (n 54).

78 (1) *Euthanasia Compositions/MICHIGAN STATE UNIV* (n 54); the patent claims defined a pharmaceutical composition: a solution for the euthanasia of lower mammals; (2) *no headword*, Decision of 25 November 2010, Case No. T 0385/09 (n 54); the patent contained claims for a method of cooling animals such as cows in which a liquid reduced to a fine spray is applied to the animals and air is blown over the wetted animals; (3) *no headword*, Decision of 24 January 2013, Case No. T 0149/11 (n 54); the patent contained claims for a method and device for processing a slaughtered animal or part thereof in a slaughterhouse; (4) *Procédé et système de transport collectif* (n 54); the patent claims encompassed a process and system of public transport where people are sharing individual vehicles.

79 (1) Enlarged Board of Appeal (European Patent Office), *Verwendung von Embryonen/WARF*, Decision of 25 November 2008, Case No. G 0002/06, EP:BA:2008:G000206.20081125; (2) Enlarged Board of Appeal (European Patent Office), *Utilisation d'embryons/WARF*, Decision of 25 November 2008, Case No. G 0002/06, EP:BA:2008:G000206.20081125; (3) Enlarged Board of Appeal (European Patent Office), *Paprika (im Anschluss an „Tomate II" und „Broccoli II")*, Decision of 14 May 2020, Case No. G 0003/19, ECLI:EP:BA:2020:G000319.20200514; (4) Enlarged Board of Appeal (European Patent Office), *Poivron (faisant suite à "Tomate II" et "Brocoli II")*, Decision of 14 May 2020, Case No. G 0003/19, ECLI:EP:BA:2020:G000319.20200514; (5) Board of Appeal (European Patent Office), *Krebsmaus*, Decision of 3 October 1990, Case No. T 0019/90, EP:BA:1990:T001990.19901003; (6) Board of Appeal (European Patent Office), *Souris oncogene*, Decision of 3 October 1990, Case No. T 0019/90, EP:BA:1990:T001990.19901003; (7) Board of Appeal (European Patent Office), *Pflanzenzellen*, Decision of 21 February 1995, Case No. T 0356/93, EP:BA:1995:T035693.19950221; (8) Board of Appeal (European Patent Office), *Cellules de plantes*, Decision of 21 February 1995, Case No. T 0356/93, EP:BA:1995:T035693.19950221; (9) Board of Appeal (European Patent Office), *Stammzellen/WARF*, Decision of 7 April 2004, Case No. T 1374/04, EP:BA:2006:T137404.20060407; (10) Board of Appeal (European Patent Office), *Cellules souches/WARF*, Decision of 7 April 2004, Case No. T 1374/04, EP:BA:2006:T137404.20060407; (11) Board of Appeal (European Patent Office), *Genetisch manipulierte Tiere/HARVARD*, Decision of 6 July 2004, Case No. T 0315/03, EP:BA:2004:T031503.20040706; (12) Board of Appeal (European Patent Office), *Animaux transgeniques/HARVARD*, Decision of 6 July 2004,

and seven decisions in English were repeated in the search results.[80] Setting these three groups of decisions aside, there were 29 EPO decisions from the period 1990-2022 on biotechnological inventions[81] and one decision

Case No. T 0315/03, EP:BA:2004:T031503.20040706; (13) Board of Appeal (European Patent Office), *Tomaten II/STAAT ISRAEL*, Decision of 31 May 2012, Case No. T 1242/06, EP:BA:2012:T124206.20120531; (14) Board of Appeal (European Patent Office), *Tomates II/ÉTAT D'ISRAËL*, Decision of 31 May 2012, Case No. T 1242/06, EP:BA:2012:T124206.20120531.

80 (1) Enlarged Board of Appeal (European Patent Office), *Use of embryos/WARF*, Decision of 25 November 2008, Case No. G 0002/06, EP:BA:2008:G000206.20081125; (2) Enlarged Board of Appeal (European Patent Office), *Pepper (follow-up to Tomatoes II and Broccoli II)*, Decision of 14 May 2020, Case No. G 0003/19, ECLI:EP:BA:2020:G000319.20200514; (3) Board of Appeal (European Patent Office), *Onco-Mouse,* Decision of 3 October 1990, Case No. T 0019/90, EP:BA:1990:T001990.19901003; (4) *Plant cells/PLANT GENETIC SYSTEMS* (n 22); (5) Board of Appeal (European Patent Office), *Stem Cells/WARF*, Decision of 7 April 2004, Case No. T 1374/04, EP:BA:2006:T137404.20060407; (6) Board of Appeal (European Patent Office), *Transgenic animals/HARVARD,* Decision of 6 July 2004, Case No. T 0315/03, EP:BA:2004:T031503.20040706; (7) Board of Appeal (European Patent Office), *Tomatoes II/STATE OF ISRAEL*, Decision of 31 May 2012, Case No. T 1242/06, EP:BA:2012:T124206.20120531.

81 (1) *Use of embryos/WARF* (n 80); (2) *Pepper (follow-up to Tomatoes II and Broccoli II)* (n 80); (3) *Onco-Mouse* (n 80); (4) *Plant cells/PLANT GENETIC SYSTEMS* (n 22); (5) Board of Appeal (European Patent Office), *Heat treated Factor VIII/CEDARS-SINAI*, Decision of 18 November 1998, Case No. T 0919/93, EP:BA:1998:T091993.19981118; (6) Board of Appeal (European Patent Office), *Relaxin/HOWARD FLOREY INSTITUTE*, Decision of 23 October 2002, Case No. T 0272/95, EP:BA:2002:T027295.20021023; (7) *Stem Cells/WARF* (n 80); (8) Board of Appeal (European Patent Office), *Phosphinothricin-Resistenzgen/BAYER*, Decision of 15 June 2004, Case No. T 0475/01, EP:BA:2004:T047501.20040615; (9) *Transgenic animals/HARVARD* (n 80); (10) Board of Appeal (European Patent Office), *Gene trap/ARTEMIS*, Decision of 21 January 2006, Case No. T 0606/03, EP:BA:2006:T060603.20060112; (11) *Breast and Ovarian Cancer/UNIVERSITY OF UTAH* (n 22) (12) Board of Appeal (European Patent Office), *Mutation/UNIVERSITY OF UTAH*, Decision of 13 November 2008, Case No. T 0666/05, EP:BA:2008:T066605.20081113; (13) Board of Appeal (European Patent Office), *Method of diagnosis/UNIVERSITY OF UTAH*, Decision of 19 November 2008, Case No. T 0080/05, EP:BA:2008:T008005.20081119; (14) Board of Appeal (European Patent Office), *Stem cells/CALIFORNIA*, Decision of 24 May 2009, Case No. T 0522/04, EP:BA:2009:T052204.20090528; (15) Board of Appeal (European Patent Office), *Perfused microtissue/MIT*, Decision of 4 September 2009, Case No. T 0329/06, EP:BA:2009:T032906.20090904; (16) *Tomatoes II/STATE OF ISRAEL* (n 80); (17) Board of Appeal (European Patent Office), *Non-invasive localization/LELAND STANFORD*, Decision of 13 July 2012, Case No. T 1262/04, EP:BA:2012:T126204.20120713; (18) Board of Appeal (European Patent Office), *Modulation of stem cells/SANGAMO BIOSCIENCES*, Decision of 16 October 2012,

of the EPO Boards of Appeal from the same period of time concerning the protection of a non-biotechnological invention but a pharmaceutical composition,[82] which nonetheless falls within the field of the biomedical sciences. Also, based on the scholarly literature,[83] four additional decisions from the EPO Opposition Division[84] and one decision from the EPO Examining Division[85] were identified and analysed in this research.

In total, this research analysed 35 EPO decisions dealing with inventions relating to: (1) animals; (2) plants; (3) human genes, genetic tests and other elements isolated from the human body; (4) human stem cells and the use of human embryos; and (5) a pharmaceutical composition.

Case No. T 1176/09, EP:BA:2012:T117609.20121016; (19) Board of Appeal (European Patent Office), *Gewinnung von embryonalen Stammzellen/WÜRFEL*, Decision of 9 April 2013, Case No. T 1836/10, EP:BA:2013:T183610.20130409; (20) *Culturing stem cells/TECHNION* (n 23); (21) Board of Appeal (European Patent Office), *Embryonic stem cells, disclaimer/ASTERIAS*, Decision of 9 September 2014, Case No. T 1441/13, EP:BA:2014:T144113.20140909; (22) Board of Appeal (European Patent Office), *Neurale Vorläuferzellen/BRÜSTLE*, Decision of 26 February 2015, Case No. T 1808/13, EP:BA:2015:T180813.20150226; (23) Board of Appeal (European Patent Office), *Human pluripotent progenitor stem cells/PROGENITOR LABS*, Decision of 31 May 2016, Case No. T 2365/13, EP:BA:2016:T236513.20160531; (24) Board of Appeal (European Patent Office), *In vitro differentiated cardiomyocytes/AXIOGENESIS*, Decision of 11 September 2019, Case No. T 0385/14, ECLI:EP:BA:2019:T038514.20190911; (25) Board of Appeal (European Patent Office), *Non-human organism/INTREXON*, Decision of 5 June 2020, Case No. T 0682/16, ECLI:EP:BA:2020:T078916.20200605; (26) Board of Appeal (European Patent Office), *Non-human organism/INTREXON*, Decision of 5 June 2020, Case No. T 0789/16, ECLI:EP:BA:2020:T078916.20200605; (27) Board of Appeal (European Patent Office), *Human hepatocytes/OREGON UNIVERSITY*, Decision of 21 July 2020, Case No. T 1111/14, ECLI:EP:BA:2020:T111114.20200721; (28) Board of Appeal (European Patent Office), *Rabbit skin extract/VANWORLD (RUGAO)*, Decision of 28 September 2020, Case No. T 1553/15, ECLI:EP:BA:2020:T155315.20200928; (29) Board of Appeal (European Patent Office), *Non-human animals/MAX PLANCK*, Decision of 1 February 2021, Case No. T 0186/18, ECLI:EP:BA:2021:T018618.20210201.

82 *Euthanasia Compositions/MICHIGAN STATE UNIV* (n 54); the patent claims defined a pharmaceutical composition: a solution for the euthanasia of lower mammals.

83 E.g. Hellstadius, *A Quest for Clarity: Reconstructing Standards for the Patent Law Morality Exclusion* (n 6) 215 and 258; Sterckx, 'European patent law and biotechnological inventions' (n 64) 23-27; Mills, *Biotechnological Inventions: Moral Restraints and Patent Law* (n 4) 61; Sheila Jasanoff, *Designs on Nature: Science and Democracy in Europe and the United States* (Princeton University Press 2005) 219.

84 (1) Opposition Division (European Patent Office), *Lubrizol Genetics Inc.*, Decision of 5 June 1992, EP 84302533.9; (2) *Leland Stanford/Modified Animals* (n 45); (3) *Oncomouse/HARVARD* (n 27); (4) *Edinburgh Patent* (n 23).

85 *Harvard/Onco-Mouse* (n 75).

Furthermore, on the basis of secondary sources,[86] this research also took into consideration the decision of the EPO Examining Division on European Patent No. 89913146.0,[87] covering genetically modified animals, and not available on the EPO website. Also, due to the small number of cases concerning inventions in the field of biomedical sciences, this study analysed one decision of the EPO Boards of Appeal, the subject-matter of which was not related to the aforementioned field of science, but was taken on the basis of Art. 53(a) EPC, concerning the commercial exploitation of an invention.[88] Finally, despite the fact that the European patent system and the EU legal order are two separate and formally independent legal systems, due to their almost identical legal provisions on patenting of biotechnological inventions and the objective of effectively maintaining harmony,[89] four decisions of the Court of Justice were analysed.[90]

The EPO decisions, which were broken down into the above-mentioned groups according to the type of inventions analysed, were subsequently merged together, by employing the *synthesis method*, based on the underlying philosophy behind the arguments put forward by the EPO. In this way, it was intended to establish a link between the type of invention and the tests and standards that the EPO applied for the interpretation of Art. 53(a) of the Convention.

Systemic analysis was also important in this study for: (1) analysing the position and importance of Art. 53(a) EPC in the European patent system and the relationship of this system with the EU legal order, as well as the novelties brought about by the Unitary Patent package;[91] (2) identifying

86 E.g. Mills, *Biotechnological Inventions: Moral Restraints and Patent Law* (n 4) 60-61; Hellstadius, *A Quest for Clarity: Reconstructing Standards for the Patent Law Morality Exclusion* (n 6) 320.

87 European Patent Application No. 89913146.0 'Transgenic mice for the analysis of hair growth', submitted 17 November 1989, rejected 25 July 1993.

88 *no headword*, Decision of 24 January 2013, Case No. T 0149/11 (n 54); the patent claims defined a method and device for processing a slaughtered animal or part thereof in a slaughterhouse.

89 For more information, see '1.2. The Relationship between Article 53(a) of the European Patent Convention and the Biotechnology Directive'.

90 Case C-377/98 *Netherlands v Parliament and Council* [2001] ECR I-07079; Opinion of the Court 1/09 [2011] ECR I-01137; Case C-34/10 *Oliver Brüstle v Greenpeace eV* [2011] ECR- I-09821; Case C-364/13 *International Stem Cell Corporation v Comptroller General of Patents, Designs and Trade Marks*, EU:C:2014:2451.

91 The Unitary Patent package consists of: Regulation (EU) No 1257/2012 of the European Parliament and of the Council of 17 December 2012 implementing enhanced cooperation in the area of the creation of unitary patent protection, OJ, 2012 L 361, p.

the main characteristics of the categories 'morality' and '*ordre public*' as well as their definitions in various decisions of the EPO Divisions and the concepts of these categories in the legal paradigms analysed in this research (legal positivism, school of natural law and legal realism); (3) defining the concept of the biomedical sciences and their relationship with the field of biotechnology; and (4) showing the possible economic impact of the application and interpretation of Art. 53(a) EPC.

The *historical method of research* was also used in this study. It was used to analyse the development of biotechnology and the history of the inclusion of Art. 53(a) in the text of the EPC and its subsequent amendments.

The analysis of the relationship between European patent law and the biomedical sciences in deciding on the grant of patents in respect of biotechnological inventions under Art. 53(a) EPC covers a rather extensive field and numerous issues, many of which are significant not only to the field of law but also to economics and legal philosophy. Hence, during this study, it was important to take into consideration economic literature on patent law and sources of legal philosophy.

The relationship between this research and the research conducted around the world. The issues related to Art. 53(a) EPC have been analysed by many authors, the most notable of whom are the following: M. Bagley,[92] R. Brownsword,[93] J. Cockbain,[94] D. M. Gitter,[95] A. Hellsta-

208 (Regulation 1257/2012); Council Regulation (EU) No 1260/2012 of 17 December 2012 implementing enhanced cooperation in the area of the creation of unitary patent protection with regard to the applicable translation arrangements, OJ, 2012 L 361, p. 89 (Regulation No 1260/2012); Agreement on a Unified Patent Court, OJ C 175, 20.6.2013, p. 1 (Agreement on a Unified Patent Court). All of the aforementioned documents are the basis of the reform of the European patent system.

92 Margo Bagley, 'Patent First, Ask Questions Later: Morality and Biotechnology in Patent Law' (2003) 45 William Mary Law Review 469; Margo Bagley, 'The New Invention Creation Activity Boundary in Patent Law' (2009) 51 William Mary Law Review 577.

93 Beyleveld and Brownsword, *Mice, Morality and Patents: The Onco-mouse Application and Article 53(a) of the European Patent Convention* (n 21).

94 Sigrid Sterckx and Julian Cockbain, *Exclusions from Patentability, How Far Has the European Patent Office Eroded Boundaries?* (Cambridge University Press 2012).

95 Donna M Gitter, 'Led Astray by the Moral Compass: Incorporating Morality into European Union Biotechnology Patent Law' (2001) 19 Berkeley Journal of International Law 1.

dius,[96] G. van Overwalle,[97] A. Plomer,[98] I. Schneider,[99] S. Sterckx,[100] J. Straus.[101] However, except for a few,[102] in none of these works has a detailed analysis been conducted from the perspectives of general legal theory, history of law or philosophy of law. This situation shows that the relationship between European patent law, as a part of the Western legal tradition, and the biomedical sciences, as a tradition, in the context of Art. 53(a) EPC is a topic that has not been extensively explored, and therefore leaves much room for analysis.

Overview of the sources used for this research. Both primary and secondary legal sources were analysed in this study. The primary sources were legislation (the EPC, the relevant provisions of the 12 December 2002 Implementing Regulations to the European Patent Convention (the 'EPC Implementing Regulations') and other legal acts relevant to the investigation),

96 Hellstadius, *A Quest for Clarity: Reconstructing Standards for the Patent Law Morality Exclusion* (n 6).

97 Van Overwalle, 'Gene Patents and Human Rights' (n 47); Geertrui van Overwalle, 'Human Rights' Limitations in Patent Law' in Willem Grosheide (ed), *Intellectual property and human rights. A Paradox* (Edward Elgar Publishing Limited 2010) 236-271.

98 Aurora Plomer, 'Human Dignity, Human Rights, and Art. 6(1) of the EU Directive on Biotechnological Inventions' in Aurora Plomer and Paul Torremans (eds) *Embryonic Stem Cell Patents: European Law and Ethic*s (OUP 2009) 203-226; Aurora Plomer, 'Human Dignity and Patents' in Christophe Geiger (ed) *Research Handbook on Human Rights and Intellectual Property Rights* (Edward Elgar Publishing Limited 2015) 479-495.

99 Schneider, 'Exclusions and Exceptions to Patent Eligibility Revisited: Examining the Political Functions of the 'Discovery' and 'Ordre Public' Clauses in the European Patent Convention and the Arenas of Negotiation' (n 52).

100 Sterckx, 'European patent law and biotechnological inventions' (n 64) 1-112; Sterckx and Cockbain, *Exclusions from Patentability, How Far Has the European Patent Office Eroded Boundaries?* (n 94).

101 Joseph Straus, 'Medicine Between Ethics and Scientific Progress: How Much Ethics Needs Medicine, How Much Ethics Can it Afford?' (2015) 8 Medicine, Law & Society 47; Straus, '*Ordre public* and morality issues in patent eligibility' (n 56); Joseph Straus, 'Research, Exploitation and Patenting in the Area of Human Embryonic Stem Cells in Europe – A Case of Concern Causing Inconsistency' (2016) 25 European Review 107.

102 Beyleveld and Brownsword, *Mice, Morality and Patents: The Onco-mouse Application and Article 53(a) of the European Patent Convention* (n 21); Brian Salter, 'Patents and morality: governing human embryonic stem cell science in Europe' <https://www.researchgate.net/publication/228881170_Patents_and_morality_governing_human_embryonic_stem_cell_science_in_Europe> accessed 30 May 2023; Gitter, 'Led Astray by the Moral Compass: Incorporating Morality into European Union Biotechnology Patent Law' (n 95).

while the secondary sources were mainly the case law of the EPO Boards of Appeal and the legal doctrine. The legal doctrine can be categorised into the following groups: (1) sources analysing the categories relevant for this study ('morality', '*ordre public*', 'Western legal tradition');[103] (2) literature relating to the philosophy of science;[104] (3) works analysing the relationship between law and the natural sciences;[105] (4) works analysing the economic aspects of the grant of patents.[106]

103 E.g. Berman, *Teisė ir revoliucija: vakarų teisės tradicijos formavimasis* (n 41); Harold J Berman, 'The Western Legal Tradition in a Millennial Perspective: Past and Future' (2000) 60 Louisiana Law Review 739; Sterckx, 'European patent law and biotechnological inventions' (n 64) 1-112; Sterckx and Cockbain, *Exclusions from Patentability, How Far Has the European Patent Office Eroded Boundaries?* (n 94).

104 E.g. Kuhn, *The Structure of Scientific Revolutions* (n 70); Thomas S Kuhn, *The Essential Tension: Selected Studies in Scientific Tradition and Change* (The University Chicago Press 1977).

105 E.g. Jasanoff, *Science at the Bar. Law, Science, and Technology in America* (n 72); Jasanoff, 'The Idiom of Co-Production' in Sheila Jasanoff (n 4); Parthasarathy, 'Co-producing knowledge and political legitimacy. Comparing life form patent controversies in Europe and the United States' (n 17).

106 E.g. Hall and Harhoff, 'Recent Research on the Economics of Patents' (n 56); Sebastian Hoenen and others, 'The diminishing signalling value of patents between early rounds of venture capital financing' (2014) 43 Research Policy 956, 959-960.

1. The European Patent System

1.1. Article 53(a) of the European Patent Convention in the European Patent System

One of the ways of obtaining patent protection for an invention is, according to the procedure prescribed by the EPC and the EPC Guidelines for Examination, to apply for a European patent, which would be valid in the EPOrg Member States requested by the applicant.[107] In this way, based on a single patent application, it is possible to obtain a bundle of national patents,[108] each of which is valid in the territory of a particular Contracting State[109] specified in that application.

At the same time, this means that the EPC procedure does not provide for the opportunity to obtain one patent valid in all the Member States. Thus, in the event of a legal dispute concerning the infringement or validity of a European patent, it would be resolved before a national court under the law of the country where that particular patent is validated.[110] Nevertheless, the EPC provides for certain substantive patentability requirements and exceptions which apply to European patents valid in the EPOrg Member States,[111] including Art. 53(a) EPC which is analysed in this study. The

107 Gerard Porter, 'The Drafting History of the European Biotechnology Directive' in Aurora Plomer and Paul Torremans (eds) *Embryonic Stem Cell Patents: European Law and Ethic*s (OUP 2009) 3-26, 6. The Contracting States of the European Patent Convention are: Albania, Austria, Belgium, Bulgaria, Croatia, Cyprus, the Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Liechtenstein, Lithuania, Luxembourg, Macedonia, Malta, Monaco, Montenegro, the Netherlands, Norway, Poland, Portugal, Romania, San Marino, Serbia, Slovakia, Slovenia, Spain, Sweden, Switzerland, Turkey, and the United Kingdom (List of member states sorted according to the date of accession (n 32)).

108 Albrecht Krieger, 'When will the European Community patent finally arrive?' (1998) 29 International Review of Intellectual Property and Competition Law 855, 855.

109 Porter, 'The Drafting History of the European Biotechnology Directive' (n 107) 6.

110 Rob J Aerts, 'The Patenting of Biotechnological Inventions in the EU, the Judicial Bodies Involved and the Objectives of the EU Legislator' (2014) 49 European Intellectual Property Review 88, 90.

111 Porter, 'The Drafting History of the European Biotechnology Directive' (n 107) 6.

latter provision has given rise to considerable debate since the beginning of the discussion of the EPC project[112] and this continues today, as there is no common position among the EPOrg Contracting States as to what should be recognised as moral and/or complying with *ordre public* and what should not.

In the scholarly literature it is agreed that the *ordre public* and morality-based exception in Art. 53(a) EPC, which establishes that 'European patents shall not be granted in respect of: [...] inventions the commercial exploitation of which would be contrary to *ordre public* or morality',[113] is as old as patent law itself.[114] However, a more active application of Art. 53(a) EPC can be witnessed only since the 1980s-1990s,[115] when a sudden change in the field of biomedical sciences occurred, and even today there are only a small number of patent applications that were rejected because of this particular provision or analogous provisions in other patent systems.[116] The search results of the publicly available database of EPO case law show that the biggest number of questions regarding compliance of the commercial exploitation of inventions with regard to *ordre public* and/or morality arise primarily in the field of biomedical sciences (more specifically in biotechnology), although at the same time they also confirm the small number of cases of this type.[117]

When defining the limits of an invention, it is important to take into account Art. 69(1) of the Convention, which provides that '[t]he extent of the protection conferred by a European patent or a European patent application shall be determined by the claims',[118] the interpretation of which

112 Gideon Jan Oudemans (with foreword by JA Kemp), *The draft European Patent Convention: a commentary with English and French texts* (Stevens & Sons 1963) 21; Parthasarathy and Walker, 'Observing the Patent System in Social and Political Perspective: A Case Study of Europe' (n 16) 325.

113 EPC, Art. 53(a).

114 Ulrich Schatz, 'Patents and morality' in Sigrid Sterkcx (ed), *Biotechnology, Patents and Morality* (2nd edn, Ashgate 2000) 217-228, 217; Parthasarathy, 'Co-producing knowledge and political legitimacy. Comparing life form patent controversies in Europe and the United States' (n 17) 77.

115 Parthasarathy, 'Co-producing knowledge and political legitimacy. Comparing life form patent controversies in Europe and the United States' (n 17) 78-79.

116 Amanda Warren-Jones, 'Finding a "Common Morality Codex" for Biotech – A Question of Substance' (2008) 39 International Review of Intellectual Property and Competition Law 638, 638.

117 European Patent Office, Law & practice. Search in the Boards of Appeal decisions database (n 54).

118 EPC, Art. 69(1).

must be based on the description and drawings.[119] Furthermore, Art. 83 EPC is very important, stating that a 'patent application shall disclose the invention in a manner sufficiently clear and complete for it to be carried out by a person skilled in the art'.[120] Such regulation illustrates that, when applying Art. 53(a) EPC, it is appropriate to analyse the invention specifically set out in the claims of a given patent application and, where appropriate, reference should be made to the description and drawings.

Another important element for the interpretation of Art. 53(a) EPC is commercial exploitation, which is defined neither in the Convention nor in the EPC Implementing Regulations. The Guidelines for Examination provide only limited information on this concept, indicating that a patent may not be granted for an invention if there is only a single method of exploitation of an invention and that method is inconsistent with *ordre public* or morality.[121] This means that in the case where there is at least one method of exploitation which is compatible with the latter categories, Art. 53(a) EPC will not be an obstacle for obtaining a patent. The latter provision of the Guidelines for Examination allows for the application of a broad concept of patentability, which was already established during the EPC negotiations[122] and aims at a narrow interpretation of all the provisions related to the exceptions to patentability.

However, in the EPO case law, the discussed concept is interpreted both narrowly and broadly.[123] When relying on the narrow (verbatim) interpretation, only the 'commercial exploitation' of an invention is analysed with respect to *ordre public* and/or morality, without evaluating the aspects of an invention, technology or patent itself that go beyond the boundaries of the patent claims. The latter aspects do not have any influence on the interpretation and application of Art. 53(a) EPC. By contrast, when the concept 'commercial exploitation' is perceived more broadly, the aim of going beyond the patent claims is to find out whether the grant of a patent would be contrary to *ordre public* and/or morality, allowing the evaluation of more aspects that may influence the patentability of an invention. Thus, the EPO case law with regard to the discussed question analysed in this

119 EPC, Art. 69(1).
120 ibid Art. 83.
121 Guidelines for Examination, March 2023 (n 63), pt G-II, 4.1.2.
122 Sterckx and Cockbain, *Exclusions from Patentability, How Far Has the European Patent Office Eroded Boundaries?* (n 94) 30.
123 See 1.4.3. 'The Concept and Scope of the Term 'Commercial Exploitation'.

research does not exactly comply with the provisions of the Guidelines for Examination.

It is important for this work that the nature of a patent as an intellectual property right determines a narrow effect of Art. 53(a) EPC to science and technologies. This exclusive intellectual property right gives its holder the possibility only to prohibit third parties from using an invention that is protected by a patent.[124] For this reason, the rejection of a patent application on the basis of Art. 53(a) EPC does not imply a prohibition on exploiting the invention or a particular technology,[125] but rather a loss of control over who can exploit it. In this way, by granting or rejecting a patent application, the EPO demonstrates its support or lack thereof for certain inventions and sets 'the invisible line beyond which human research should never go',[126] and thus is able to influence the incentives to conduct research in those fields of science and technology for whose further development patents are important.[127]

Also, Art. 53(a) EPC, which states that the commercial exploitation of an invention 'shall not be deemed to be so contrary merely because it is prohibited by law or regulation in some or all of the Contracting States',[128] suggests that the approval or disapproval under national legislation of the exploitation of an invention is not a sufficient criterion for the assessment of an invention under Art. 53(a) EPC. This provision confirms that the European patent system is independent of other legal systems, but, on the other hand, it presents major challenges, because the EPO and its organs are obliged to autonomously define the normative content of such abstract categories as '*ordre public*' and 'morality' and to apply them.[129]

Despite the vagueness of the aforementioned categories and the autonomy of the European patent system, the EPC Implementing Regulations, which, according to Art. 164(1) EPC are an integral part of the

124 O'Connell, *Harvesting External Innovation: Managing External Relationships and Intellectual Property*. (n 57) 43.

125 Margarete Singer and Dieter Stauder, *The European Patent Convention. A Commentary*, vol 1 (3rd edn, Carl Heymanns and Sweet & Maxwell 2003) 87.

126 Pires de Carvalho, *The TRIPS Regime of Patent Rights* (n 29) 294.

127 ibid; Kamperman Sanders A and others, 'Final Report of the Expert Group on Patent Law in the Field of Development and Importance of Biotechnology and Gene Technology' (n 58).

128 EPC, Art. 53(a).

129 Schatz, 'Patents and morality' (n 114) 220.

Convention,[130] can aid in interpreting the content of Art. 53(a) EPC. Rule 28(1) of the EPC Implementing Regulations states that '[u]nder Article 53(a), European patents shall not be granted in respect of biotechnological inventions which, in particular, concern the following: (a) processes for cloning human beings; (b) processes for modifying the germ line genetic identity of human beings; (c) uses of human embryos for industrial or commercial purposes; (d) processes for modifying the genetic identity of animals which are likely to cause them suffering without any substantial medical benefit to man or animal, and also animals resulting from such processes'.[131] In addition, Rule 29(1) of the EPC Implementing Regulations indicates that '[t]he human body, at the various stages of its formation and development, and the simple discovery of one of its elements, including the sequence or partial sequence of a gene, cannot constitute patentable inventions',[132] except when the invention sought to be patented is an 'element isolated from the human body or otherwise produced by means of a technical process, including the sequence or partial sequence of a gene'.[133]

The aforementioned Rules 28(1) and 29(1) of the EPC Implementing Regulations are considered to be a 'relatively clear'[134] list of exceptions. Thus, the commercial exploitation of inventions that fall directly under the latter list should be considered as being against *ordre public* and/or morality, and the conferring of legal protection on them should be refused without any need for further analysis of Art. 53(a) EPC.[135] However, due to the rapid progress in science and technology, the EPC Implementing Regulations are not able to cover all the inventions and ways of exploiting them. Thus, the list of exceptions provided in these Rules of the EPC Implementing Regulations is non-exhaustive – so, even if a certain invention does not fall under any of the said provisions, this does not mean that its commercial exploitation will be in accordance with *ordre public* and/or morality. Hence, it will need to be examined from the general perspective

130 EPC, Art. 164(1).
131 EPC Implementing Regulations, r 28(1).
132 ibid r 29(1).
133 ibid r 29(2).
134 Kathleen Liddell, 'Immorality and Patents: The Exclusion of Inventions Contrary to Ordre Public and Morality' in Annabelle Lever (ed), *New Frontiers in the Philosophy of Intellectual Property* (Cambridge University Press 2012) 140-171, 143.
135 *Transgenic animals/HARVARD* (n 80), para 6.1.

of Art. 53(a) EPC.[136] Therefore, despite the fact that Rules 28-29 of the EPC Implementing Regulations provide for a certain clarity regarding the compliance of the commercial exploitation of a particular invention with *ordre public* and/or morality, the compatibility with Art. 53(a) EPC of the commercial exploitation of inventions which do not fall under these provisions must be assessed separately. The autonomy of the European patent system from other legal systems makes the aforementioned evaluation more complicated.

Taking into account all the above considerations, it is possible to conclude that, in order to interpret and apply Art. 53(a) EPC, (1) it is necessary to understand the scope of an invention and, therefore, an analysis, which requires scientific knowledge, of the claims of the patent application is needed; (2) it is necessary to evaluate which aspects related to the invention in the context of Art. 53(a) EPC fall under the category 'commercial exploitation'; and (3) in certain situations, when, due to the rapid development of science and technology, application of the EPC Implementing Regulations is not possible, Art. 53(a) EPC, the interpretation of which is not obliged to follow the provisions of other legal systems, is applied. In view of the discussed situation, it is possible to conclude that the EPO Examining Division and EPO Boards of Appeal are under the obligation to perform a highly challenging task in order to assess the commercial exploitation of an invention with regard to Art. 53(a) EPC.

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

The history of the creation of the patent system in Europe reveals that the origins of the relationship between the EPOrg and the EU legal order date back to the very beginning of the integration of the European states. At that time after the Second World War, a unitary European patent system was regarded as one of the possible factors that were supposed to ensure peace and prosperity on this continent. The idea of a unitary European patent system was initiated by the Council of Europe in 1949 and its implementation was taken over by the predecessor of the EU, the EEC, in

136 *Transgenic animals/HARVARD* (n 80), para 6.1; Liddell, 'Immorality and Patents: The Exclusion of Inventions Contrary to Ordre Public and Morality' (n 134) 143.

1958.[137] The result of the EEC's work was the project of the European Patent Convention as of 1962, which foresaw the establishment of the European Patent Office and the European Patent Court, whose function should have been the examination of the appeals concerning decisions made by the aforementioned organisation and the interpretation of the provisions of this Convention.[138]

However, later, due to disagreements as to whether this European Patent Convention should include only the EEC states or whether it could be joined by countries outside this community, e.g. the United Kingdom,[139] a version of this document as an international treaty began to be considered, and ultimately the latter option was chosen.[140] As a result, an international treaty, the EPC, which established the EPOrg,[141] legally independent of the EEC and later of the EU, was signed on 5 October 1973,[142] and is considered to be a major achievement of Europe.[143] After the adoption of the EPC, the creation of substantive regulation on EU patents was suspended until 1988, when the preparation of Directive 98/44/EC of the European Parliament and of the Council of 6 July 1998 on the legal protection of biotechnological inventions (the 'Biotech Directive' or 'Directive')[144] began.

Art. 53(a) EPC, analysed in this study, is based on Art. 2(a) of the 1963 version of the Convention on the Unification of Certain Points of Substantive Law on Patents for Invention (the 'Strasbourg Convention'),[145] which

137 Aurora Plomer, 'A Unitary Patent for a (Dis)United Europe: The Long Shadow of History' (2015) 46 International Review of Intellectual Property and Competition Law 508, 515.

138 ibid 517.

139 Peter Drahos, *The Global Governance of Knowledge: Patent Offices and Their Clients* (Cambridge University Press 2010) 120; Winfried Tilmann, 'Moving towards completing the European Patent System: an Overview of the draft Agreement on a Unified Patent Court' (2012) 13 ERA Forum 87, 88.

140 Plomer, 'A Unitary Patent for a (Dis)United Europe: The Long Shadow of History' (n 137) 519-520.

141 EPC, Art. 4(1).

142 Thomas Jaeger, 'Reset and Go: The Unitary Patent System Post-Brexit' (2017) 48 International Review of Intellectual Property and Competition Law 254, 255.

143 Drahos, *The Global Governance of Knowledge: Patent Offices and Their Clients* (n 139) 118.

144 Directive 98/44/EC of the European Parliament and of the Council of 6 July 1998 on the legal protection of biotechnological inventions, OJ, 1998 L 213, p. 13 (Biotech Directive).

145 Convention on the Unification of Certain Points of Substantive Law on Patents for Invention of 27 November 1963 (ETS No. 047) (adopted 27 November 1963).

establishes exceptions to patentability on the grounds of morality and *ordre public*.[146] The full text of the Strasbourg Convention, the aim of which was to unify substantive European patent law, was incorporated into the 1973 version of the EPC after the Contracting States agreed to base the content of the EPC on the provisions of the Strasbourg Convention.[147] During the drafting of the EPC, the 'morality exception' was intended to prevent the patenting of inventions which, based on the morality norms prevailing in all the Contracting States, would be deemed unacceptable.[148]

However, for a long time the aforementioned exception was not considered to be relevant;[149] thus, a more detailed interpretation of Art. 53(a) EPC did not exist. Only later, with growing progress in the biomedical sciences and the technologies related to them, did this legal provision become more frequently invoked, which is illustrated by the cases regarding Art. 53(a) EPC in the late 1980s. The aim of bringing more clarity to the rapidly developing sector of biotechnology, which is expected to experience dramatic growth in the 21st century,[150] influenced the adoption of the Biotech Directive,[151] which was the result of long negotiations. The latter act was intended to ensure unified regulation of the legal protection for biotechnological products and processes in Europe[152] in order to make this market more competitive in comparison to the Japanese and U.S. markets,[153] and more attractive for investment.[154]

146 Hellstadius, *A Quest for Clarity: Reconstructing Standards for the Patent Law Morality Exclusion* (n 6) 190.

147 Parthasarathy and Walker, 'Observing the Patent System in Social and Political Perspective: A Case Study of Europe' (n 16) 327.

148 Hellstadius, *A Quest for Clarity: Reconstructing Standards for the Patent Law Morality Exclusion* (n 6) 190.

149 Schneider, 'Exclusions and Exceptions to Patent Eligibility Revisited: Examining the Political Functions of the 'Discovery' and 'Ordre Public' Clauses in the European Patent Convention and the Arenas of Negotiation' (n 52) 146.

150 OECD, '21st Century Technologies: Promises and Perils of a Dynamic Future' (OECD Publishing 1998).

151 Biotech Directive.

152 Commission, 'Proposal for a Council Directive on the legal protection of biotechnological inventions' COM (88) 496 final, recital 3; Porter, 'The Drafting History of the European Biotechnology Directive' (n 107) 7-9.

153 Timothy Sampson, 'Achieving Ethically Acceptable Biotechnology Patents: A Lesson from the Clinical Trials Directive?' (2003) 25 European Intellectual Property Review 419, 419.

154 Commission, 'Legal protection of biotechnological inventions Frequently Asked Questions on scope and objectives of the EU Directive (98/44)', MEMO/00/39 (3

Despite the fact that the Biotech Directive was aimed at regulating the patentability of inventions by providing more legal protection for investors and encouraging research, ethical questions emerged almost immediately. In fact, they even began dominating economic questions, and for a while were fundamental in analysing the peculiarities of patent protection of biotechnological inventions in the EU.[155] Thus, the Directive became a legal act which placed emphasis on ethical aspects in deciding on the patentability of biotechnological inventions in the Union.

The EU legislative framework concerning the patentability of biotechnological inventions, which has been in place since 1998, makes the situation with regard to compliance with morality and *ordre public* in the context of Art. 53(a) of the Convention even more complex. Despite the fact that the European patent system and the EU legal order are formally independent of each other,[156] questions concerning the relationship between them, including Art. 53(a) EPC and the Biotech Directive, arise from the current situation, which is characterised by the following facts: (1) 27 states[157] out of the 39 EPOrg Member States are members of the EU; (2) certain provisions of the Biotech Directive are identical to Art. 53(a) EPC and the rules of the EPC Implementing Regulations; (3) the relationship between the case law of the EPO and that of the Court of Justice, which are under the obligation to interpret and apply identical or almost identical provisions regarding the patentability of biotechnological inventions, is not clearly defined.

In the scholarly literature it is indicated that, despite the legal independency between the European patent system and the EU legal order, harmony between these systems concerning the patenting of biotechnological inventions was, in fact, desirable.[158] Therefore, when the Biotech Directive was

July 2000) <http://europa.eu/rapid/press-release_MEMO-00-39_en.htm?locale=en> accessed 30 May 2023.

155 Porter, 'The Drafting History of the European Biotechnology Directive' (n 107) 11.

156 Salter, 'Patents and morality: governing human embryonic stem cell science in Europe' (n 102).

157 Austria, Belgium, Bulgaria, Croatia, Cyprus, Czechia, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, the Netherlands, Poland, Portugal, Romania, Slovakia, Slovenia, Spain, Sweden (European Union, Principles, countries, history, Country profiles <https://european-union.europa.eu/principles-countries-history/country-profiles_en> accessed 30 May 2023).

158 Franz Zimmer, 'New Rules and the European Patent Office for Biotechnological Inventions'. <https://grunecker.de/fileadmin/Gruenecker/Informationen/Veroeffentlichungen/biorules.pdf> accessed 30 May 2023.

being drafted, an almost identical provision to Art. 53(a) of the Convention was included in it, while the EPO Administrative Council on 16 June 1999 decided to transpose certain provisions of the Biotech Directive into the EPC Implementing Regulations.[159] Therefore, with regard to the patenting of biotechnological inventions, the Directive and the Convention together with the Implementing Regulations are almost identical.

According to Art. 5(1) of the Biotech Directive, '[t]he human body, at the various stages of its formation and development, and the simple discovery of one of its elements, including the sequence or partial sequence of a gene, cannot constitute patentable inventions'.[160] This provision is identical to Rule 29(1) of the EPC Implementing Regulations in English, German and French.[161] Furthermore, Art. 6(1) of the Biotech Directive, similarly to Art. 53(a) EPC in English, German and French,[162] establishes that '[i]nventions shall be considered not patentable where their commercial exploitation would be contrary to *ordre public* or morality; however, exploitation shall not be deemed to be so contrary merely because it is prohibited by law or regulation'.[163]

Further, the non-exhaustive list in Art. 6(2) of the Biotech Directive states that, in accordance with the aforementioned Art. 6(1), the following are non-patentable: (a) processes for cloning human beings; (b) processes for modifying the germ line genetic identity of human beings; (c) uses of human embryos for industrial or commercial purposes; (d) processes for modifying the genetic identity of animals which are likely to cause them suffering without any substantial medical benefit to man or animal, and also animals resulting from such processes.[164] These provisions are trans-

159 Decision of the EPO Administrative Council dated 16 June 1999, concerning amendments to the Implementing Regulations to the European Patent Convention (EPC), OJ EPO 7/1999, p. 437.

160 Biotech Directive, Art. 5(1).

161 EPC Implementing Regulations, r 29(1) (in English): <https://new.epo.org/en/legal/epc/2020/r29.html>; EPC Implementing Regulations, r 29(1) (in German): <https://new.epo.org/de/legal/epc/2020/r29.html>; EPC Implementing Regulations, r 29(1) (in French): <https://new.epo.org/fr/legal/epc/2020/r29.html> accessed 30 May 2023.

162 EPC, Art. 53(a) (in English): <https://new.epo.org/en/legal/epc/2020/a53.html>; EPC, Art. 53(a) (in German): <https://new.epo.org/de/legal/epc/2020/a53.html>; EPC, Art. 53(a) (in French): <https://new.epo.org/fr/legal/epc/2020/a53.html> accessed 30 May 2023.

163 Biotech Directive, Art. 6(1).

164 ibid Art. 6(2).

posed in Rule 28(1) of the EPC Implementing Regulations, which states that, according to Art. 53(a) EPC, patents shall not be granted to precisely the same categories of biotechnological inventions.[165]

As the list of exceptions included in the EPC Implementing Regulations and Art. 6(2) of the Biotech Directive is non-exhaustive, it is not to be assumed that, if an invention does not appear on this list, it complies with the requirements of *ordre public* and/or morality. In this case, general provisions are invoked and the commercial exploitation of an invention is assessed under either Art. 53(a) EPC or Art. 6(1) of the Biotech Directive.[166] In contrast, with regard to inventions falling directly under the non-exhaustive list of exceptions in Rule 28(1) of the EPC Implementing Regulations or Art. 6(2) of the Biotech Directive, the grant of legal protection *must* be refused without further analysis of Art. 53(a) EPC or Art. 6(1) of the Biotech Directive.[167]

The link between the EPOrg and the EU legal framework on patents is also reflected in the response of the European Parliament to specific European patents and the related decisions of the EPO Boards of Appeal. In its statements on the patentability of human embryonic stem cells, this EU institution indicated, that despite these systems being separate and independent of each other, they are linked by Rule 28[168] of the Implementing Regulations,[169] based on Art. 6(2) of the Biotech Directive. In addition, on 30 March 2000, the European Parliament adopted a resolution stating that it was 'deeply shocked' by the granting of a patent[170] for technologies allowing 'the genetic modification of the germ line of human embryos

165 EPC Implementing Regulations, r 28(1): (a) processes for cloning human beings; (b) processes for modifying the germ line genetic identity of human beings; (c) uses of human embryos for industrial or commercial purposes; (d) processes for modifying the genetic identity of animals which are likely to cause them suffering without any substantial medical benefit to man or animal, and also animals resulting from such processes.

166 *Transgenic animals/HARVARD* (n 80), para 6.1 (at the time of the *Transgenic animals/HARVARD* decision and before 13 December 2007: EPC Implementing Regulations, r 23d(d)).

167 ibid.

168 Before 13 December 2007: EPC Implementing Regulations, r 23d(d).

169 Salter, 'Patents and morality: governing human embryonic stem cell science in Europe' (n 102).

170 European Patent No. EP 0695351, 'Isolation, selection and propagation of animal transgenic stem cells', application date 21 April 1994. Later, this patent was changed by adding the term 'non-human' before the term 'animal' in the patent claims. (*Edinburgh Patent* (n 23), paras 11 and 3.3.2).

and of the embryos themselves',[171] as well as the isolation, selection, and propagation of animal and transgenic stem cells that can be used for the cloning of human beings.[172] Furthermore, the European Parliament called on the EPO 'to ensure that all existing patents and patent applications in Europe do not violate the principle of non-patentability of humans, their genes or cells in their natural environment and human embryos'.[173] This resolution even questioned the activities of the EPO, requesting a 'review of the operations of the EPO to ensure that it becomes publicly accountable in the exercise of its functions, and to amend its operating rules to provide for it revoking a patent on its own initiative'.[174]

The almost identical provisions of the EPC, the EPC Implementing Regulations and the Biotech Directive discussed above, as well as this resolution of the European Parliament show that, despite the legal independence of the EPOrg and the EU legal order, there exists a need to 'bridge the gap' between these systems[175] and to maintain a maximally uniform legal framework for the patenting of biotechnological inventions across Europe.[176] On the one hand, this makes it possible to acknowledge an actual link between the EPOrg and the EU legal system. On the other hand, given the formal independence of these systems, their relationship is reasonably described in the scholarly literature as 'complex'[177] and 'uncertain'.[178] The interpretation provided by the EPO and the CJEU has a significant influence on the content of the aforementioned norms, including the relationship between these two legal systems. Hence, in order to better understand the connection

171 European Parliament resolution on the decision by the European Patent Office with regard to patent No EP 695 351 granted on 8 December 1999, 30 March 2000, OJ C 378, p. 95, para 1.

172 ibid.

173 ibid para 9.

174 ibid.

175 Aerts, 'The Patenting of Biotechnological Inventions in the EU, the Judicial Bodies Involved and the Objectives of the EU Legislator' (n 110) 89.

176 ibid 91.

177 Christine Godt, 'Experts and Politics in Patent Policy: The Final Report of the Expert Group on the Development and Implications of Patent Law in the Field of Biotechnology and Genetic Engineering of the European Commission 17 May 2016' (2016) 47 International Review of Intellectual Property and Competition Law 960, 961.

178 Rob J Aerts, 'The European Commission's notice on Directive 98/44 and the European Patent Organization's response: the unpredictable interaction of EU and EPC law' (2018) 13 Journal of Intellectual Property Law & Practice 721, 724.

between Art. 53(a) EPC and the Biotech Directive, the case law and the relationship between these institutions need to be analysed.

In 2011, the Court of Justice, in its opinion on the establishment and status of the European and Community Patents Court, stated that, according to Art. 19(1) of the Treaty on the European Union (the 'EU Treaty'),[179] 'the guardians of that legal order [i.e. the European Union legal order] and the judicial system of the European Union are the Court of Justice and the courts and tribunals of the Member States'.[180] Additionally, according to this opinion, 'it is for the Court to ensure respect for the autonomy of the European Union legal order',[181] and Art. 4(3) of the EU Treaty establishes the principle of sincere cooperation, which means that the EU Member States must ensure the application of, and compliance with, Union law within their territory.[182] Finally, the CJEU held that the European and Community Patents Court, which would not be part of the EU institutional and judicial system, but would have exclusive jurisdiction over the interpretation and application of EU law in patent disputes between individuals, and which would deprive national courts of the right to hear such cases and to refer matters to the Court of Justice for a preliminary ruling,[183] is incompatible with the EU Treaty and the Treaty on the Functioning of the European Union.[184]

According to the legal doctrine, such an interpretation by the Court of Justice means that the EPO Divisions established by international agreement, i.e. the EPC, are not regarded as appropriate subjects for the interpretation and application of the provisions of the Biotech Directive, even those coinciding with the provisions of the EPC Implementing Regulations, because they are not part of the EU legal order.[185] If the said institutions were able to directly interpret and apply the Biotech Directive, the EPO Divisions would deprive the CJEU and national courts of the EU Member

179 Consolidated version of the Treaty on the European Union, OJ, 2016 C 202, p. 13 (EU Treaty).
180 Opinion of the Court 1/09 (n 90), para 66.
181 ibid para 67.
182 ibid para 68.
183 ibid paras 78-81 and 84-85.
184 Consolidated version of the Treaty on the Functioning of the European Union, OJ, 2016 C 202, p. 47; Opinion of the Court 1/09 (n 90), para 89.
185 Aerts, 'The Patenting of Biotechnological Inventions in the EU, the Judicial Bodies Involved and the Objectives of the EU Legislator' (n 110) 91.

States of the discussed exclusive power in relation to EU law.[186] Therefore, according to the aforementioned opinion of the Court of Justice, the EPO Divisions are able to interpret the EPC and the EPC Implementing Regulations in the light of this Directive, but, even though the provisions of the Biotech Directive are transposed into the EPC Implementing Regulations, EPO Divisions cannot directly interpret and apply the provisions of that legal act.[187]

The European patent system also distances itself from the Biotechnology Directive and the CJEU case law. In the *Use of embryos/WARF* case, in which the issue of referral to the CJEU on the interpretation of Art. 6(2) of the Biotech Directive was raised, the EPO Enlarged Board of Appeal stated that the EPO decisions concerning patents could only be reviewed by the appellate bodies within the Office and not by any external judicial institutions.[188] According to the Board, the existence of identical provisions in both the EPC Implementing Regulations and the Biotech Directive does not mean that the Court of Justice has the authority to make decisions concerning the interpretation of the EPC instead of the EPO Boards of Appeal.[189] This position is in line with Art. 23(3) EPC, which reflects the independence of the EPO Boards of Appeal by stating that '[i]n their decisions the members of the Boards shall not be bound by any instructions and shall comply only with the provisions of this Convention'.[190]

However, the EPO case law has noted that, although the decisions of the CJEU are not binding, they can be considered 'persuasive'.[191] Also, the EPOrg itself has recognised the need for unity of the European patent system with the Biotech Directive.[192] This is also confirmed by Rule 26(1) of the EPC Implementing Regulations, which states that this Directive must be used as a supplementary means of interpretation concerning the applications and patenting of biotechnological inventions.[193]

186 Opinion of the Court 1/09 (n 90), para 80.
187 Aerts, 'The Patenting of Biotechnological Inventions in the EU, the Judicial Bodies Involved and the Objectives of the EU Legislator' (n 110) 91.
188 *Use of embryos/WARF* (n 80), paras 4-5.
189 ibid para 6.
190 EPC, Art. 23(3).
191 *Culturing stem cells/TECHNION* (n 23), para 39.
192 Notice dated 1 July 1999 concerning the amendment of the Implementing Regulations to the European Patent Convention, OJ EPO 08-09/1999, p. 573.
193 EPC Implementing Regulations, r 26(1).

The latter objective is illustrated by the 2016 decision of the EPO Board of Appeal in the case *Human pluripotent progenitor stem cells/PROGENITOR LABS*.[194] In this case, the EPO Board of Appeal, on its own initiative, decided to resubmit the assessment of the commercial exploitation of an invention under Art. 53(a) EPC to the EPO Examining Division in the light of the CJEU's ruling in the *International Stem Cell Corporation* case,[195] which held that exploitation of parthenogenetically derived human pluripotent stem cells is not regarded as exploitation of a human embryo.[196] All this not only shows the usefulness of the decisions of the Court of Justice to the European patent system, but also means that the EPO is able to deliberately comply with the EU law[197] and understands the necessity of the compatibility between the case law of the EPO and that of the Court of Justice.

The situation described above may be affected by the reform of the European patent system with the establishment of Unitary Patent protection.[198] This reform is based on the Agreement on a Unified Patent Court,[199] Regulation (EU) No 1257/2012 of the European Parliament and of the Council of 17 December 2012, which implements enhanced cooperation in the area of the creation of unitary patent protection ('Regulation 1257/2012')[200] and Council Regulation (EU) No 1260/2012 of 17 December 2012, which implements enhanced cooperation in the area of the creation of unitary patent protection with regard to the applicable translation arrangements ('Regulation No 1260/2012').[201] It is argued that the Unitary Patent package, which took effect after the Agreement on a Unified Patent Court entered into force,[202] will lead to even more complex interactions between

194 *Human pluripotent progenitor stem cells/PROGENITOR LABS* (n 81).
195 *International Stem Cell Corporation v Comptroller General of Patents, Designs and Trade Marks* (n 90).
196 *Human pluripotent progenitor stem cells/PROGENITOR LABS* (n 81), para 2.
197 On its website, the EPO acknowledges that 'The EPO also follows the rulings of the European Court of Justice on the correct interpretation of the Directive, and has incorporated such rulings into its working practice.' (European Patent Office, The role of the EPO (15 November 2022) <https://www.epo.org/en/news-events/in-focus/biotechnology-patents/the-role-of-the-epo> accessed 30 May 2023).
198 Also referred to as the 'Unitary Patent package'.
199 Agreement on a Unified Patent Court.
200 Regulation 1257/2012.
201 Regulation 1260/2012.
202 According to Art. 89 of the Agreement on a Unified Patent Court, this Agreement will come into force four months after it has been ratified by 13 Contacting States,

the EU and the European patent legal systems,[203] which are considered to be the independent pillars of patent protection in Europe.[204]

Regulation 1257/2012 provides for the possibility of obtaining a European patent with unitary effect (the 'Unitary Patent'),[205] which, unlike the 'classic' European patent, is valid generally in the participating EU Member States.[206] The Agreement on a Unified Patent Court provides for the establishment of a Unified Patent Court (the 'UPC'), which has exclusive jurisdiction in a number of cases relating to European patents, including cases concerning infringements of such patents and their revocation.[207] This means that, despite certain exceptions, competence concerning European patent litigation is essentially transferred from the national courts of the EPO Contracting States to a supranational court set up by an international treaty.

Despite the aforementioned novelties, the procedure for granting the Unitary Patent remains the same as for the 'classic' European patent and takes place at the Office. Only later, after the aforementioned process has ended and after the European patent has been granted, will its holder have the right to apply to the EPO to request the unitary effect of the European patent in all the participating Member States.[208] This means that, during the procedure for the granting of a Unitary Patent, the EPO in particular assesses the invention not only against the patentability requirements, but also against the exceptions, including Art. 53(a) of the Convention.

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including three Member States with the largest number of European patents (Agreement on a Unified Patent Court, Art 89).

203 Frederica Baldan and Esther Van Zimmeren, 'The future role of the unified patent court in safeguarding coherence in the European patent system' (2015) 52 Common Market Law Review 1529, 1531.

204 ibid 1534.

205 Regulation 1257/2012, Art. 2(c).

206 ibid Art. 3(1). As of May 2023, there were 24 EU Member States that have signed the Agreement on a Unified Patent Court and were considered UPC Member States (Unified Patent Court's official website. UPC Member States <https://www.unified-patent-court.org/en/organisation/upc-member-states> accessed 30 May 2023).

207 Agreement on a Unified Patent Court, Articles 3 and 32. However, during the transitional period of seven years, actions for infringement or revocation may still be brought before national courts. In addition, actions pending before national courts before the end of the transitional period of seven years will remain before the national courts. Also the proprietors of European patents granted or applicants for European patents applied for before the end of the transitional period of seven years can opt out of the competence of the UPC for their patents or applications (ibid, Art. 83(1) and (3)).

208 Regulation 1257/2012, recital 17 and Art. 9(1)(a); EPC, Art. 142.

Similarly as with any European patent, it is possible to challenge the Unitary Patent at the Office by filing an opposition[209] under the grounds set out in Art. 100 EPC within nine months from the date of its publication in the European Patent Bulletin.[210] Therefore, during the opposition procedure, the EPO has the right to, and in accordance with Art. 53(a) EPC may, revoke the Unitary Patent already granted. However, in accordance with the Agreement, with the exception of the opposition procedure mentioned above, after the registration of a Unitary Patent, it is the UPC that has exclusive jurisdiction to resolve all disputes arising from the Unitary Patent[211] and, after a transitional period, from all 'classic' European patents.[212]

Such legal regulation may increase the likelihood of conflicting decisions between the EPO and the Unitary Patent system. On the one hand, the UPC is not obliged to follow the interpretation of the Office as regards Art. 53(a) EPC. Therefore, there is a possibility that the decisions of the former body in relation to this legal norm of the Convention may not be in line with the position of the latter institution. On the other hand, as previously discussed in this research, the EPO itself, as an independent autonomous organisation, is not obliged to follow the case law of the UPC. At present, there is no formal mechanism to integrate the UPC's interpretation and application of the relevant provisions of EU law, the EPC and other sources of law into the European patent system based on the Convention. Thus, if the UPC, based on Art. 6(1) of the Biotech Directive and Art. 53(a) EPC,[213] revokes a Unitary Patent which was previously gran-

209 Rob J Aerts, 'Biotechnology patenting caught between Union law and EPC law: European bundle patents, unitary patents and intentional harmonization of decisions in the internal market' (2016) 6 Queen Mary Journal of Intellectual Property 287, 294

210 EPC, Art. 99.

211 Agreement on a Unified Patent Court, Art. 32(1).

212 ibid Art. 83(1). The proprietors of European patents granted or applicants for European patents applied for before the end of the transitional period of seven years can opt out of the competence of the UPC for their patents or applications (ibid Art. 83(1) and (3)).

213 According to Art. 20 of the Agreement on a Unified Patent Court, the UPC shall apply EU law in its entirety and shall respect its primacy; however, according to Art. 24 of the Agreement on a Unified Patent Court, in full compliance with Art. 20, when hearing a case brought before it under the Agreement on a Unified Patent Court, the UPC can *inter alia* base its decisions on the EPC (ibid Articles 20 and 24).

ted by the EPO, after the revocation of this intellectual property right and submission of this decision to the Office,[214] the latter, when deciding on other patent applications in the future and interpreting Art. 53(a) of the Convention, is not under any formal obligation to follow the interpretation of the UPC.[215] Thus, under the Unified Patent package, the decisions of the said institutions on the patentability of the biotechnological inventions will not necessarily ensure harmony between these patent systems in force in parallel within the EU Member States.[216]

The problem of conflicting decisions between the UPC and the EPO may also arise during the opposition proceedings. If the opposition has been filed within nine months of the publication of the mention of the grant in the European Patent Bulletin, a Unitary Patent may be revoked by a decision of the Office, in accordance with Art. 53(a) EPC.[217] In parallel, proceedings for the revocation of the same Unitary Patent can also take place before the UPC seeking the abolishment of this exclusive right.[218] According to the Agreement on a Unified Patent Court, the party in the opposition proceedings must inform the UPC, which may suspend the proceedings until the decision is made by the EPO.[219] However, the UPC may refuse to suspend the proceedings, which would mean the likelihood of conflicting decisions between the EPO and the UPC.[220]

Scholarly literature indicates that the Office interprets and applies Art. 53(a) EPC in order to ensure the broadest possibility of patenting of inventions. Thus, there is a high likelihood that, if the UPC does not revoke

214 Agreement on a Unified Patent Court, Art. 65(5).

215 Aurora Plomer, 'The Unified Patent Court: Past, Present and Future' in Marise Cremona, Anne Thies and Ramses Wessel (eds) *The European Union and International Dispute Settlement* (Hart Publishing 2017) 275-292, 290.

216 Aerts, 'Biotechnology patenting caught between Union law and EPC law: European bundle patents, unitary patents and intentional harmonization of decisions in the internal market' (n 209) 290. This refers to the 'classic' European Patents and the Unitary Patents.

217 EPC, Articles 99 and 100.

218 This procedure can also take place in the national court if the EU State is not party to the Agreement on a Unified Patent Court.

219 Agreement on a Unified Patent Court, Art. 33(10).

220 Baldan and Van Zimmeren, 'The future role of the unified patent court in safeguarding coherence in the European patent system' (n 203) 1568; McMahon, 'An Institutional Examination of the Implications of the Unitary Patent Package for the Morality Provisions: a Fragmented Future too Far?' (n 35) 52.

the Unitary Patent, the EPO will also uphold it.[221] The greater likelihood of contradictions between the decisions of the EPO and the UPC arises when the latter revokes a patent which was found valid by the Office.[222] This situation would mean the invalidity of the patent in the EU countries which are part of the Agreement on a Unified Patent Court; however, it would remain valid in those countries which do not participate in the mentioned agreement.[223]

In view of the situation discussed above, it can be indicated that, in order to achieve greater harmony between the patent systems existing in Europe, the EPO may organise informal meetings with the judges of the UPC in the same way as meetings with judges of national courts and with the members of the Boards are currently organised.[224] Although such cooperation is encouraged for greater harmony, scholarly literature emphasises that, regardless of the degree of uniformity which is reached in the interpretation of the legal rules by the UPC at a stage after the granting of a patent, without changing the Convention, this cannot have any formal effect for the interpretation and application of the EPC carried out by the EPO.[225]

However, legal doctrine indicates that the possibility for the UPC to refer to the Court of Justice, in accordance with Art. 21 of the Agreement on a Unified Patent Court, in order to 'ensure the correct application and uniform interpretation of Union law'[226] may potentially reduce the differences between the interpretations of those entities with respect to the highly similar legal rules.[227] Although the interpretation of the Court of Justice does not have any formal effect on the decisions of the Office, in the light of the above-mentioned intention of the EPO and the CJEU to factually maintain harmony between the interpretations of Art. 53(a) EPC together with the provisions of the EPC Implementing Regulations and the relevant provisions of the Biotech Directive, preliminary rulings consistent with the case law of the EPO may help the UPC to take decisions that are more in line with the EPO's position. Also, looking at the current approach

221 McMahon, 'An Institutional Examination of the Implications of the Unitary Patent Package for the Morality Provisions: a Fragmented Future too Far?' (n 35) 52.
222 ibid 52-53.
223 ibid 53.
224 Plomer, 'The Unified Patent Court: Past, Present and Future' (n 215) 290.
225 ibid 290-291.
226 Agreement on a Unified Patent Court, Art. 21.
227 McMahon, 'An Institutional Examination of the Implications of the Unitary Patent Package for the Morality Provisions: a Fragmented Future too Far?' (n 35) 60.

of the EPO with regard to the case law of the Court of Justice regarding the aforementioned Directive, the Office itself is able to further take into consideration the rulings of the CJEU.

These institutions, which are under an obligation to interpret and apply almost identical EPC and EU legal norms regarding the patenting of biotechnological inventions, are not obliged to follow each other. Therefore, the establishment of a third supranational body, i.e. the UPC, which would interpret and apply both Art. 53(a) of the Convention with related provisions and the relevant norms of the Biotech Directive, may even increase the possibility of contradictory decisions between the aforementioned new judicial institution and the Divisions of the Office. However, based on the above-discussed factual objective of maintaining harmony between the rulings of the EPO and the CJEU regarding the patenting of biotechnological inventions, the decisions of the Court of Justice, which are binding on the UPC, are able to reduce the possibility for the latter to adopt decisions contrary to the point of view of the Office.

Based on everything discussed above, it is possible to conclude that, currently, both the Convention and the Biotech Directive, despite their almost identical provisions analysed above as well as the objective of effectively sustaining harmony in the system for patent granting in Europe, are two separate legislative acts which are formally independent of each other. Therefore, the EPO, when interpreting the content of Art. 53(a) EPC and deciding on the patentability of biotechnological inventions, is under no legal obligation to comply with the Directive and the related interpretation of the Court of Justice. Similarly, the EU legal system is under no obligation to comply with the European patent system and the EPO case law. The only possible connection between them is the fact that the Office can voluntarily interpret Art. 53(a) of the Convention in the light of the Biotech Directive.[228] This is reflected in some of the EPO case law,[229] where the importance of the CJEU's interpretation of the Directive to patent law has been recognised. This shows that the EPO has a rather flexible approach towards the case law of the Court of Justice and other EU legal sources on matters related to the patenting of the aforementioned inventions. Therefore, based

228 Aerts, 'The Patenting of Biotechnological Inventions in the EU, the Judicial Bodies Involved and the Objectives of the EU Legislator' (n 110) 92. See also Aerts, 'Biotechnology patenting caught between Union law and EPC law: European bundle patents, unitary patents and intentional harmonization of decisions in the internal market' (n 209) 301.

229 See e.g. *Culturing stem cells/TECHNION* (n 23), para 39.

on Rule 26(1) of the EPC Implementing Regulations, when deciding on the discussed questions, it retains the possibility of relying on the experience of the EU legal framework in addressing these issues. This reveals the importance of the case law of the EPO Divisions for the interpretation and application of Art. 53(a) EPC and the EPC Implementing Rules, not only in the long-standing European patent legal framework but also in the context of the Unitary Patent package.

1.3. The Role of the Divisions of the European Patent Office in the Interpretation and Application of Article 53(a) of the European Patent Convention

In 1961, the EPC Working Party indicated that a universally acknowledged European definition of *ordre public* and morality did not exist.[230] Despite the fact that it was possible to characterise the national legal systems of participating countries by their different perceptions of *ordre public* and morality, all of the participants in the EPC negotiations agreed on the necessity of establishing a provision in the European patent system which would prevent the grant of a patent for inventions that are 'contrary to morality or *ordre public*'.[231] According to the EPC Working Party, the obligation to define what constitutes the content of these categories fell on the 'European institutions'.[232]

Such a position to leave the latter decision to the European institutions could be related to the fact that the idea of the European patent system appeared in the initial phase of the integration of the Old Continent,[233] when the vision of the union of European countries was rather abstract.[234] At that stage it was not clear what the structure of the European Community would be, and the possibility of establishing a European Community pat-

230 Oudemans, *The draft European Patent Convention: a commentary with English and French texts* (n 112) 21; Parthasarathy and Walker, 'Observing the Patent System in Social and Political Perspective: A Case Study of Europe' (n 16) 325.

231 Parthasarathy and Walker, 'Observing the Patent System in Social and Political Perspective: A Case Study of Europe' (n 16) 325.

232 Proceedings of the 1st meeting of the Patents Working Party, Document IV/2767/61-E (Brussels, 17-28 April 1961) <https://www.epo.org/law-practice/legal-texts/epc/archive/traveaux.html> accessed 30 May 2023, 7-8.

233 Porter, 'The Drafting History of The European Biotechnology Directive' (n 107) 6.

234 Plomer, 'A Unitary Patent for a (Dis)United Europe: The Long Shadow of History' (n 137) 509.

ent was also discussed for some time.[235] Taking into consideration these circumstances, the instruction of the drafters of the EPC that the obligation to define the content of the discussed categories falls on the European institutions should be considered understandable. However, the EPC never became an agreement of the European Community, or later the EU. In view of this, looking at the current situation where, as analysed in this study, the EPOrg is regarded as an autonomous legal order, it is possible to conclude that the institution in question should be the EPO, and more precisely, its Divisions. The most important of these with regard to the interpretation of Art. 53(a) EPC are the EPO's Examining Division,[236] Opposition Division,[237] Boards of Appeal[238] and Enlarged Board of Appeal.[239]

Essentially, the EPC foresees a centralised procedure for European patent granting[240] and the procedure for challenging a patent, i.e. an opposition that can be filed within nine months after 'the publication of the mention of the grant of the European patent in the European Patent Bulletin'.[241] After this centralised procedure for the granting of a European patent is completed, the patent in question becomes a bundle of individual national patents,[242] every part of which no longer falls under the jurisdiction of the EPOrg but rather under the jurisdiction of the institutions of a Contracting State and is valid in the territory of that state.[243] For this reason, and because of the absence of a centralised dispute resolution body in the European patent system, in order to file a claim regarding a patent infringement or patent validity, at the national stage one has to individually refer to the competent court of each Member State where the patent in

235 E.g. Krieger, 'When will the European Community patent finally arrive?' (n 108) 855; 1975 Convention for the European Patent for the common market (Community Patent Convention) (not in force).
236 EPC, Art. 18.
237 ibid Art. 19.
238 ibid Art. 21.
239 ibid Art. 22.
240 ibid Articles 52-66.
241 ibid Art. 99.
242 European Patent Office, How to apply for a European patent <https://www.epo.org/applying/basics.html> accessed 30 May 2023; Krieger, 'When will the European Community patent finally arrive?' (n 108) 856.
243 Gitter, 'Led Astray by the Moral Compass: Incorporating Morality into European Union Biotechnology Patent Law' (n 95) 20.

question is valid.[244] The decisions of the latter court will only have force in the territory of the state where a certain European patent, granted on the basis of the aforementioned procedure, is valid.

The above discussion shows that the centralised functioning of the European patent system which is based on the EPOrg manifests itself in the stages of the patent granting and the opposition proceedings. Therefore, the above-mentioned units of the EPO are those subjects which have the competence to interpret the provisions of the EPC and the EPC Implementing Regulations at the level of the European patent system, within the boundaries established by the Convention.[245] Furthermore, even the scholarly legal literature states that patent examination, grant and national court decisions form 'tacit policy-making practices masked as mere administrative execution of law'.[246] Therefore, in order to understand the peculiarities of the application and interpretation of Art. 53(a) EPC with regard to biotechnological inventions, the case law of both the EPO Boards of Appeal and other EPO Divisions should be analysed.

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

The EPO's position regarding certain issues related to the granting of European patents is reflected in the Guidelines for Examination and the EPO case law. According to the Guidelines for Examination, there cannot be statements in the patent application that are against *ordre public* or morality.[247] For this reason, the Receiving Section of the EPO may check the description, claims and drawings of a European patent application to ensure the absence of the latter type of statements.[248]

244 EPC, Art. 138(3); *Patent litigation in Europe* (European Patent Office 2019) <https://documents.epo.org/projects/babylon/eponot.nsf/0/05B84848CBCF7338C1257833003C2531/$FILE/patent_litigation_in_europe_2019_en.pdf> accessed 30 May 2023, 3.

245 EPC, Articles 21-22.

246 Schneider, 'Exclusions and Exceptions to Patent Eligibility Revisited: Examining the Political Functions of the 'Discovery' and 'Ordre Public' Clauses in the European Patent Convention and the Arenas of Negotiation' (n 52) 156-157.

247 Guidelines for Examination, March 2023 (n 63), pt A-III, 8.1.

248 ibid.

To achieve this, during the examination the question is raised as to whether there are no statements that could incite riots or other actions contrary to *ordre public*, racial, religious or similar kinds of discrimination, criminal acts or other grossly obscene content in the application.[249] Furthermore, the Guidelines for Examination indicate that examples of inventions in the field of biotechnology that are contrary to *ordre public* or morality are presented in the non-exhaustive lists in Rule 28(1) and Rule 29(1) of the EPC Implementing Regulations.[250]

The Guidelines for Examination also state that the provision in Art. 53(a) of the Convention can be applied only in rare and extreme cases, and a fair test is 'to consider whether it is probable that the public in general would regard the invention as so abhorrent that the grant of patent rights would be inconceivable'.[251] The possibility of an invention being improperly exploited cannot allow rejection of a patent application if the same invention can also be exploited in ways that are not contrary to *ordre public* or morality.[252] These provisions of the Guidelines for Examination allow it to be stated that the Office is aiming for a rather narrow interpretation and application of Art. 53(a) EPC, which is also supported by some of the case law of the EPO Divisions as well as by the legal doctrine.[253]

EPO Boards of Appeal do not have many decisions concerning patentability of biotechnological inventions where Art. 53(a) EPC would be interpreted and applied on the basis of biomedical sciences. Although this provision has become more relevant in recent decades due to the advances in the field of biomedical sciences, attention to Art. 53(a) EPC in the EPO case law has not helped to reach a consensus on the interpretation and application of the discussed provision when deciding on issues concerning the patentability of inventions in the scientific field in question. This situ-

249 Guidelines for Examination, March 2023 (n 63), pt A-III, 8.1.
250 ibid pt G-II, 4.1 and 5.3.
251 ibid.
252 ibid pt G-II, 4.1.
253 *Onco-Mouse* (n 80), para 4.5; *Plant cells/PLANT GENETIC SYSTEMS* (n 22), para 8; *Euthanasia Compositions/MICHIGAN STATE UNIV* (n 54), para 5.4; Gitter, 'Led Astray by the Moral Compass: Incorporating Morality into European Union Biotechnology Patent Law' (n 95) 23.

ation is acknowledged by the patent examiners[254] working at the EPO and illustrated by the EPO case law, which is often analysed by scholars.[255]

However, in order to understand the relationship between European patent law and the biomedical sciences in the context of Art. 53(a) EPC, it is necessary to analyse the EPO case law[256] revealing the current interpretation and application of the latter provision of the Convention with regard to biotechnological inventions and those of other spheres of biomedical sciences,[257] which, taking into consideration scientific progress, will only develop in the future. Taking into account the objective and the tasks of this study as well as other research carried out so far, when analysing the EPO case law, the following aspects are identified: (1) tests for assessing compliance with Art. 53(a) EPC; (2) standards for assessing compliance with Art. 53(a) EPC; (3) the concept and scope of the term 'commercial exploitation'.

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

The EPO case law indicates that, based on Art. 53(a) EPC, the question of whether a patent can be granted for a particular invention has to be answered separately in each individual case.[258] The fact that the interpretation and application of the discussed provision of the Convention requires evaluation of the commercial exploitation of an invention with regard to such abstract and 'inherently vague'[259] categories as *ordre public* and mor-

254 Parthasarathy and Walker, 'Observing the Patent System in Social and Political Perspective: A Case Study of Europe' (n 16) 340-343.

255 See e.g. Roger Brownsword, 'Human Dignity, Ethical Pluralism, and the Regulation of Modern Biotechnologies' in Thérèse Murphy (ed), New Technologies and Human Rights (OUP 2009) 19-84; Sterckx and Cockbain, *Exclusions from Patentability, How Far Has the European Patent Office Eroded Boundaries?* (n 94) 243-308; Hellstadius, *A Quest for Clarity: Reconstructing Standards for the Patent Law Morality Exclusion* (n 6).

256 For more information about the identification of the decisions of the EPO case law, see 'Introduction'.

257 In certain exceptional cases, this study also discusses inventions that do not fall within the field of biomedical sciences.

258 *Plant cells/PLANT GENETIC SYSTEMS* (n 22), para 13.

259 Clement Salung Petersen, Thomas Riis and Jens Hemmingsen Schovsbo, 'The Unified Patent Court (UPC) in Action: How Will the Design of the UPC Affect Patent Law?' in Rosa Maria Ballardini, Marcus Norrgård and Niklas Bruun (eds) *Transi-*

ality suggests that finding any common ground in the EPO case law is not an easy task. Therefore, although the tests for assessing compliance with Art. 53(a) EPC have already been quite extensively discussed in the legal literature, there is no final agreement on how and under what circumstances they should be applied.[260] However, there is a consensus in the scholarly literature that each of the aforementioned tests is based on one of the ethical theories existing in the Western legal tradition: deontology or utilitarianism.[261]

The first most widely known instance when an issue concerning patent granting for an invention on the grounds of Art. 53(a) EPC occurred was when the Harvard Medical School filed an application for a patent containing claims for a process to create a genetically modified mouse by way of inserting an activated oncogene and using such an animal for research into disease.[262] In 1989, the EPO Examining Division rejected the patent application on the grounds of Art. 53(b) EPC[263] and Art. 83 EPC, indicating that the genetically modified mouse falls under the scope of these provisions of the Convention.[264] In this decision, the EPO Examining Division noted separately that Art. 53(a) EPC was not the basis for rejection of this application.[265]

In response to this situation, the applicant filed an appeal, which, unlike the previous proceedings, involved an interpretation and application of

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tions in European Patent Law: Influences of the Unitary Patent Package (Kluwer Law International 2015) 37-57, 47.

260 E.g. Amanda Warren-Jones, 'Vital parameters for patent morality – a question of form' (2007) 2 International Review of Intellectual Property and Competition Law 832; Brownsword, 'Human Dignity, Ethical Pluralism, and the Regulation of Modern Biotechnologies' (n 255); Liddell, 'Immorality and Patents: The Exclusion of Inventions Contrary to Ordre Public and Morality' (n 134) 152-154; Straus, '*Ordre public* and morality issues in patent eligibility' (n 56); Hellstadius, *A Quest for Clarity: Reconstructing Standards for the Patent Law Morality Exclusion* (n 6).

261 E.g. Sterckx and Cockbain, *Exclusions from Patentability, How Far Has the European Patent Office Eroded Boundaries?* (n 94); Hellstadius, *A Quest for Clarity: Reconstructing Standards for the Patent Law Morality Exclusion* (n 6) 236.

262 European Patent Application No. 85 304 490.7, published as No. 0 169 672.

263 Art. 53(b) EPC: 'European patents shall not be granted in respect of: [...] b) plant or animal varieties or essentially biological processes for the production of plants or animals; this provision shall not apply to microbiological processes or the products thereof'; Art. 83 EPC: 'The European patent application shall disclose the invention in a manner sufficiently clear and complete for it to be carried out by a person skilled in the art.' (EPC, Articles 53(b) and 83).

264 *Harvard/Onco-Mouse* (n 75), paras 7.1.5-7.1.8 and 11.2-11.4.

265 ibid para 10.3.

Art. 53(a) EPC. In 1990, one of the available tests, the weighing test, was applied in this *Onco-mouse/HARVARD* case.[266] In this case, it was concluded that the decision as to whether Art. 53(a) EPC limits the patentability of this invention mostly depends on the result of the careful weighing of the arguments concerning the suffering of the animal and potential risks to the environment against the arguments regarding the benefit this patent could bring to humanity as a whole.[267]

In 1992, after the patent analysed in the *Onco-mouse/HARVARD* case was granted,[268] the aforementioned weighing test was applied by the EPO Examining Division in assessing the compliance of the commercial exploitation of another invention with regard to *ordre public* and morality. The claims of the invention in question encompassed a genetically modified mouse gradually losing its hair, which could be used to create treatment for human hair loss and to develop wool production technologies.[269] After weighing the benefits of the invention (the possibility of treating hair loss or producing wool) against the drawbacks (the suffering of these genetically modified animals), the EPO Examining Division established that the latter outweigh the benefits and stated, according to Art. 53(a) EPC, that the commercial exploitation of the invention in question can be contrary to morality.[270]

After the Biotech Directive came into force, a provision similar to its Art. 6(2)(d) was transposed into Rule 23d(d)[271] of the EPC Implementing Regulations. This rule excludes European patents for biotechnological inventions specifically related to 'processes for modifying the genetic identity

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

267 ibid.

268 The mention of the grant of Patent No. 0 169 672 was published in the European Patent Bulletin 1992/20 of 13 May 1992 ([1992] EPO OJ 292).

269 European Patent No. 89913146.0, 'Transgenic mice for the analysis of hair growth', application date 17 November 1989, application rejected on 25 July 1993. See also 'Bioethics and Patent Law: The Case of the Oncomouse' (2006) 3 WIPO MAGAZINE <https://www.wipo.int/wipo_magazine/en/2006/03/article_0006.html> accessed 30 May 2023; Enrico Bonadio, 'Patents and Morality in Europe' in Irene Calboli and Srividhya Ragavan (eds), *Diversity in Intellectual Property: Identities, Interests, and Intersections* (Cambridge University Press 2015) 149-168, 159.

270 Jasanoff, *Designs on Nature: Science and Democracy in Europe and the United States* (n 83) 219; Bently Lionel and Brad Sherman, *Intellectual Property Law* (3rd edn, OUP 2009) 455-456.

271 Since 13 December 2007: r 28(d), EPC Implementing Regulations; since 1 July 2017: EPC Implementing Regulations, r 28(1)(d).

of animals which are likely to cause them suffering without any substantial medical benefit to man or animal, and also animals resulting from such processes'.[272] This utilitarianism-based test presented in this legal provision is not identical to the one formulated in the case law of the EPO Boards of Appeal: Rule 23d(d) (currently Rule 28(1)(d))[273] differs from the interpretation in the *Onco-mouse/HARVARD* case in that it aims to weigh the likely animal suffering against the likely substantial medical benefit to humans or animals,[274] whereas the latter seeks to evaluate not only the animal suffering, but also the possible harm to the environment as well as the possible usefulness of an invention to mankind.[275] The EPO case law indicates that Rule 28(1)(d) of the EPC Implementing Regulations takes precedence over the test formulated in the *Onco-mouse/HARVARD* case.[276] Therefore, the latter is used only when it is not possible to apply the rule in question.[277]

This weighing test was also used in several other cases by the EPO Boards of Appeal[278] and the EPO Opposition Division.[279] For example, in *Gene trap/ARTEMIS*, the invention involved mice that can be characterised by a 'modification in genetic identity'[280] resulting in 'a mutated phenotype'.[281] The EPO Board of Appeal stated that where the mutated gene is essential, the mouse will suffer.[282] Despite the likely suffering of this animal, the procedure will not be of medical benefit, 'let alone of substantial medical benefit'.[283] Thus, according to Rule 23d(d)[284] of the EPC Implementing Regulations, after applying the weighing test, the main

272 Biotech Directive, Art. 2(d); EPC Implementing Regulations, r 28(1)(d).
273 Since 13 December 2007: EPC Implementing Regulations, r 28(d); since 1 July 2017: r 28(1)(d), EPC Implementing Regulations.
274 *Transgenic animals/HARVARD* (n 80), paras 6.2. and 9.2; *Gene trap/ARTEMIS* (n 81), para 4.
275 *Transgenic animals/HARVARD* (n 80), paras 10.5-10.6.
276 ibid paras 6.1. and 10.1 (at the time of the *Transgenic animals/HARVARD* decision and before 13 December 2007: EPC Implementing Regulations, r 23d(d)).
277 *Non-invasive localization/LELAND STANFORD* (n 81), para 15.
278 *Gene trap/ARTEMIS* (n 81), paras 13-14*; Non-invasive localization/LELAND STANFORD* (n 81), para 22.
279 *Leland Stanford/Modified Animals* (n 45).
280 *Gene trap/ARTEMIS* (n 81), para 2.
281 ibid.
282 ibid paras 3-4.
283 ibid para 3.
284 Since 13 December 2007: EPC Implementing Regulations, r 28(d); since 1 July 2017: EPC Implementing Regulations, r 28(1)(d).

request and the auxiliary request regarding the 16th claim of this patent were rejected.[285]

In the *Non-invasive localization/LELAND STANFORD* decision, an invention encompassing a process which helps to detect cells of a tumour in a mouse used as a model of human diseases[286] was analysed. According to the claims of this patent, it was clear that the invention also encompassed deliberate generation of tumours in the organisms of mice, meaning that the animals undergoing this procedure will suffer.[287] However, taking into consideration the fact that the invention may bring substantial benefit to medical research on human cancer, the Board ruled that the commercial exploitation of such an invention conforms the criteria of Rule 28(d) of the EPC Implementing Regulations, allowing non-application of the exception to patentability.[288] Additionally, in this case, the use of the utilitarian approach is clear from the fact that when taking a decision, it was important for the EPO Board of Appeal that the use of the discussed invention would reduce the number of mice needed, meaning that fewer animals will suffer.[289]

In this case, it was also questioned whether the weighing test can be applied in such situations where an animal covered by the patent claims is likely to suffer but is not genetically modified. Taking into consideration the fact that the mice analysed in the *Non-invasive localization/LELAND STANFORD* decision were regarded as genetically modified, this question was not analysed further.[290] However, in the lower-level *Leland Stanford* decision before the EPO Opposition Division with regard to another invention,[291] it was stated that although, literally considered, only genetically modified animals fall under Rule 23d(d)[292] of the EPC Implementing Regulations, the 'spirit of the rule'[293] requires the application of the weighing test also with regard to non-genetically modified animals.[294] Therefore, this

285 *Gene trap/ARTEMIS* (n 81), paras 4-5.
286 *Non-invasive localization/LELAND STANFORD* (n 81), para 13.
287 ibid paras 16 and 19.
288 ibid para 22 (since 1 July 2017: r 28(1)(d), EPC Implementing Regulations).
289 ibid.
290 ibid paras 16-17 and 22.
291 European Patent No. EP0322240, 'Chimeric immune compromised non-human mammals and their use', application date 22 December 1988.
292 Since 13 December 2007: EPC Implementing Regulations, r 28(d); since 1 July 2017: EPC Implementing Regulations, r 28(1)(d).
293 *Leland Stanford/Modified Animals* (n 45), pt 8.
294 ibid.

utilitarian test could be applied on the basis of both Art. 53(a) EPC and Rule 23d(d)[295] of the EPC Implementing Regulations with regard to all inventions encompassing animals.

Nevertheless, when evaluating the patentability of inventions encompassing animals under Art. 53(a) EPC, the discussed test is not always applied. In the *Euthanasia Compositions/MICHIGAN STATE UNIV.* case, where the patent application filed covered a pharmaceutical composition, i.e. a solution intended to euthanise lower mammals,[296] one of the arguments of the EPO Board of Appeal was that euthanasia is one of the most unpleasant and disputable parts of veterinary practice, which at the same time seeks to alleviate the suffering of animals.[297] It is clear that in the latter decision the weighing test was not applied the same way as had been done in the *Onco-mouse/HARVARD* and *Non-invasive localization/LELAND STANFORD* cases. However, the utilitarian approach of the EPO Board of Appeal in the latter argument is still apparent.

Later, in the *Lubrizol* case of the EPO Opposition Division, based on Art. 53(a) EPC, when analysing the granting of a patent for a genetically modified plant which had a higher nutritional value than conventionally bred plants, the weighing test was also applied. The decision first mentioned the test, indicated in the Guidelines for Examination, which asks whether it is possible that society in general would regard the invention as so abhorrent that the grant of patent rights would be inconceivable.[298] Such argumentation should be related to the rebuttable presumption test, which, according to the scientific sources, states that, if moral aspects create a positive presumption for patenting, the immoral aspects can deny it only when they are so significant that a decision favourable to patenting would be regarded as unsound.[299] The rebuttable presumption test is oriented towards the strongest immorality, and every time when it is not possible to establish it, this has a positive effect on the patentability.[300] However, in the

295 Since 13 December 2007: EPC Implementing Regulations, r 28(d); since 1 July 2017: EPC Implementing Regulations, r 28(1)(d).

296 *Euthanasia Compositions/MICHIGAN STATE UNIV* (n 54), para II.

297 ibid para 6.10.

298 *Lubrizol Genetics Inc* (n 84), para 9.1.2.

299 Warren-Jones, 'Vital parameters for patent morality – a question of form' (n 260) 834. This test was later used in other cases: *Phosphinothricin-Resistenzgen/BAYER* (n 81), paras 9-12; *Stem cells/CALIFORNIA* (n 81), para 6.

300 Warren-Jones, 'Vital parameters for patent morality – a question of form' (n 260) 834.

end, in this case, the weighing test was applied, and the decision indicated that the exploitation of an invention with higher nutritional value could help overcome the lack of food in the world.[301]

In the *Plant cells/PLANT GENETIC SYSTEMS* case, when deciding on an invention encompassing plants and seeds resistant to a certain class of herbicides and the processes for their production,[302] the EPO Board of Appeal stated that in this situation it was not possible to apply the weighing test, because not enough evidence had been provided regarding the negative consequences of the exploitation of the invention.[303] In this decision, the negative consequences of the exploitation of the invention were evaluated in relation to *ordre public*,[304] and it was also indicated that weighing is not the only test that can be applied in order to assess the patentability of an invention with regard to Art. 53(a) EPC.[305] Also, as indicated by the EPO Board of Appeal in the aforementioned case, unlike in the *Lubrizol* case, such a test is 'perhaps'[306] useful in situations where there exists 'an actual damage and/or disadvantage',[307] such as animal suffering, as discussed in the case of *Onco-mouse/HARVARD*.[308] This means that, in the absence of any proof of factual damage, other tests can be applied.

However, despite the fact that the use of genetically modified plants was assessed from the perspective of morality as an improper 'dominion gained by man over the natural world',[309] no other possible tests or methods that are used for the evaluation of inventions related to plants with regard to Art. 53(a) of the Convention were discussed in this decision. Although the weighing in the *Plant cells/PLANT GENETIC SYSTEMS* case was not applied, it confirms that the aforementioned test, which is based on the ethical theory of utilitarianism, can be applied for the evaluation with regard to Art. 53(a) EPC not only of inventions related to animals but also of those relating to plants. However, the small number of EPO decisions on assessing the commercial exploitation of plant-related inventions with regard to *ordre public* and/or morality reveals that the exploitation of genetically

301 *Lubrizol Genetics Inc.* (n 84), paras 9.1.2 and 9.1.4.
302 European Patent No. 0242236, 'Plant cells resistant to glutamine synthetase inhibitors, made by genetic engineering', application submitted on 21 January 1987.
303 *Plant cells/PLANT GENETIC SYSTEMS* (n 22), para 18.8.
304 ibid para 17.3.
305 ibid para 18.8.
306 ibid.
307 ibid.
308 ibid.
309 ibid para 16.

modified plants is generally considered to be acceptable. Therefore, the weighing test focuses on the damage caused by the commercial exploitation of these inventions.

Nonetheless, specifically the argumentation in the *Lubrizol* and *Plant cells/PLANT GENETIC SYSTEMS* decisions provided a boost to another test, i.e. the rebuttable presumption test. Based on this test, when trying to achieve the rejection of a patent application under Art. 53(a) EPC, the aforementioned immoral aspects must be so strong that they could not be outweighed by any benefit from the commercial exploitation of the invention. In other words, the conferral of legal protection on them in any case would be unjustified. In this regard, it can be stated that the rebuttable presumption test will be applied only if the commercial exploitation is capable of violating the fundamental values of a certain society. Such a test is based on deontological ethics, indicating that actions can be regarded as good or bad, right or wrong *per se*, whereas the consequences do not provide any value to the action.[310]

In the *Leland Stanford* case in the EPO Opposition Division, when analysing the commercial exploitation with regard to *ordre public* and morality of an invention which included the procedure of an animal host being injected with xenogeneic stem cells, organs or their precursors,[311] it was stated that, from an ethical point of view, the creation of human or animal chimeras by taking cells and tissues from the foetus after the abortion is not acceptable.[312] This argument, supported by certain principles determining what is acceptable and what is not, can be regarded as deontological.

However, the response of the EPO Opposition Division to the latter argument was utilitarian. It was stated that the commercial exploitation of this invention would have undisputable medical benefit.[313] In order to properly evaluate the invention with regard to the risks related to xenotransplantation under Art. 53(a) EPC, these risks must not only be possible, but must also be persuasively documented.[314] This case shows that, in assessing the compatibility with *ordre public* and morality of the exploitation of inventions that comprise isolated cells of a dead human being and animals,

310 Arno Anzenbacher, *Etikos įvadas* (aidai 1995) 32.

311 European Patent No. EP0322240, 'Chimeric immune compromised non-human mammals and their use', application date 22 December 1988 (*Leland Stanford/Modified Animals* (n 45), pt 8).

312 ibid.

313 ibid.

314 ibid.

the EPO Opposition Division is more inclined not to adopt a deontological perspective; rather, by referring to reliable data regarding the risks and benefits, it may apply the weighing test, which is based on utilitarianism.

Interpretation of Art. 53(a) EPC and Rules 23d(c) and 23e(1)[315] of the EPC Implementing Regulations based on the deontological perspective was used for the first time by the EPO Opposition Division in the *Edinburgh Patent* case, where the question of the patentability of an invention concerning isolation, selection and propagation of animal transgenic stem cells other than embryonic stem cells was analysed.[316] The opponents in this case stated that the subject-matter of the patent claims encompassed human embryonic stem cells,[317] and thus the invention should not be granted a patent.

With regard to the arguments specified above, in this decision of the EPO Opposition Division it was stated that Rule 23d(c)[318] together with Rule 23e(1)[319] of the EPC Implementing Regulations must be interpreted broadly, i.e. as encompassing not only the industrial and commercial exploitation of human embryos, but also the production of human embryo stem cells, when embryos are being destroyed.[320] This means that the latter evaluation must be performed also by analysing the aspects which, at the time, are related to the creation and development of an invention.

With regard to that, the applicant's main request was rejected based on the fact that, even after the patent claims had been amended to include the term 'non-human',[321] the invention still did not conform to the requirements of Art. 53(a) EPC together with Rule 23d(c)[322] of the EPC Implementing Regulations.[323] However, the auxiliary request with the amend-

315 Since 13 December 2007: EPC Implementing Regulations, r 28(c) and 29(1); since 1 July 2017: EPC Implementing Regulations, r 28(1)(c).
316 European Patent No. EP0695351, 'Isolation, selection and propagation of animal transgenic stem cells other than embryonic stem cells', application date 21 April 1994 (*Edinburgh Patent* (n 23)).
317 ibid para 2.5.1.
318 Since 13 December 2007: EPC Implementing Regulations, r 28(c); since 1 July 2017: EPC Implementing Regulations, r 28(1)(c).
319 Since 13 December 2007: EPC Implementing Regulations, r 29(1).
320 *Edinburgh Patent* (n 23), para 2.5.3.
321 ibid para 11.
322 Since 13 December 2007: EPC Implementing Regulations, r 28(c); since 1 July 2017: EPC Implementing Regulations, r 28(1)(c).
323 *Edinburgh Patent* (n 23), para 2.5.5.

ment indicating 'animal stem cells, excluding embryonic stem cells',[324] was recognised as patentable under Art. 53(a) of the Convention, because the invention clearly does 'not extend to the human body and its elements in their natural environment'.[325]

This interpretation of Rule 23d(c)[326] of the EPC Implementing Regulations, which prohibits the patentability of inventions that are related to the use of human embryos for industrial and commercial purposes, and Rule 23e(1),[327] which establishes an exception for the patentability of inventions that cover the human body in different stages of its formation and development or the discovery of its elements, without analysing the benefit of a certain invention, shows that the prohibited aspects render irrelevant any kind of positive consequences of the exploitation of an invention. Therefore, for such cases, a rebuttable presumption test based on deontological ethics is applied.

Arguably the most famous process where the application of the weighing test in relation to Art. 53(a) EPC was denied took place with regard to an invention which encompasses the use of primate embryonic stem cells and the process of their creation.[328] In the *Stem Cells/WARF* decision of the EPO Board of Appeal, it is possible to see a change from the previously prevailing utilitarian view reflected in most of the decisions analysed above – which would encourage weighing of all the different arguments relating to the commercial exploitation of an invention with regard to *ordre public* and morality – to a rebuttable presumption test based on deontology, indicating that certain things are not allowed even though they provide more benefit than the negative consequences they cause.

In this case the EPO Board of Appeal had doubts whether, when it comes to 'human life, it would be ethically acceptable to make a decision by weighing the interests of human beings who could potentially benefit from the exploitation of the technology against a right, if any, of human embryos [...] to get to life and of not being destroyed for the benefit of others'.[329] After stating its view regarding the weighing test without finding a solution,

324 *Edinburgh Patent* (n 23), para 3.3.2.
325 ibid.
326 Since 13 December 2007: EPC Implementing Regulations, r 28(c); since 1 July 2017: EPC Implementing Regulations, r 28(1)(c).
327 Since 13 December 2007: EPC Implementing Regulations, 29(1).
328 European Patent No. EP 0770125, 'Primate embryonic stem cells', application date 19 January 1996.
329 *Stem Cells/WARF* (n 80), para 55.

the Board referred questions to the EPO Enlarged Board of Appeal which were analysed in the *Use of embryos/WARF* decision.[330] In the latter process, the conformity of the exploitation of the invention indicated in the claims of the patent application with regard to Art. 53(a) EPC was discussed very broadly: even the stage of the development of the invention was evaluated, because the creation encompassed processes for which, at the time of the filing of the application, destruction of human embryos was needed.

According to the EPO Enlarged Board of Appeal, the fact that the destruction of human embryos is necessary for the creation of the invention in question allows for application of Rule 28(c) of the EPC Implementing Regulations,[331] which stipulates that '[u]nder Article 53(a), European patents shall not be granted in respect of biotechnological inventions which, in particular, concern the following: [...] (c) uses of human embryos for industrial or commercial purposes'.[332] In the case in question, it was indicated that, by enacting Rule 28(c) of the EPC Implementing Regulations, the EPOrg legislator aimed not to grant patents for inventions that require the destruction of human embryos.[333] This allows the conclusion that, under Art. 53(a) of the Convention, the EPO Boards of Appeal tend to be stricter with regard to inventions that may be harmful to human dignity by converting one's body into an economic good. In the case in question, based on the rebuttable presumption test, such an invention was recognised as unpatentable *per se* with regard to *ordre public* and morality.

This rebuttable presumption test was also employed in the *Stem cells/CALIFORNIA* case, in which the conformity of an invention covering a method of proliferating *in vitro* a clonal population of mammalian neural crest stem cells[334] was evaluated with regard to Art. 53(a) EPC. Similarly as with the *Use of embryos/WARF* case, the problem occurred because, for the creation of this invention, the necessary embryonic stem cells had to be procured from human embryos that had been destroyed. Despite the fact that the applicant had indicated in the appeal that the needed stem cells can be procured from the peripheral or the central nervous system of an adult,

330 *Use of embryos/WARF* (n 80).
331 ibid para 22.
332 EPC Implementing Regulations, r 28(c) (since 1 July 2017: EPC Implementing Regulations, r 28(1)(c)).
333 *Use of embryos/WARF* (n 80), para 31 (since 1 July 2017: EPC Implementing Regulations, r 28(1)(c)).
334 European Patent No. EP0658194, 'Mammalian multipotent neural stem cells', application date 27 July 1993 (*Stem cells/CALIFORNIA* (n 81)).

and had attempted to change the patent claims by means of using phrases like '[stem cells] not derived from an embryo' and 'capable of being derived from adult tissue',[335] the patent application in question was rejected. The EPO Board of Appeal indicated that, at the time of the patent application, the only way of procuring human neural crest stem cell cultures was the destruction of human embryos.[336] For this reason, and based on Art. 53(a) EPC and Rule 28(c) of the Implementing Regulations, the invention was regarded as not patentable.[337]

The *Culturing stem cells/TECHNION* case is another example of the application of the rebuttable presumption test.[338] This time, the invention concerned human stem cells, the only method of obtaining which, at the time of the filing of the application, was the destruction of human embryos.[339] The patent applicant indicated that publicly available embryonic stem cell lines can be used for the creation of this invention, and therefore human embryos are not *de novo* destroyed in this case.[340] However, the EPO Board of Appeal disagreed with this argument, and emphasised that, at the time of the patent application, all publicly available human stem cell lines were 'initially derived from the inner cell mass of blastocyst stage human embryos resulting in the destruction of the human embryos',[341] and thus recognised the commercial exploitation of this invention as contrary to Art. 53(a) of the Convention and Rule 28(c) of the EPC Implementing Regulations.[342] This approach in the *Culturing stem cells/TECHNION* decision was confirmed in the later EPO case law.[343] The above-discussed EPO case law shows that in cases where the creation of an invention requires the destruction of human embryos, which according to Rule 28(1)(c) is equal to the use of human embryos for industrial or commercial purposes, the

335 *Stem cells/CALIFORNIA* (n 81), para XII.
336 ibid para 7.
337 ibid (since 1 July 2017: EPC Implementing Regulations, r 28(1)(c)).
338 *Culturing stem cells/TECHNION* (n 23).
339 ibid para 36.
340 ibid para VIII.
341 ibid para 28.
342 ibid para 29 (since 1 July 2017: EPC Implementing Regulations, r 28(1)(c)).
343 E.g. *Embryonic stem cells, disclaimer/ASTERIAS* (n 81), para 11; *Neurale Vorläuferzellen/BRÜSTLE* (n 81), para 8; *In vitro differentiated cardiomyocytes/AXIOGENESIS* (n 81), para 4 (a decision of the Opposition Division was revisited based on the EPO's interpretation of r 28(c) (currently r 28(1)(c)) of the Implementing Regulations) in view of *Oliver Brüstle v Greenpeace eV* (n 90) and *International Stem Cell Corporation v Comptroller General of Patents, Designs and Trade Marks* (n 90)).

benefits of the exploitation do not have a positive influence on the granting of a patent.

The above-analysed decisions demonstrate that Rules 28(1)(c) and 29(1) of the EPC Implementing Regulations embody the principle of the prohibition of the patenting of a living human body or processes in which it is used. In spite of the potential benefits of a particular invention involving prohibited aspects, this principle cannot be violated. Therefore, when analysing inventions falling within the scope of these rules, and at the same time deciding on the scope of Rules 28(1)(a) and (b) of the EPC Implementing Regulations, the rebuttable presumption test based on deontological ethics is used.

However, such an interpretation of Art. 53(a) EPC and the related EPC Implementing Regulations is not applied when dealing with the patenting of elements isolated from the human body or otherwise produced by means of a technical process. This situation arises because Rule 29(2) of the EPC Implementing Regulations explicitly states that '[a]n element isolated from the human body or otherwise produced by means of a technical process, including the sequence or partial sequence of a gene, may constitute a patentable invention, even if the structure of that element is identical to that of a natural element'.[344] This rule means that, from a deontological point of view, patenting of elements isolated from the human body is acceptable in the European patent system.

One example is the *Breast and Ovarian Cancer/UNIVERSITY OF UTAH* case, in the opposition of which against a patent covering the BRCA1 gene, revealing the inclination to develop ovarian cancer, it was stated that the applicant did not show any evidence regarding the obtainment of informed consent from the donor of the cells.[345] In this case, it was agreed that the requirement of such consent is fundamental in medical science, but it was also stated that the EPC does not include a rule which would require the patent applicant to provide proof of such consent or a benefit-sharing agreement.[346] Taking into consideration the case law of the CJEU, where similar arguments were analysed, the EPO Board of Appeal indicated in the *Breast and Ovarian Cancer/UNIVERSITY OF UTAH* case that the Court of Justice has stated, when dealing with a similar argument, that the right to integrity to the extent that it 'encompasses, in the context of medicine

344 EPC Implementing Regulations, r 29(2).
345 *Breast and Ovarian Cancer/UNIVERSITY OF UTAH* (n 22), para 47.
346 ibid paras 48-50.

and biology, the free and informed consent of the donor and recipient'[347] is 'misplaced as against a directive [the Biotech Directive] which concerns only the grant of patents and whose scope does not therefore extend to activities before and after that grant, whether they involve research or the use of the patented products'.[348]

Furthermore, it was indicated in the opposition that the granting of a patent would mean concentration of the cancer research in the hands of the patent proprietor and making patients dependent on them, which is contrary to human dignity.[349] Notwithstanding the fact that this argument seems understandable, especially when speaking about the availability of the diagnostic testing of the mentioned disease, the EPO Board of Appeal indicated that, according to Art. 53(a) of the Convention, the commercial exploitation not of the patent but of the invention should be evaluated, and therefore the latter human dignity-based argument was rejected.[350] Also as one of the reasons for rejecting this opposition, the EPO Board of Appeal indicated the fact that the invention disclosed in the first claim of the patent application, according to Rule 23e(2) of the Implementing Regulations[351] interpreting Art. 53(a) EPC, does not distinguish it as not patentable.[352]

Similar argumentation can also be noted in the *Relaxin/HOWARD FLOREY INSTITUTE* case, where the opponents indicated that the taking of tissue from a human body without obtaining consent for a specific exploitation is a 'fundamental violation of a person's rights'.[353] However, in this case the EPO Board of Appeal stated that the patent claims directly or indirectly encompass DNA encoding the human protein preprorelaxin or the human preprorelaxin *per se*,[354] which is obtained by technical processes. Therefore, it conforms to the definition of the patentable elements of the human body established by Rule 23e(2) of the Implementing Regula-

347 *Netherlands v Parliament and Council* (n 90) para 78.
348 *Breast and Ovarian Cancer/UNIVERSITY OF UTAH* (n 22), para 50 citing Judgment of the Court of Justice of the European Communities in case C-377/98 dated 9 October 2001.
349 ibid para 52.
350 ibid para 53.
351 Since 13 December 2007: r 29(2), Implementing Regulations.
352 *Breast and Ovarian Cancer/UNIVERSITY OF UTAH* (n 22), para 53.
353 *Relaxin/HOWARD FLOREY INSTITUTE* (n 81), para XII.
354 ibid para 8.

tions.[355] In this way, based on the discussed rule, the Board rejected the appeal without analysing the fundamental violations of human rights.

Although in certain cases it can be difficult to separate the above-mentioned weighing and rebuttable presumption tests, it is possible to see certain trends in the assessment of *ordre public* and/or morality regarding the commercial exploitation of the biotechnological or biomedical sciences' inventions. The case law of the Office shows that the weighing test is usually applied to the patenting of inventions related to animals or plants. The EPO Divisions, in deciding on the patenting of inventions encompassing animals with regard to Art. 53(a) EPC use the utilitarian test, during the application of which, based on Rule 28(1)(d) of the EPC Implementing Rules or the EPO case law established in the *Onco-mouse/HARVARD* case, the potential negative consequences must be weighed against the likely benefits of the commercial exploiting of a particular invention. The examination of the commercial exploitation of plant-based inventions in relation to Art. 53(a) of the Convention may be subject to both the weighing test and the rebuttable presumption test. However, the weighing test for commercial exploitation of inventions encompassing plants or related processes, according to the limited number of examples in the case law of the Office, is most useful when there is 'an actual damage and/or disadvantage'.[356]

Addressing the issues of inventions encompassing a living human body or elements separated from the human body, the weighing test is not generally applicable. The test used to evaluate the latter inventions is attributable to a rebuttable presumption test based on deontological ethics. Based on this test, the EPO Divisions can respond in two ways. In the first case, where the provisions of patent claims cover the living body of a human being in various forms and stages of its development or processes related to it, according to Rules 28(1)(c)[357] and 29(1) of the EPC Implementing Regulations, a particularly rigorous approach is employed, meaning that even the positive aspects of the commercial exploitation of an invention cannot lead to the grant of a patent. In the second case, the evaluation of the commercial exploitation of isolated or otherwise produced elements of the human body with regard to *ordre public* and/or morality is also based on a rebuttable presumption test, but in this case the EPO employs a narrower approach based on Rule 29(2) of the EPC Implementing Regu-

355 Since 13 December 2007: EPC Implementing Regulations, r 29(2).
356 *Plant cells/PLANT GENETIC SYSTEMS* (n 22), para 18.8.
357 Also see EPC Implementing Regulations, r 28(1)(a) and (b).

lations. When an object of the invention falls within the scope of the said rule, it will be considered acceptable from the perspective of *ordre public* and/or morality. Therefore, in this case, a patent will be granted on the basis of Art. 53(a) EPC and the above-mentioned provision of the EPC Implementing Regulations.

1.4.2. The Standards for Applying Article 53(a) of the European Patent Convention

The decisions of the EPO Divisions can be distinguished not only according to the tests, but also according to the standards used in assessing the compliance of the commercial exploitation of an invention under Art. 53(a) EPC. Legal literature indicates that the weighing and rebuttable presumption tests have led to the development of two standards which help to assess the invention's compliance with the aforementioned provision of the Convention. These are (i) the standard of abhorrence and (ii) the standard of unacceptability.[358]

The first one, the standard of abhorrence, is mentioned in the Guidelines for Examination, stating that Art. 53(a) EPC can only be applied in rare and extreme cases, and that '[a] fair test to apply is to consider whether it is probable that the public in general would regard the invention as so abhorrent that the grant of patent rights would be inconceivable'.[359] If this is the case in a particular situation, 'an objection is raised under Art. 53(a)'.[360] Based on the Guidelines for Examination, the procedure of examining a patent in such cases includes raising the question of whether there are no statements inciting riots, acts contrary to *ordre public* or morality, racial, religious or other discrimination, criminal acts or grossly obscene content in the application.[361] Considering all of the above, one can accept that this standard presents an extremely high threshold for rejecting a patent application on the basis of *ordre public* and/or morality.[362] This means that the invention can be recognised as non-patentable on the basis of the

358 E.g. Warren-Jones, 'Vital parameters for patent morality – a question of form' (n 260) 835; Hellstadius, *A Quest for Clarity: Reconstructing Standards for the Patent Law Morality Exclusion* (n 6) 213-218.

359 Guidelines for Examination, March 2023 (n 63), pt G-II, 4.1.

360 ibid.

361 ibid pt A-III, 8.1.

362 Hellstadius, *A Quest for Clarity: Reconstructing Standards for the Patent Law Morality Exclusion* (n 6) 214.

latter aspects only if its commercial exploitation is likely to undermine the fundamental principles of society. Therefore, its application is not frequent and may usually be more associated with the rebuttable presumption test based on deontological ethics.

The case law of the Office illustrates that the abhorrence standard can have significant consequences. One of the best examples is the decision in *Use of embryos/WARF*,[363] where it was clearly indicated that a formal analysis of a patent application does not suffice in order to assess the commercial exploitation of an invention in accordance with Art. 53(a) EPC. According to the EPO Enlarged Board of Appeal, and based on the fact that Rule 28(c) places the emphasis not on the patent claims but rather on the use of inventions, not only does the explicit wording of the claims need to be looked at, but the technical teaching of the application as a whole as to how the invention should be performed also needs to be evaluated.[364]

In order to exploit cultures of human stem cells, they have to be created, and this is only possible by using a method that includes the destruction of human embryos.[365] Considering this, the EPO Enlarged Board of Appeal assessed the stage of creation of the invention in question and identified it as an integral part of the commercial exploitation of the invention.[366] This means that the past, i.e. the stage of creation, was taken into consideration, thus rejecting the applicant's arguments that such analysis goes beyond the limits of the necessary exploitation of the patent, based on Rule 28 of the EPC Implementing Regulations.[367] Such an approach is considered as not complying with Art. 69(1) and Art. 83 EPC,[368] which regard the patent claims, together with drawings, as the essential tools for defining the invention.

Such an approach by the EPO provoked many discussions concerning the limits of assessment of the commercial exploitation of an invention.[369] Despite the latter discussions and different opinions, the objective of the Boards is rather clear: a patent application for any invention the creation of which may require destruction of a human embryo is to be rejected. Such a strict interpretation and application of Rule 28 of the EPC Implementing

363 *Use of embryos/WARF* (n 80).
364 ibid para 22 (since 1 July 2017: EPC Implementing Regulations, r 28(1)(c)).
365 ibid.
366 ibid para 25.
367 ibid paras 26-29 (since 1 July 2017: EPC Implementing Regulations, r 28(1)).
368 EPC, Articles 69(1) and 83.
369 E.g. Van Overwalle, 'Gene Patents and Human Rights' (n 47) 1019.

Regulations reveals the desire to prevent the commodification of human embryos[370] and can be considered as one of the ways of protecting human dignity. Despite the fact that patent law forms only a small part of the regulation governing science and technology, the rebuttable presumption test based on the standard of abhorrence has been applied in this case, because the aspects to be protected are of particular importance in contemporary Western society.[371] To do otherwise would imply extreme disregard for the norms of *ordre public* and/or morality.

Another standard analysed in the case law of the EPO Boards of Appeal and in the legal literature is the standard of unacceptability. Although it is not mentioned in the Guidelines for Examination, it is nevertheless employed in the EPO case law. Based on the interpretation provided in the *Plant cells/PLANT GENETIC SYSTEMS* case, in the situation where the mentioned standard is applied, the question to be raised is whether actions and products indicated in the patent claims can be considered unacceptable in relation to 'conventionally accepted standards of conduct of European culture'.[372]

When applying the weighing test, the unacceptability standard was also invoked, i.e. the 'moral disapproval in European culture'[373] was used, in the *Transgenic animals/HARVARD* decision. Meanwhile, in the *Plant cells/PLANT GENETIC SYSTEMS* case, when deciding on the patentability of genetically modified plants, the EPO Board of Appeal stated that the unacceptability standard should be applied,[374] but neither with the help of the weighing test as it was in the *Transgenic animals/HARVARD* case[375] nor using any other test in this case.

In the *Euthanasia Compositions/MICHIGAN STATE UNIV.* case, a slightly different standard can be observed, i.e. the standard of acceptability.[376] After analysing the patentability of an invention with regard to Art. 53(a) EPC in this case (a solution intended to euthanise lower mammals),[377] the Board of Appeal ruled that 'no veterinarian enjoys euthanising

370 *Use of embryos/WARF* (n 80), para 18 (since 1 July 2017: EPC Implementing Regulations, r 28(1)).
371 See '3.2. The Concept of the Western Legal Tradition in the 21st Century'.
372 *Plant cells/PLANT GENETIC SYSTEMS* (n 22), para 17.3.
373 *Transgenic animals/HARVARD* (n 80), paras 13.2.10 and 13.2.21.
374 *Plant cells/PLANT GENETIC SYSTEMS* (n 22), para 18.8.
375 ibid.
376 *Euthanasia Compositions/MICHIGAN STATE UNIV* (n 54).
377 ibid para II.

animals and veterinarians consider it nevertheless as their moral obligation based on generally accepted ethics and norms which the board accepts are deeply rooted in the culture inherent in European society and civilization'.[378] Also, the EPO Opposition Division, in its *Leland Stanford* decision, stated that the use of donated human body tissue is 'widely accepted' where there is donor consent,[379] but added that currently there is no common agreement or disagreement in European society about the technology in question, i.e. xenotransplantation.[380] Despite the aforementioned slightly different argumentation regarding unacceptability, it is evident that the objective of a part of the EPO case law is to assess the possible reaction of society with regard to a concrete invention based on the established standards recognised in a particular European society.[381]

In applying the weighing and rebuttable presumption tests, the discussed standards, which are different in their 'sensitivity' to any potential breach of *ordre public* and/or morality caused by the commercial exploitation of an invention, are employed. Considering the case law of the Office, it can be held that the standard of abhorrence is rather strict and is applied to inventions whose commercial exploitation can be equated to extreme disregard for the norms of *ordre public* and/or morality. In this case, when evaluating the commercial exploitation of an invention, this assessment is not limited to the analysis of the claims of a patent application; other aspects of the creation of the invention should also be considered.[382] The aforementioned standard is used rather seldom, usually while applying a rebuttable presumption test. The standard of unacceptability is weaker and, when assessing the acceptability or unacceptability of an invention in compliance with the standards accepted by European society, it is limited to the analysis of the patent application.[383] This standard is associated with the weighing test.

However, these observations cover only a part of the Office's decisions in relation to Art. 53(a) EPC. This situation is criticised in the legal literat-

378 *Euthanasia Compositions/MICHIGAN STATE UNIV* (n 54), para 6.13.
379 *Leland Stanford/Modified Animals* (n 45), pt 8.
380 ibid.
381 E.g. *Plant cells/PLANT GENETIC SYSTEMS* (n 22), para 14; *Leland Stanford/Modified Animals* (n 45), pt 8.
382 *Use of embryos/WARF* (n 80); *Stem cells/CALIFORNIA* (n 81); *Culturing stem cells/TECHNION* (n 23).
383 *Onco-Mouse* (n 80); *Plant cells/PLANT GENETIC SYSTEMS* (n 22); *Euthanasia Compositions/MICHIGAN STATE UNIV* (n 54).

ure,[384] where it is indicated that an explanation does not exist as to which of the afore-discussed standards should be applied and in what kind of circumstances. In this regard, a further and more in-depth analysis of the interpretation and application of Art. 53(a) of the Convention and the relevant provisions of the EPC Implementing Regulations is necessary in order to identify at least minimum trends in the interpretation of this provision of the European patent system.

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

The EPO case law reveals that the concept and scope of the term 'commercial exploitation', which is considered to be essential for the application of Art. 53(a) EPC,[385] are not clear. This term referred to in Art. 53(a) of the Convention has not been thoroughly analysed by the EPO Divisions, and there are only a small number of decisions that have tried to explain this term. Hence, it is essential to discuss the definition of this category, which is important for the interpretation and application of Art. 53(a) EPC.

The 1973 version of Art. 53(a) EPC stated that patents shall not be granted for inventions the publication or commercial exploitation of which is contrary to *ordre public* or morality.[386] Although, during the EPC negotiations, the Swiss delegation proposed a change to the provision in question by elimination of the term 'publication',[387] this amendment was only implemented during the revision of the EPC[388] in 2000. This amendment

384 Gitter, 'Led Astray by the Moral Compass: Incorporating Morality into European Union Biotechnology Patent Law' (n 95) 34. See also *Plant cells/PLANT GENETIC SYSTEMS* (n 22); Lionel Bently, 'Sowing Seeds of Doubt on Onco Mouse: Morality and Patentability' (1994-1995) 5 Kings College Law Journal 188, 189; Liddell, 'Immorality and Patents: The Exclusion of Inventions Contrary to Ordre Public and Morality' (n 134) 154.

385 Hellstadius, *A Quest for Clarity: Reconstructing Standards for the Patent Law Morality Exclusion* (n 6) 241.

386 Singer and Stauder, *The European Patent Convention. A Commentary* (n 125) 87.

387 Sterckx and Cockbain, *Exclusions from Patentability, How Far Has the European Patent Office Eroded Boundaries?* (n 94) 48.

388 The Administrative Council of the European Patent Organisation, 'MR/2/00, Basic proposal for the revision of the European Patent Convention', EPO Administrative Council, Munich 13 October 2000 <http://documents.epo.org/projects/babylon/eponet.nsf/0/43F40380331CE97CC125727A0039243C/$File/00002a_en.pdf> accessed 30 May 2023, 45 (MR/2/00, Basic proposal for the revision of the European Patent Convention).

is supported in the scholarly literature, which indicates that it is difficult to imagine a situation where the exploitation of an invention would not warrant legal or ethical grounds to protest it, but the publication of this same invention would.[389] In addition, the elimination of the term 'publication' was also intended to help make Art. 53(a) EPC more consistent with Art. 27(2) of the TRIPS Agreement and Art. 6(1) of the Biotech Directive.[390] However, despite the goal of harmonising the regulation in question with regard to these international or supranational laws, the EPO case law did not become clearer or more unanimous with regard to the term 'commercial exploitation'. For this reason, two interpretations of it can be found in the legal literature: (1) the narrow interpretation and (2) the broad interpretation.[391]

An example of the narrow interpretation of the term in question is the *Transgenic animals/HARVARD* case, in which the EPO Board of Appeal assessed the compliance of the invention with the 1973 version of Art. 53(a) EPC,[392] and indicated that this provision does not question the patenting of that particular invention or its morality *per se*.[393] According to the EPO Board of Appeal, Art. 53(a) of the Convention concerns exclusively the compliance of the 'publication and exploitation' of the invention with morality and *ordre public*: in this case, neither the invention, i.e. the process of creating the genetically modified mouse, nor the fact of patenting this invention has any significance to the application of this EPC article.[394]

In the *Euthanasia Compositions/MICHIGAN STATE UNIV.* case, based on the 1973 version of the EPC, the narrow interpretation of Art. 53(a) EPC was also applied. Similarly to the decision in the *Transgenic animals/HARVARD* case, this decision stated that the term 'commercial exploitation' does not cover any of the following aspects: (1) the invention *per se*; (2) the act of

389 Singer and Stauder, *The European Patent Convention. A Commentary* (n 125) 87.

390 MR/2/00, Basic proposal for the revision of the European Patent Convention, 45.

391 Hellstadius, *A Quest for Clarity: Reconstructing Standards for the Patent Law Morality Exclusion* (n 6) 246-269.

392 Art. 53(a) EPC: 'European patents shall not be granted in respect of inventions the publication or exploitation of which would be contrary to "ordre public" or morality, provided that the exploitation shall not be deemed to be so contrary merely because it is prohibited by law or regulation in some or all of the Contracting States' (Convention on the Grant of European Patents of 5 October 1973 (European Patent Convention): <https://new.epo.org/en/legal/epc-1973/2006/convention.html> accessed 30 May 2023 (EPC 1973)).

393 *Transgenic animals/HARVARD* (n 80), para 4.2.

394 ibid.

granting of a patent for a particular invention; (3) actions performed during the process of creation or production of an invention.[395] According to the Board of Appeal, this term in the context of Art. 53(a) of the Convention should be understood as 'the normal avowed use indicated in the patent [...] of the invention's teaching'.[396]

The Board emphasised that the exploitation of an invention does not constitute 'experiments […] carried out during the making or development of the invention'.[397] Also, according to this decision, the exploitation in question which is contrary to *ordre public* and/or morality must be the only one. If there are other ways of commercially exploiting an invention that do not fall within the scope of Art. 53(a) of the Convention, the patent may not be refused based on this provision.[398] This means that, based on the *Euthanasia Compositions/MICHIGAN STATE UNIV.* case, for the analysis of Art. 53(a) EPC, the likely exploitation of a particular invention is important.

In the *Breast and Ovarian Cancer/UNIVERSITY OF UTAH* case, on the basis of the 1973 version of the EPC, the EPO Board of Appeal also emphasised that specifically the 'publication or exploitation'[399] of an invention must be assessed for their compliance with Art. 53(a) EPC. Similarly, in response to the opponents' arguments regarding the socio-economic implications of granting the patent (i.e. an increase in the costs to patients after the grant of the disputed patent), the Board of Appeal stated that the opponents were talking about the commercial exploitation of the patent itself and not of the invention.[400] This case law has been followed in other cases on similar opposition arguments concerning the socio-economic consequences of the grant of a patent.[401] Due to the fact that the exploitation and publication[402] of an invention itself are relevant for the application

395 *Euthanasia Compositions/MICHIGAN STATE UNIV* (n 54), para 5.6. a)-c).
396 ibid para 5.7.
397 ibid para 6.8.
398 ibid para 5.8.
399 *Breast and Ovarian Cancer/UNIVERSITY OF UTAH* (n 22), para 56.
400 ibid para 53.
401 *Mutation/UNIVERSITY OF UTAH* (n 81), paras 81-82 (in this case, the aim was to patent an isolated DNA encoding BRCA1 mutations, as well as polymorphisms, markers, processes for the generation of DNA, and methods for determining predisposition to breast and ovarian cancer); *Method of diagnosis/UNIVERSITY OF UTAH* (n 81), paras 64-65 (in this case, the aim was to patent a process that would help diagnose predisposition of breast and ovarian cancer).
402 EPC 1973.

of Art. 53(a) of the Convention, the EPO Board of Appeal did not assess the opponents' arguments regarding the implications of the granting of a patent. All this leads to the conclusion that the Board, at least for a certain period of time, when applying the 1973 version of Art. 53(a) EPC, tended to construe the word 'exploitation' narrowly.

The question of informed consent for taking human tissue was also raised in the *Breast and Ovarian Cancer/UNIVERSITY OF UTAH* case,[403] but the EPO Board of Appeal did not analyse the arguments presented by its critics, and applied Art. 53(a) EPC together with Rule 23e[404] of the EPC Implementing Regulations.[405] However, in the *Gene trap/ARTEMIS* case, where the opponents sought to apply a weighing test for a second auxiliary request, it was confirmed that, when assessing the compliance of an invention with Art. 53(a) EPC, the invention needs to be analysed strictly within the limits of the patent application.[406] This means that genetically modified animals (in this case, mice), which would possibly be subjected to suffering but are not a part of the patent application, are outside the scope of the invention which is being considered for patent granting. Hence, their suffering should not be considered as a factor in the assessment of the compliance of the commercial exploitation of an invention with regard to Art. 53(a) of the Convention.[407]

Similarly, in the *Lubrizol* case, in which a decision was made on the granting of a patent for a genetically modified plant, the EPO Opposition Division stated that, when interpreting and applying Art. 53(a) of the Convention, the term 'commercial exploitation' must be understood narrowly. This means that the exploitation of an invention itself, rather than the exploitation of rights arising from patents, must be immoral.[408] The same position was expressed in the decision of the EPO Board of Appeal in *Plant Cells/PLANT GENETIC SYSTEMS*, in which the need to analyse the claimed subject-matter was emphasised in the context of the commercial exploitation of certain herbicide-resistant plants and seeds as well as the processes for their creation.[409]

403 *Breast and Ovarian Cancer/UNIVERSITY OF UTAH* (n 22), para XII.
404 Since 13 December 2007: EPC Implementing Regulations, r 29.
405 *Breast and Ovarian Cancer/UNIVERSITY OF UTAH* (n 22), para 59.
406 *Gene trap/ARTEMIS* (n 81), para 13.
407 ibid.
408 *Lubrizol Genetics Inc.* (n 84), para 9.1.1.
409 *Plant cells/PLANT GENETIC SYSTEMS* (n 22), para 18.7. The EPO Board of Appeal even noted that, with regard to certain inventions (e.g. chemical compounds for

Based on Art. 69(1) and Art. 83 EPC,[410] the objective of interpreting the term 'commercial exploitation' within the limits of a patent application should be regarded as appropriate. These legal provisions show that it is precisely the claims of the patent or its application that define an invention whose commercial exploitation is being analysed when applying and interpreting Art. 53(a) EPC and the relevant rules of the EPC Implementing Regulations.

However, in some cases, such a narrow interpretation may cast doubt on the rationale of the decisions of the EPO Divisions. This situation is illustrated by the decision of the EPO Board of Appeal of 24 January 2013.[411] In this decision, the commercial exploitation of a non-biotechnological invention comprising the processing of a slaughtered animal, which among other things included at least one observer positioned along the slaughter line in order to carry out the supervision of the slaughtered object,[412] was analysed with regard to Art. 53(a) EPC.

In this case, the EPO Board of Appeal, in accordance with the abovementioned cases, i.e. *Transgenic animal/HARVARD*, *Euthanasia Compositions/MICHIGAN STATE UNIV.* and *Breast and Ovarian Cancer/UNIVERSITY OF UTAH*, stated that, when assessing an exploitation of an invention with regard to morality and *ordre public*, the assessment has to be made on the basis of an invention indicated in the documents of the patent application.[413] According to the patent claims in this case, it was established that the invention includes at least one observer, i.e. a human being,[414] which means that the latter is regarded as an 'object of private property'.[415] Therefore, the commercial exploitation of this invention would not comply with the fundamental standards of human rights and would be contrary to *ordre public*.[416]

This suggests a narrow interpretation of the term 'commercial exploitation' and leads to a rather formalistic assessment of Art. 53(a) EPC: by

pharmaceutical use), at the time of the patent application, patent granting authorities can assess the commercial exploitation in a very limited way (ibid para 18.4).

410 EPC, Articles 69(1) and 83.

411 This decision does not have a headword in the database of the EPO.

412 European Patent No. EP819381, 'The method and device for processing a slaughtered animal or its part in a slaughterhouse', application filed 16 July 1997.

413 *no headword*, Decision of 24 January 2013, Case No. T 0149/11 (n 54), para 2.1.

414 ibid paras 2.3.-2.4.

415 ibid para 2.6.

416 ibid para 2.7.

modelling the possible commercial exploitation of an invention, the invention that is literally defined in the documents of the patent application is invoked. This term is interpreted narrowly, regardless of whether the commercial exploitation of a particular invention as it is defined in the patent application is actually possible. Therefore, the decision in question did not analyse whether international human rights standards and the national legislation implementing them would allow such a patent to be enforced, for example, by requesting the destruction of an invention infringing the patent.[417] In addition, the EPO Board of Appeal has explicitly stated that it is not relevant whether or not there are actual or potential violations of human rights at a certain moment.[418]

In the light of this decision, on the one hand, Art. 53(a) of the Convention explicitly states that the assessment of the commercial exploitation of an invention with regard to morality and *ordre public* does not depend on national law. Therefore, on the basis of the existing regulation, the EPO Board of Appeal acted correctly in this case, only taking into consideration the rules of European patent law. On the other hand, the question arises as to whether the autonomy of the European patent system is rational and whether it should reconsider its relationship with other legal systems.

However, not all cases are characterised by such a narrow conception of the term 'commercial exploitation' in the context of the article in question. In certain decisions of the Boards, this term has been interpreted more broadly to cover not only the commercial exploitation of an invention, but also the stage of its creation and development. The most famous decision in which a very broad meaning was given to the term 'commercial exploitation' is *Use of embryos/WARF*.[419] Notwithstanding the broad interpretation of the provisions of the Convention in question, the Board, in accordance with the case law of the Office discussed above,[420] acknowledged in this decision that patenting itself does not fall within the scope of Art. 53(a) EPC.[421] However, such an interpretation is contrary to the EPO Opposition Division decision in the *Edinburgh Patent* case, in which patenting is considered to be part of a commercial exploitation, stating

417 *no headword*, Decision of 24 January 2013, Case No. T 0149/11 (n 54), para 2.6.
418 ibid.
419 *Use of embryos/WARF* (n 80).
420 *Breast and Ovarian Cancer/UNIVERSITY OF UTAH* (n 22); *Mutation/UNIVERSITY OF UTAH* (n 81).
421 *Use of embryos/WARF* (n 80), para 29.

that the submission of a patent application means that 'there is always an industrial or commercial purpose implied because the only function of a granted patent is to stop others from commercially/industrially exploiting the invention'.[422]

The key issue raised in the *Use of embryos/WARF* case was whether the invention, the patent claims of which, at the date of filing of the patent application, included human stem cells obtained by destroying human embryos, did not contradict Art. 53(a) EPC.[423] In this case, it is important that the claims of the invention did not encompass the process describing the destruction of human embryos necessary for the creation of the invention: in the description, which is a part of the patent application in question and can be used to interpret the patent claims, pre-implantation embryos were identified as the source of the stem cells. In addition, the EPO Enlarged Board of Appeal was asked whether, after the filing of the application, the emergence of technology allowing the proper procedure to be carried out without the destruction of human embryos would have an impact on the evaluation of the exploitation of an invention in the *Use of embryos/WARF* case.

With regard to the first aspect mentioned above, the EPO Enlarged Board of Appeal stated that, despite the fact that the patent claims do not directly address the issue of the destruction of embryos, there is a need to look at the situation broadly and not only examine what is specified in the patent application, but also to analyse the technical teaching of the application as a whole, i.e. to evaluate the actions necessary for the creation of the invention, which in this case involve the destruction of human embryos.[424] In view of the fact that Rule 28(c) of the EPC Implementing Regulations prohibits the patenting of inventions covered by patent claims encompassing objects which, at the time when the application is filed, are created through the destruction of human embryos, the Board found that the commercial exploitation of this invention was contrary to morality and *ordre public*.[425]

On the second issue, the EPO Board of Appeal stated that the fact that, after the filing of an application for a European patent, a technology changes and makes it possible to obtain human stem cells without destroy-

422 *Edinburgh Patent* (n 23), para 2.5.3.
423 *Use of embryos/WARF* (n 80), para 15.
424 ibid para 22.
425 ibid paras 31-32 (since 1 July 2017: EPC Implementing Regulations, r 28(1)(c)).

ing the embryo is irrelevant, because the EPO must assess the commercial exploitation of an invention at the time of the filing of the application.[426] An opposite conclusion would lead to greater legal uncertainty and would be detrimental to third parties who have developed a non-hazardous way of obtaining stem cells.[427] Based on the arguments above, the Board refused to grant a patent for this invention.

In the *Stem cells/CALIFORNIA* case, the conformity of the commercial exploitation of an invention comprising a method of proliferating *in vitro* a clonal population of mammalian neural crest stem cells[428] with regard to *ordre public* and/or morality was analysed. The documents of the application for this patent indicated that to create the invention, human embryos must be used to isolate the cells.[429] According to the applicant's statements in the appeal procedure, at the time of the application, the neural crest stem cells could have been obtained in other ways, i.e. from the peripheral and central nervous systems of an adult, without destroying human embryos.[430] However, the EPO found that, given the fact that the patent application referred to the discussed method of isolating cells only by using human embryos, it should be considered the only way that the cells in question were isolated at that time.[431] Therefore, a patent was not granted for this invention.

Whether the inclusion of the aspects related to the development of an invention into the analysis of its 'commercial exploitation' is appropriate is still highly debated.[432] On the one hand, the afore-discussed interpretation in the *Use of embryos/WARF* and *Stem cells/CALIFORNIA* cases is a deviation from the narrow interpretation which is generally required by the EPO Guidelines for Examination. On the other hand, considering the examples in the *Use of embryos/WARF* and *Stem cells/CALIFORNIA* cases, it seems that the development phase of certain inventions is more

426 *Use of embryos/WARF* (n 80), paras 33-34.
427 ibid para 31.
428 European Patent No. EP0658194, 'Mammalian multipotent neural stem cells', application date 27 July 1993 (*Stem cells/CALIFORNIA* (n 81)).
429 *Use of embryos/WARF* (n 80), para 5.
430 ibid paras 5-6.
431 ibid para 7.
432 E.g. Paul LC Torremans, 'Legal Problems Raised by Patents on Human Stem Cell-Based Inventions' in Kristina Hug and Göran Hermerén (eds), *Translational Stem Cell Research. Stem Cell Biology and Regenerative Medicine* (Humana Press 2011) 287–307, 301-307; Van Overwalle, 'Gene Patents and Human Rights' (n 47) 1045-1048.

worrisome than that of others, even if the actions performed are outside the patent claims. The latter situation occurs when the invention encompasses a living human organism in a certain stage of its formation or development. In these cases, as the EPO case law shows, there is a tendency to expand the concept of the term 'commercial use' in Art. 53(a) EPC.

Based on the aspects mentioned above, it can be concluded that, despite the narrower interpretation of Art. 53(a) EPC in the EPO Guidelines for Examination,[433] in the case law of the EPO Divisions[434] and in the legal doctrine,[435] more recent rulings of the Boards illustrate that this narrower perspective is not always followed.[436] The previously discussed EPO case law reveals that, in the context of the EPC, the term 'commercial exploitation' can be interpreted differently and, depending on the particular invention and possible ways of its exploitation, the term in question may be interpreted more broadly than is established in the EPO Guidelines for Examination or in a part of the case law of the EPO Boards of Appeal.

When interpreting inventions encompassing animals, plants or isolated elements from the human body, a narrow interpretation is given to the term 'commercial exploitation'. From this point of view, this term is perceived as the commercial exploitation of an invention as defined in the patent application documents. In this case, the invention itself, the grant of a patent to an invention or the consequences of the exploitation of a patent are not assessed from the *ordre public* and/or morality perspective. However, when analysing an invention which encompasses a human body at any stage of its formation and development, the term is interpreted broadly, by including in the term 'commercial exploitation' the creation and development stages of an invention and, in certain cases, even the fact of patenting of an invention itself. For this reason, it can be stated that, in the light of the advances in the field of biomedical sciences and the seeking of legal protection for inventions that may have an influence on categories that are important in the legal systems of the EPO Member States, encompassing the protection of human life, dignity and rights, a relatively narrow perspective prompting the individual analysis of every single case within the limits of a patent

433 Guidelines for Examination, March 2023 (n 63), pt A-III, 8.1. and pt G-II, 4.1.

434 See e.g. *Onco-Mouse* (n 80), para 4.5; *Plant cells/PLANT GENETIC SYSTEMS* (n 22), para 8; *Euthanasia Compositions/MICHIGAN STATE UNIV* (n 54), para 5.4; *Gene trap/ARTEMIS* (n 81), para 13.

435 Gitter, 'Led Astray by the Moral Compass: Incorporating Morality into European Union Biotechnology Patent Law' (n 95) 23.

436 *Use of embryos/WARF* (n 80); *Stem cells/CALIFORNIA* (n 81).

application is replaced by a broader interpretation of the provision in question.

Considering the analysed EPO case law, it is possible to agree with S. Jasanoff's position that, in situations where the influence of science and technology is particularly strong, the decision-making bodies are involved in an interactive process of social and technological change.[437] In this study, the EPO Examination Division, the EPO Opposition Division, the EPO Boards of Appeal and the EPO Enlarged Board of Appeal can be regarded as such decision-making bodies. These EPO Divisions become partners of society in discovering new rules and redefining the changed field of opportunities.[438] This situation, together with the position of the EPO Divisions in the light of the rapid advances in the biomedical sciences, encourages the search for ways to understand the trends in the interpretation and application of Art. 53(a) EPC in relation to the patenting of biotechnological inventions.

1.5. Preliminary Conclusion

Despite the objective of the European patent system to maintain harmony with the EU legal norms governing the patenting of biotechnological inventions as well as the potential impact of the entry into force of the Unitary Patent package, this system remains a formally autonomous and independent legal order from the EU law and its institutions when deciding on the granting of patents for biotechnological inventions. Therefore, the EPO Divisions play a key role in deciding on the patenting of biotechnological and other inventions arising from the field of biomedical sciences, in accordance with Art. 53(a) EPC and the related EPC Implementing Regulations.

Analysis of the Office's case law reveals that when making decisions based on the above-mentioned provisions, the EPO applies tests based on one of the branches of philosophy of Western intellectual thought, i.e. utilitarianism or deontological ethics. The weighing test, based on the first approach, applies to the patenting of inventions involving animals, whereas the second one, the rebuttable presumption test, based on deontology, is applied with regard to inventions covering the living body of a human

437 Jasanoff, *Science at the Bar. Law, Science, and Technology in America* (n 72) 19.
438 ibid.

being or elements isolated from it. Both of these tests can be applied to inventions involving plants. In addition, based on the sparse EPO case law, the standard of unacceptability with regard to the commercial exploitation of an invention is normally applied in the case of a weighing test, and abhorrence is applied in relation to the rebuttable presumption test. Also, the former is more likely to adopt a narrower interpretation of 'commercial exploitation', whereas the latter is more likely to interpret it more broadly to cover the acts of creating the invention.

The selection of the aforementioned elements used for the application and interpretation of Art. 53(a) of the Convention depends on the assessment of the content of the invention, which requires the knowledge of the biomedical sciences. Therefore, in order to grasp the trends in the interpretation and application of the above-mentioned EPC provision and the legal norms related to it, it is necessary to analyse, in the context of this provision of the Convention, the concept of the biomedical sciences, which provide the necessary knowledge, and their relation to European patent law belonging to the Western legal tradition.

2. The Biomedical Sciences

2.1. The Concept and Position of the Biomedical Sciences in the 21st Century

As this study is based on the doctoral dissertation defended at Vilnius University in Lithuania, the selection of the term 'biomedical sciences' for this research was determined by the terms used in this country's national legal provisions. The Universal Lithuanian Encyclopaedia indicates that biomedical sciences are 'one of the scientific fields according to the European Union Commission's classification of the sciences. As of 2012, biomedical sciences include: biophysics, biology, botany, ecology (and environmental sciences), pharmacy, medicine, nursing, odontology, dentistry, public health and zoology'.[439]

This definition is in line with the former Order of the Ministry of Education and Science of the Republic of Lithuania of 16 October 2012 (the 'Order of 2012'), which divided science into the following fields: (1) humanities; (2) social sciences; (3) physical sciences; (4) agricultural sciences; (5) biomedical sciences; (6) technological sciences.[440] The Order of 2012 divided the field of biomedical sciences into: biology, biophysics, ecology and environmental sciences, botany, zoology, medicine, odontology, pharmacy, public health and nursing.[441] The Order of 2012 remained in force until 6 February 2019, when a new Order adopting the Classifications of the Fields of Science and the Fields of Art was approved (the 'Order of 2019'), which currently provides the following classification of the fields of science: (1) natural sciences; (2) technological sciences; (3) medical and health sciences; (4) agricultural sciences; (5) social sciences; (6) humanities.[442]

The term 'biomedical sciences' was chosen for this study because of the Order of 2012 that was in force in the Republic of Lithuania until 6

439 Visuotinė Lietuvių Enciklopedija <https://www.vle.lt/straipsnis/biomedicinos-mokslai/> accessed 30 May 2023.

440 16 October 2012 Order 'On the Confirmation of the List of Study Branches Comprising Science Fields' (*Dėl mokslo krypčių patvirtinimo*). *Valstybės žinios (Official Gazette)*, 2012, No. V-1457 (Order of 2012).

441 ibid.

442 6 February 2019 Order 'On the adoption of the Classifications of the Fields of Science and of the Fields of Art' (*Dėl Mokslo krypčių ir Meno krypčių klasifikatorių patvirtinimo*). *Valstybės žinios (Official Gazette)*, 2019, No. V-93 (Order of 2019).

February 2019. However, after the new Order of 2019 was approved, the term 'biomedical sciences' disappeared from the legal rules. Although at first glance that does not seem a very favourable development for this research, the decision of the Lithuanian Government not to use the term 'biomedical sciences' can be considered rather rational, in both a national and an international context.

The Order of 2012 included the term 'biomedical sciences'. However, apart from referring to the above-mentioned ten areas,[443] it did not provide any definition of this term. That would have been useful, as different classifications of the fields of science are given in both scholarly[444] and practical[445] sources, making biomedical sciences, which are a part of the object of this study, even more difficult to define and distinguish from other scientific and technological fields. The situation was further complicated by the fact that, in principle, neither Lithuanian nor foreign sources[446] provide a definition of the Lithuanian term 'biomedicinos mokslai' or the English term 'biomedical sciences'. Also, the terms 'life sciences'[447] and 'biotechnology'[448] which, at first glance, seem to be related to the analysed field of science, are commonly used in both Lithuanian and foreign schol-

443 Biology, biophysics, ecology and environmental sciences, botany, zoology, medicine, odontology, pharmacy, public health and nursing (Order of 2012).

444 E.g. George A Cogswell, 'The Classification of the Sciences' (1899) 8 The Philosophical Review 494, 494.

445 E.g. Organisation for Economic Co-operation and Development, Directorate for Science, Technology and Industry, Committee for Scientific and Technological Policy, 'Revised Field of Science and Technology (FOS) Classification in the Frascati Manual' (26 February 2007) <http://www.oecd.org/science/inno/38235147.pdf> accessed 30 May 2023 (Revised Field of Science and Technology (FOS) Classification in the Frascati Manual).

446 E.g. the term in question is met more frequently in accidental sources, the purpose of which is not to provide the scientific definition of 'biomedical sciences', but to explain the term to the general public. For example, the University of Oxford, in its publicly available information on study programmes, provides a definition of the term 'biomedical sciences' which states that it is an interesting and dynamic field that can help in understanding and treating illnesses and that is focused on 'how cells, organs and systems function in the human body' (University of Oxford, Admissions, Undergraduate, Courses A-Z of courses, Biomedical Sciences <https://www.ox.ac.uk/admissions/undergraduate/courses-listing/biomedical-sciences?wssl=1> accessed 30 May 2023). The term 'biomedical sciences' is also used in other sources, but the definition is not given (e.g. Jasanoff, *Science at the Bar. Law, Science, and Technology in America* (n 72) 5).

447 In Lithuanian: 'gyvybės mokslai'.

448 In Lithuanian: 'biotechnologija'.

arly literature. This situation concerning the term 'biomedical sciences' has led this study to search for related categories and analyse their relationship. Therefore, the adoption of the Order of 2019, which removed the term 'biomedical sciences' from the legal provisions and introduced two fields, natural sciences (*inter alia* including chemistry, biochemistry, biology, biophysics, botany and zoology)[449] and medical and health sciences (*inter alia* including medicine),[450] as possibly closest to the biomedical sciences, has not changed the focus of this study.

According to the classification of scientific and technological fields presented by the Organisation for European Economic Co-operation and Development (the 'OECD'), which is followed by the EU's statistics office (Eurostat), the following fields of science and technology exist: (1) natural sciences; (2) engineering and technology; (3) medical and health sciences; (4) agricultural sciences; (5) social sciences; (6) humanities.[451] Based on this classification, these fields are further divided into smaller areas (for example, natural sciences are comprised of mathematics, computer and information sciences, physical sciences, chemical sciences, earth and related environmental sciences, biological sciences and other natural sciences),[452] and then into even smaller units.[453]

In this international classification of the scientific and technological fields, the term 'biomedical sciences' is not used, and its definition is not available in any English-language sources. Based on a comparison of the content of the mentioned international documents and the Order of 2012,[454] it can be stated that, according to the classification outlined in the Order of 2012, the areas of science and technology that belong to the biomedical sciences fall under (1) the biological sciences that are part of the field of the natural sciences, and (2) the field of medical and health

449 Order of 2019.
450 ibid.
451 Revised Field of Science and Technology (FOS) Classification in the Frascati Manual (n 445) 12.
452 ibid 6-7.
453 E.g. biological sciences are comprised of cell biology, microbiology, virology, biochemistry and molecular biology, biochemical research methods, mycology, biophysics, genetics and heredity, reproductive biology, developmental biology, plant sciences, botany, zoology, ornithology, entomology, behavioural sciences biology, marine biology, freshwater biology, limnology, ecology, biodiversity conservation, biology (theoretical, mathematical, thermal, cryobiology, biological rhythm), evolutionary biology, other biological topics (ibid 7).
454 Order of 2012.

sciences.[455] These are the areas listed in the current Order of 2019[456] which also seem to be closest to biomedical sciences.

The classification of the biomedical sciences as part of the two fields mentioned above (biology, as part of the natural sciences, and medicine) is supported by the Convention for the protection of Human Rights and Dignity of the Human Being with regard to the Application of Biology and Medicine (Convention on Human Rights and Biomedicine), in the title of which biology and medicine are used as equivalents to 'biomedicine'.[457] The content of the aforementioned Convention on Human Rights and Biomedicine reveals that this legislation covers only actions related to the human body.[458] However, the definition of the term 'biomedical' provided by the Oxford Dictionary indicates that it should be understood 'as relating to both biology and medicine'.[459] The latter definition is also provided in Taber's Cyclopedic Medical Dictionary, where it is stated that the term 'biomedical' refers to the application of natural sciences in medical research.[460] In other sources, it is also indicated that the term 'biomedicine' is perceived as combining 'the traditional basic science of biology with the traditional technical practice of medicine',[461] adding that it is not clear where the said knowledge and medical practice begin and where they end: they are interconnected and interwoven.[462] In view of this, it can be held that the term 'biomedicine' can cover human, animal and plant-related aspects.

In the OECD Glossary of Statistical Terms, 'biomedical research' is described as: (1) the study of specific diseases and conditions (mental or physical), including the detection, cause, prophylaxis, treatment and rehabilitation of persons; (2) the design of methods, drugs and devices used to diagnose, support and maintain the individual during and after treatment for specific diseases or conditions; (3) the scientific investigation required to understand the underlying life processes affecting disease and

455 Revised Field of Science and Technology (FOS) Classification in the Frascati Manual (n 445) 7-9.
456 (1) natural sciences and (2) medical and health sciences (Order of 2019).
457 Convention for the protection of Human Rights and Dignity of the Human Being with regard to the Application of Biology and Medicine: Convention on Human Rights and Biomedicine (ETS No. 164) (adopted 4 June 1997).
458 ibid Articles 1-27.
459 Angus Stevenson (ed), 'Biomedical', *Oxford Dictionary of English* (3rd edn, OUP 2010) 168.
460 Donald Venes, 'Biomedical', *Taber's Cyclopedic Medical Dictionary* (2017) 266.
461 John M Ziman, *Science in Civil Society* (Imprint Academic 2007) 22.
462 ibid.

human well-being, including such areas as cellular and molecular bases of diseases, genetics and immunology.[463] Although this definition pertains to the aforementioned fields of biology and medicine, compared to the previously discussed sources, it can be viewed as narrower and limited to the activities related to human beings and their physical or psychological health.

The term 'life sciences' covers sciences that study living organisms: biology, botany, zoology, microbiology, physiology, biochemistry and related subjects.[464] According to the OECD classification,[465] all of these sciences belong to either biological or medical fields. As both of these sciences fall under the category 'biomedical sciences' outlined in the Order of 2012,[466] the term 'life sciences' can be equated with the biomedical sciences.

Scientific and technological advances affect not only the definition of biomedical sciences, but also the differentiation of their narrower constituent areas, for example, genetics, cell biology, ecology, microbiology, biochemistry and molecular biology.[467] It may be argued that this situation was influenced by the new tools and ideas that have emerged in the 21st century and have been used in biology in order to reveal new links between different fields of life sciences or erase the existing boundaries between them.[468] Organisations responsible for the policy of science indicate that the integration of science and technology will only increase, bringing more and more benefits to public health, food safety, environmental protection and other important socio-economic needs while extending beyond the biomedical sciences to areas such as information technology.[469] Therefore, biomedical sciences can be intertwined not only with related scientific fields, but also with branches of science and technology outside them.

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463 OECD, *OECD Glossary of Statistical Terms* (OECD Publishing 2008).

464 Stevenson, *Oxford Dictionary of English* (n 459) 1021.

465 Revised Field of Science and Technology (FOS) Classification in the Frascati Manual (n 445) 7-8.

466 Order of 2012. Currently, the sciences falling under the category 'biomedical sciences' according to the Order of 2012 are divided into two categories: (1) natural sciences and (2) medical and health sciences (Order of 2019).

467 Jerome H Reichman, Paul F Uhlir and Tom Dedeurwaerdere, 'Uncertain Legal Status of Microbial Genetic Resources' in Jerome H Reichman, Paul F Uhlir and Tom Dedeurwaerdere (eds) *Governing Digitally Integrated Genetic Resources, Data, and Literature: Global Intellectual Property Strategies for a Redesigned Microbial Research Commons* (Cambridge University Press 2016) 1-33, 20.

468 ibid 20 citing NAT'L RESEARCH COUNCIL (NRC), A NEW BIOLOGY FOR THE 21ST CENTURY (Natl'l Acads. Press 2009) at 41-42.

469 ibid 20-21.

One example of technologies related to the biomedical sciences is biotechnology, which has a large amount of definitions.[470] Scholarly literature indicates that biotechnology is not a completely new phenomenon.[471] Certain biological processes, for example the fermentation of cheese, wine and beer,[472] have been known for thousands of years, but the term 'biotechnology' was first used only in 1917, and modern biotechnology[473] (also known as new, innovative or advanced biotechnology)[474] appeared only around the 1970-1980, when scientists discovered a way to alter the genetic constitution of living organisms with the help of processes from traditional breeding practices.[475] The developed genetic engineering influenced both traditional spheres of biotechnology as well as further accomplishments in the fields of medicine and agriculture.[476]

Currently, modern biotechnology includes such processes as genetic modification carried out using recombinant DNA techniques, cell-fusion technologies and modern traditional biotechnological processes.[477] Hence, it is usually indicated in the literature that the manipulation of live organisms is the main tool of modern biotechnology.[478] This advancement in biotechnology has changed a long-standing perception of the surrounding environment, at the same time raising complex issues with regard to the regulation of the relevant field of technology, which leads to the necessity of comprehensive assessments of the impact of these technologies.

Essentially, this field of technology is described as the application of scientific knowledge and technologies to living organisms, as well as their segments, products or models, in order to modify animate or inanimate material in such a way that new goods and services may be produced or

470 There are sources that give several definitions of the term 'biotechnology'. See e.g. John E Smith, *Biotechnology* (5th edn, Cambridge University Press 2009) 3.
471 Smith, *Biotechnology* (n 470) 8.
472 *Netherlands v Parliament and Council* (n 90) para 10; Mills, *Biotechnological Inventions: Moral Restraints and Patent Law* (n 4) 8.
473 Mills, *Biotechnological Inventions: Moral Restraints and Patent Law* (n 4) 8.
474 Andrea Stazi, *Biotechnological Inventions and Patentability of Life. The US and European Experience* (Edward Elgar Publishing 2015) 2.
475 Smith, *Biotechnology* (n 470) 4-5.
476 ibid.
477 ibid 3.
478 Martina Newell-McGloughlin and Edward Re, *The Evolution of Biotechnology. From Natufians to Nanotechnology* (Springer 2006) xi.

new knowledge acquired.[479] According to the Convention on Biological Diversity of 5 June 1992, the term 'biotechnology' encompasses 'any technological application that uses biological systems, living organisms, or derivatives thereof, to make or modify products or processes for specific use'.[480] In other sources, biotechnology is understood as a range of enabling technologies which can be applied in different areas of industry,[481] for example by manipulating living organisms or individual components of their cells in order to create beneficial goods, products or services,[482] or as 'the use of biological processes, organisms or systems to manufacture products intended to improve the quality of human life or modernise industry'.[483] The OECD assigns this area of technology to the fields of medicine and health sciences, engineering and technologies as well as agricultural sciences.[484]

One of the most prominent features of biotechnology is its interdisciplinarity.[485] First, biotechnology is not only used in the field of biomedical sciences (medicine, veterinary, environmental protection,[486] pharmacy[487]) but also in agricultural sciences, engineering and other fields.[488] Second, biotechnology is also characterised by its interdisciplinarity because it is based on a wide range of disciplines, such as 'microbiology, biochemistry, molecular biology, cell biology, immunology, protein engineering, enzymology, classified breeding techniques, and the full range of bioprocess technologies'.[489] All this makes it reasonable to consider biotechnology as the

479 Organisation for Economic Co-operation and Development, Directorate for Science, Technology and Industry, Committee for Scientific and Technological Policy, 'A Framework for Biotechnology Statistics' (2005) <https://www.oecd.org/health/biotech/aframeworkforbiotechnologystatistics.htm> accessed 30 May 2023, 9 (A Framework for Biotechnology Statistics).

480 5 June 1992 Convention on Biological Diversity <https://www.cbd.int/convention/text/> accessed 30 May 2023.

481 Smith, *Biotechnology* (n 470) 4.

482 Newell-McGloughlin and Re, *The Evolution of Biotechnology. From Natufians to Nanotechnology* (n 478) xi.

483 European Patent Office, 'Biotech patents' (2 November 2022) <https://www.epo.org/en/news-events/in-focus/biotechnology-patents> accessed 30 May 2023.

484 Revised Field of Science and Technology (FOS) Classification in the Frascati Manual (n 445) 12; Smith, *Biotechnology* (n 470) 4-5.

485 Smith, *Biotechnology* (n 470) 6.

486 Newell-McGloughlin and Re, *The Evolution of Biotechnology. From Natufians to Nanotechnology* (n 478) xi.

487 Smith, *Biotechnology* (n 470) 6.

488 Revised Field of Science and Technology (FOS) Classification in the Frascati Manual (n 445) 12; Smith, *Biotechnology* (n 470) 4-5.

489 Smith, *Biotechnology* (n 470) 4.

'integration of natural and engineering sciences'[490] or 'integration of natural sciences and organisms, cells, parts thereof, and molecular analogues for products and services'.[491]

In the light of the aforementioned interdisciplinarity and applicability of biotechnology in various fields as well its rapid development, it is not unexpected that the provision of a 'concrete legal *terminus technicus* in this area is impossible and unnecessary'.[492] The OECD publication 'A Framework for Biotechnology Statistics' highlights the difficulties in describing this field of technology with a single definition and, based on the analysis performed in the member countries and non-member countries, recommends the use of both a definition of the term 'biotechnology' and a list of technologies belonging to this branch in order to achieve reliable statistical results.[493] Therefore, biotechnology can be regarded as part of the biomedical sciences, which in this work are perceived as covering aspects related to both biology and medicine, but not limited to them and connected to other areas, for example those relating to information technology, such as bioinformatics.[494]

Considering all of the above, it can be concluded that, due to the rapid advancement of science and technology and their close interconnection, a precise definition of the term 'biomedical sciences' is difficult to achieve. However, according to the analysed sources, it may be stated that the term in question essentially covers the fields of biology and medicine and can be identified with the category 'life sciences' or, in certain particular cases, with biomedicine. One of the branches of technology based on the knowledge of the biomedical sciences is biotechnology, which has made significant progress in the second half of the 20th century and is recognised as an essential element in many fields of science, including the biomedical sciences. This means that the knowledge of biomedical sciences is crucial, both for the proper functioning of biotechnology and for the overall perception as well as the assessment of its actions. The term

490 Newell-McGloughlin and Re, *The Evolution of Biotechnology. From Natufians to Nanotechnology* (n 478) 196.

491 Smith, *Biotechnology* (n 470) 2 citing European Federation of Biotechnology (EFB). Biotechnology in foods and drinks. Briefing Paper 2. Task Group on Public Perceptions of Biotechnology. Holland: EFB, 1994.

492 Paulius Jurčys, 'Biotechnologinių ir nanotechnologinių išradimų patentavimo teisiniai aspektai' (2006) 61 Justitia 68, 68.

493 A Framework for Biotechnology Statistics (479) 6-9.

494 ibid 7 and 9.

'biomedical sciences' in this study is therefore understood quite broadly and encompasses many areas of science, whose knowledge is essential for the proper assessment of biotechnology when examining inventions on the basis of Art. 53(a) EPC.

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

The term 'tradition' (in Latin: 'traditio' – 'transfer, narration')[495] is defined as the preserving and passing down of customs, rituals, images, ideas and symbols from generation to generation.[496] This term can also be used to describe 'the process of communication of knowledge, doctrine, or technique'.[497] In the anthropology of Western Europe, tradition is understood as 'beliefs, customs, values, behaviour, knowledge or experience that are passed down from generation to generation in a particular society'.[498] It can also be understood as a set of beliefs that is consistent throughout generations and that has a certain interpretation, perception and evaluation.[499]

According to A. MacIntyre, tradition is an argument extended through time, in which certain fundamental agreements are defined and redefined through two types of conflicts: (1) conflicts with critics and enemies, who do not belong to the tradition in question and reject all or certain substantive parts of those agreements; and (2) internal interpretative debates, through which the meaning of the fundamental agreements and the rationale behind them is expressed, allowing the tradition to progress.[500] Both definitions indicate that tradition can be described as having the following features: (1) certain substantive agreements, which can be expressed through customs, rituals, symbols, etc., and (2) the intergenerational *trans-*

495 Vaitkevičiūtė (ed), *Tarptautinių žodžių žodynas* (n 69) 603; H Patrick Glenn, 'Doin' the Transsystemic: Legal Systems and Legal Traditions' (2005) 50 McGill Law Journal 863, 873.

496 Vaitkevičiūtė (ed), *Tarptautinių žodžių žodynas* (n 69) 603. See also Saburo Ichii, 'On Innovation and Tradition' (1974) 21 Japan Quarterly 273, 274.

497 Glenn, 'Doin' the Transsystemic: Legal Systems and Legal Traditions' (n 495) 873 citing Romila Thapar, "Tradition" in Romila Thapar, Cultural Transaction and Early India: Tradition and Patronage (Delhi: Oxford University Press, 1994) 7 at 8.

498 Rasa Paukštytė-Šaknienė, 'Tradicijos sampratos šiuolaikinėje Lietuvoje' (2012) 88 Lituanistica 206, 206 citing SEYMOUR-SMITH, Charlotte. Macmillan Dictionary of Anthropology. London and Basingstoke: Macmillan Press LTD, 1987. 305 p. 280.

499 Edward Shils, *Tradition* (The University of Chicago Press 1981) 263.

500 Alasdair MacIntyre, *Whose Justice, Which Rationality?* (Notre Dame University Press 1988) 12.

mission of the said agreements with the possibility to rethink them in the long run.

According to E. Shils, a tradition is anything that is constant and repeated through transmission, irrespective of its content or institutional structure,[501] and regardless of how long and in what way (written or oral) it happens.[502] This means that the concept of tradition includes material objects, various beliefs, convictions about people and events, practices or institutions and encompasses 'buildings, monuments, landscapes, sculptures, paintings, books, tools, machines'.[503] Therefore, all accomplished patterns of the human mind, all patterns of belief, all modes of thinking, all achieved patterns of social relationships, all technical practices, all artefacts and all natural objects can be the objects of this *transmission* and can become a tradition.[504] Thus, traditionality can be compatible with any content.[505] Consequently, although we usually speak of artistic, political and similar traditions associated with the social sciences or humanities, it must be recognised that the natural sciences, of which the biomedical sciences are a part, as discussed in this study,[506] can also be regarded as a tradition.[507]

According to J. Jonutytė, the term 'tradition' in current public discourse is often used in ideological battles, making it 'the heart of the slogan for a single correct lifestyle or, on the contrary, the name for a dangerous form of backwardness'.[508] Due to such radical positions surrounding this term, the natural sciences, which are supposed to represent progress, cannot be identified with tradition.

Nevertheless, these extreme views discussed above can be regarded as unfounded, and, as M. Krygier states, the contrasting of tradition with the categories of 'change', 'progress' and 'modernity' is based on a deep misunderstanding of its nature and behaviour.[509] According to B. Russell, scientific and technological advancement, which is contrasted with tradition, often was the reason behind the worst living conditions in a society or parts of it.

501 Shils, *Tradition* (n 499) 16.
502 ibid 12.
503 ibid.
504 ibid 16.
505 ibid.
506 See '2.1. The Concept and Position of the Biomedical Sciences in the 21st Century'.
507 Shils, *Tradition* (n 499) 262.
508 Jonutytė, *Tradicijos sąvokos kaita* (n 39) 7 (translated from Lithuanian into English by the author of this study). See also Shils, *Tradition* (n 499) 3.
509 Martin Krygier, 'Law as Tradition' (1986) 5 Law and Philosophy 237, 251.

For example, the industrial revolution brought about by scientific advancement initially caused 'unspeakable misery' for both adults and children in England and the U.S.: child labour in appalling conditions, handicraftsmen being thrown out of work because of the advent of machines, etc.[510] Currently, with the Fourth Industrial Revolution under way, characterised by unprecedented digital changes and radical biotechnological advances,[511] the question arises as to what impact these innovations will have, not only on the economy, business and trade around the world, in various regions and in individual countries, but also on governance, international security, questions of morality and ethics or even interpersonal relationships.[512]

The aforementioned misunderstanding as regards tradition can be also illustrated by the fact that the biggest and most destructive acts of intolerance of the 20th century were performed by revolutionary regimes based on the ideas of scientific progress, which suggests that the latter, although more progressive, were hardly less intolerant than reactionary regimes.[513] Considering this, it can be agreed that tradition does not necessarily contain more dogmatism and intolerance than scientism, rationalism and secularism.[514] Consequently, tradition cannot be strictly and continuously contrasted with progress, be it social, cultural or even empirical, such as in the natural sciences. Thus, both the approach in favour of existing tradition and the approach denying or refusing it must be treated with caution.

The idea that the natural sciences, including the biomedical sciences, may be also considered a tradition is supported by the ideas of current scientific development. Scholarly literature indicates that in recent centuries, and especially in modern times, the development of the natural sciences has been perceived as a continuous process of accumulation of knowledge, where certain discovered scientific truths after a while are gradually com-

510 Bertrand Russell, *The Impact of Science on Society* (George Allen & Unwin LTD 1952) 31.

511 Klaus Schwab, *The fourth industrial revolution* (World Economic Forum 2016) 21-27.

512 ibid 32-98. The relevance and importance of the latter questions are shown by the fact that that the ethical and social aspects of patenting of inventions which involve artificial intelligence were discussed at the Conference 'Patenting Artificial Intelligence' of the European Patent Organisation (European Patent Organisation, 'Patenting Artificial Intelligence' (Conference summary, Munich, 30 May 2018) <https://e-courses.epo.org/pluginfile.php/23523/mod_resource/content/2/Summary%20Artificial%20Intelligence%20Conference.pdf> accessed 30 May 2023.

513 Shils, *Tradition* (n 499) 5.

514 ibid.

plemented by others, forming a coherent body of knowledge.[515] As the foundations of the classical natural sciences established by G. Galileo, I. Newton and other scientists became the basis on which new generations of explorers could build their knowledge, the view that scientific knowledge is constantly being accumulated gained even more supporters.[516] The development of science seemed unproblematic: 'it is as natural as the growth of a tree'.[517] It was also considered that in the future, all scientific problems will be solved and this growth will come to an end.[518]

However, the scientific achievements at the turn of the 19th and 20th centuries, i.e. the theory of relativity and quantum mechanics, could not be conceived of as new truths to complement the old ones of Newtonian mechanics.[519] This changed the attitude towards the existing fundamental knowledge on the nature and development of science itself. Despite the fact that the idea of accumulating knowledge into a single whole has not been refuted, the perception has emerged that new knowledge might contradict old knowledge, thus making uninterrupted growth of the body of knowledge not possible at all times.[520] Therefore, at present, the cumulative approach to the development of the natural sciences is not the only one, as there is also a non-cumulative perception of the development of these sciences. The latter is based not only on the accumulation of knowledge, but also on its revision, radical renewal and the formulation of new theories that may be incompatible with the preceding ones.[521]

One of the most influential theories[522] on the aforementioned situation regarding the development of natural sciences[523] was proposed by T. Kuhn,

515 Evaldas Nekrašas, *Filosofijos įvadas* (Mokslo ir enciklopedijų leidykla 1993) 117.
516 Nekrašas, *Filosofijos įvadas* (n 515).
517 ibid.
518 ibid.
519 ibid 118.
520 ibid.
521 ibid.
522 Feldman, 'Historic Perspectives on Law & Science' (n 72).
523 When using the term 'science' in his works, T S Kuhn refers to the field of science commonly referred to as 'natural sciences' (e.g. when speaking of scientific revolutions and the nature of normal science, T S Kuhn only presents examples related to natural sciences: discoveries of Nicolaus Copernicus, Isaac Newton, Max Planck or Albert Einstein) (see Kuhn, *The Structure of Scientific Revolutions* (n 70) 6-8, 11-15, 25-34). Also, the Introduction to *The Structure of Scientific Revolutions* suggests that his work seeks to separate natural sciences from social sciences (Kuhn, *The Structure of Scientific Revolutions* (n 70) viii). This position is also presented in his other works: Kuhn, *The Essential Tension: Selected Studies in Scientific Tradition*

who perceived natural sciences as consisting of: (1) so-called 'normal science', which is regarded as being cumulative[524] research that is firmly based on one or more scientific achievements of the past, and recognised by a particular scientific community for a certain period of time as a basis for its further practice;[525] and (2) revolutions, i.e. non-cumulative episodes in the development of science when the old paradigm is completely or partially replaced by a new one that is incompatible with the old one.[526] The first part emphasises convergent and the second part divergent thinking, both of which complement each other.[527] Also, according to T. Kuhn, these two ways of thinking are inevitably conflicting, and therefore the ability to withstand the tension arising between them, which may become unbearable, is a fundamental requirement for any research of good quality, which is why both ways of thinking are important for the progress of the natural sciences.[528]

As T. Kuhn indicates, the concept of 'normal science' relates closely to the category of 'paradigm',[529] which is perceived as universally acknowledged scientific achievements that, at a given point in time, provide problem-solving models and solutions to the community of practitioners.[530] The aim of a paradigm-based scientific approach is not to provide fundamentally new theories, but to ensure that research is in line with what already exists,[531] i.e. to analyse whether it corresponds to a particular prevailing tradition. Therefore, although cumulative 'normal science', which follows the tradi-

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and Change (n 104). Moreover, the fact that T S Kuhn speaks specifically about the natural sciences is also confirmed by the following authors: David C Lindberg, *The Beginnings of Western Science* (Chicago University Press 1992) 359; Algimantas Valantiejus 'Thomas Kuhno istorinė-sociologinė mokslo raidos koncepcija' (2004) 1 Sociologija. Mintis ir veiksmas 126, 126; Esther 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' (PhD thesis, Katholieke Universiteit Leuven Faculty of Law Centre for Intellectual Property Rights, 2011) 7; Sandra Halperin and Oliver Heath, *Political Research: Methods and Practical Skills* (OUP 2012) 61.

524 Kuhn, *The Structure of Scientific Revolutions* (n 70) 52.

525 ibid 10.

526 ibid 92.

527 ibid 8.

528 ibid 226.

529 ibid 10.

530 ibid viii.

531 Kuhn, *The Essential Tension: Selected Studies in Scientific Tradition and Change* (n 104) 233.

tion, increases efficiency, it does not lead to fundamental innovations and does not provide answers when a new atypical problem arises and requires resolution within the existing paradigm.[532]

Despite the fact that during the period of 'normal science' the scientific community 'does not aim at novelties of fact or theory',[533] they still occur. If 'normal science' is unable to explain them, they become anomalies, which are viewed 'with the recognition that nature has somehow violated the paradigm-induced expectations that govern normal science'.[534] Thus, the emergence of the said anomalies indicates that paradigms have reached their limits and no longer fulfil their function.[535] When their number reaches a critical limit, 'normal science' faces a crisis which can only be resolved by a fundamental paradigm shift. In such cases, in order to respond to new problems that cannot be explained by 'normal science', the tradition-bound approach requires a tradition-shifting update[536] which leads to fundamental changes, i.e. scientific revolutions,[537] that do not occur often but are of vital importance for the renewal of scientific tradition.

The concept of scientific development discussed above may be associated with A. MacIntyre's theory that every tradition has the following stages of development: (1) texts, beliefs and authorities are not questioned; (2) texts, beliefs and authorities are questioned, which leads to the occurrence of inconsistencies; (3) there is a desire to answer the aforementioned inconsistencies, and thus texts, beliefs and authorities are reviewed.[538] The first two stages can be attributed to the concept of 'normal science' proposed by T. Kuhn, whereas the last one can include the paradigm-shifting stage, where the scientific revolution is most evident.

Nevertheless, even in the non-cumulative stages of the development of the natural sciences, there are arguments for considering this scientific field, including the biomedical sciences, as a tradition. This can be inferred from T. Kuhn's rather restrained position regarding the effectiveness and process of scientific revolutions. '[R]evolutionary changes in the scientific

532 Kuhn, *The Structure of Scientific Revolutions* (n 70) 233.
533 ibid 52.
534 ibid 52-53.
535 ibid 92.
536 ibid 227.
537 ibid 92.
538 MacIntyre, *Whose Justice, Which Rationality?* (n 500) 355.

tradition'[539] he perceives as short and scarce stages of radical paradigm shift, which interfere with the relatively static and prolonged stages of question-solving in the context of 'normal science', because '[a]lmost none of the research undertaken by even the greatest scientists is designed to be revolutionary, and very little of it has any such effect'.[540]

Furthermore, scientific revolutions are not necessarily monumental, but rather encompass events affecting only a narrow subsection of the community of natural sciences.[541] In principle, it is enough for a change to have an impact on a small group of scientists to be recognised as a scientific revolution. As indicated by T. Kuhn, to astronomers, the discovery of X-rays can be only an addition to existing knowledge which does not affect their paradigm, but for Lord Kelvin, W. Crookes or V. H. Röntgen, whose studies involved radiation and cathode-ray tubes, it was an event leading to a new paradigm.[542] Hence, the extent and the importance of scientific revolutions can vary.

Moreover, according to T. Kuhn, scientists themselves are not inclined to change the paradigm immediately: the new paradigm will be taken on by the younger colleagues, and the old one will exist until scientists who support it die out.[543] Thus, the result of the scientific revolution, i.e. which paradigm will be chosen in the face of their competition, will depend on the decision of the community concerned.[544] This suggests that these revolutions are not always sudden and frequent, and that the development of the natural sciences is determined by the scientific community and not by a self-contained process isolated from society.

The difficulties faced when abandoning old theories and adopting new ones can be influenced by the teaching of the natural sciences. According to T. Kuhn, considering how the natural sciences are taught, it is clear that the convergent way of thinking is emphasised much more than the divergent way.[545] The latter theorist also claims that young scientists study the most

539 Kuhn, *The Essential Tension: Selected Studies in Scientific Tradition and Change* (n 104) 227.
540 ibid.
541 Kuhn, *The Structure of Scientific Revolutions* (n 70) 49.
542 ibid 93.
543 ibid 150-151. He was supported by M Planck (see Cohen, *Revolution in Science* (n 70) 467-468).
544 Kuhn, *The Structure of Scientific Revolutions* (n 70) 94.
545 Kuhn, *The Essential Tension: Selected Studies in Scientific Tradition and Change* (n 104) 228.

prominent paradigm at a particular time and, based on it, are trained to discover the 'right' answer.[546] Generally, students are taught only from textbooks and are not encouraged to get acquainted with classical works in certain fields of the natural sciences as well as the theories mentioned in them, which T. Kuhn believes would give them the opportunity to see the questions discussed in the textbooks from a different perspective and allow them to familiarise themselves with the concepts, problems and solutions that have already been refuted long ago.[547] Thus, young natural scientists do not have to rediscover everything, but rather follow what has already been discovered and presented in the textbooks, i.e. rely on solutions to problems that are in line with the existing paradigm,[548] which may lead to a reluctance to abandon prevailing scientific theories.

E. Shils supports the idea of the dominance of convergent thinking in the natural sciences, suggesting that patterns of reason and the scientific method are not created by each participant of a tradition, but 'are mostly inherited'.[549] All of this can reasonably affect the identification of a research topic, its formulation and the process of research itself, which makes the effect of tradition on natural sciences quite evident. According to the aforementioned theorist, in the natural sciences there is also a tradition outside the laboratory controlling the research and publications, and although, as E. Shils argues, the scientific approach does not officially bind scholars, many still follow it.[550]

Also, in the course of a scientific revolution, knowledge of the prevailing paradigm is essential even for the revolution itself, in order to recognise anomalies. According to T. Kuhn, only with sufficient knowledge of current 'normal science' is it possible to determine whether it is functioning inadequately, and what is the cause of these anomalies.[551] This situation can be illustrated by the corpuscular theory of thermal phenomena and states of matter developed by chemist R. Boyle, which replaced Aristotle's and Paracelsus' perception of these aspects.[552] Instead of relying on Aristotle's

546 Kuhn, *The Essential Tension: Selected Studies in Scientific Tradition and Change* (n 104) 228.
547 ibid 228-229.
548 ibid 229.
549 Shils, *Tradition* (n 499) 21.
550 ibid 272.
551 Kuhn, *The Structure of Scientific Revolutions* (n 70) 65.
552 Science History Institute, Robert Boyle <https://www.chemheritage.org/historical-profile/robert-boyle> accessed 30 May 2023.

definition of physical reality and analysing changes in both matter and form as the classical elements of earth, air, fire and water, or, based on Paracelsus' ideas, as three elements – salt, mercury and sulphur, R. Boyle did it in a completely new way, by using particles and their motion.[553] This led to a shift from non-empirical, logically based theories of the natural sciences to empirical ones that seek to determine if the aforementioned theory really works,[554] which seems to be routine today.

In order to propose these new ideas, R. Boyle was supposed to be well acquainted with the theories of the aforementioned ancient and medieval scholars and to question them. This reveals the existence of continuity between old and new theories of science. According to A. F. Chalmers, a similar situation exists in relation to A. Einstein's theory of relativity: identifying the problems to which this scientist proposed solutions required two hundred years of meticulous 'work in I. Newton's paradigm and a hundred years of work in limits of the theory of electricity and magnetism'.[555] This shows that scientific knowledge does not come from nowhere and no scientist can investigate or consider everything anew. Anomalies are only recognisable against the backdrop of a prevailing paradigm; therefore, knowledge of the general concepts of earlier periods is necessary for the emergence of scientific knowledge which changes the tradition. All this shows that even the revolutions of natural sciences are closely linked to traditionality.

In this context, it can be agreed with T. Kuhn that a successful scientist must have the characteristics of both a traditionalist and an iconoclast.[556] Scientists must be fully committed to the tradition, which they will abandon if the research is successful.[557] The two approaches mentioned above (tradition-bound and tradition-shifting) and the relationship between them, which was called 'the essential tension' by the latter scientist,[558] are considered to be the most prominent features of the natural sciences, and

553 Science History Institute, Robert Boyle <https://www.chemheritage.org/historical-profile/robert-boyle> accessed 30 May 2023.

554 L Pearce Williams and Henry John Steffens, *The History of Science in Western Civilization*, vol 2 (University Press of America 1978) 1.

555 Chalmers, *Kas yra mokslas?* (n 71) 143 (translated from Lithuanian into English by the author of this study).

556 Kuhn, *The Essential Tension: Selected Studies in Scientific Tradition and Change* (n 104) 227.

557 ibid 235.

558 ibid 227.

are essential for both systematic research and technological development as well as the progress of radical new innovation.

K. Popper claimed that in the field of the empirical sciences, a scientist 'constructs hypotheses, or systems of theories, and tests them against experience by observation and experiment'.[559] In view of this, he argued that, for human knowledge to be considered a scientific theory, it must be capable of being tested by experience,[560] and that 'every genuine test of a theory is an attempt to falsify it, or to refute it'.[561] Thus, 'the criterion of the scientific status of a theory is its falsifiability, or refutability, or testability'.[562]

If the conclusions prove acceptable or '*verified*',[563] for a certain period of time there is no way to reject the theory, whereas if the 'conclusions have been *falsified*, then their falsification also falsifies the theory from which they were logically deduced'.[564] In the latter case, it becomes apparent that, as T. Kuhn would argue, the theory contains anomalies and can therefore be rejected. Only when a theory stands up to extensive and rigorous testing, and is not superseded by another theory in the course of scientific progress, is it considered '*corroborated*'.[565] Still, according to K. Popper, although a scientific theory is currently tested, this does not mean that it will not be disproved in the future: a positive decision can only provide temporary support for a theory, because later negative decisions can always refute it.[566] Thus, similarly to the above-mentioned tradition-bound and tradition-shifting approaches, verification and falsification are constantly interacting with each other in the field of the empirical sciences to determine the scientific status of a theory.

The natural sciences also follow the tradition-specific characteristics presented by M. Krygier: (1) pastness, which means that the content of every tradition was formed at a certain time in the past; (2) authoritative presence, which indicates that particular practices, doctrines and convictions, formed in the past, affect the lives, thoughts and actions of the current participants of the same tradition; (3) transmission, which means

559 Karl Popper, *The Logic of Scientific Discovery* (2nd edn, Routledge 2002) 3.
560 ibid 18 and 26.
561 Karl Popper, *Conjectures and Refutations: The Growth of Scientific Knowledge* (reprint edn, Routledge 2004) 48.
562 ibid.
563 Popper, *The Logic of Scientific Discovery* (n 559) 10.
564 ibid.
565 ibid.
566 ibid.

that a tradition is deliberately or unknowingly transmitted from generation to generation, rather than being suddenly transferred from the past to the present without any link with the latter.[567]

Based on the above-mentioned characteristics and all that has been discussed above, it can be held that the natural sciences are characterised by pastness: for example, the origins of many of the natural sciences can be found in the works of classical ancient philosophers.[568] Also, in their continuous research, scientists are always influenced by their predecessors and their work, i.e. every scientist sees the object of research not only through his/her own perspective, but also from the view of his/her predecessors and colleagues.[569] Even if they are later refuted or changed, they still serve as a starting point for creating new results. While looking at the natural sciences, E. Shils points out that each generation of scientists acquires what was achieved by their predecessors through consistent research and analysis, after rigorous rational reflection and refined articulation.[570] This means that the results of these actions and experiences are transferred to the subsequent generations.

The recognition of the natural sciences, including the biomedical sciences, as a tradition, discussed in this part of the study, suggests that the preservation of the prevailing theories of the natural sciences or, on the contrary, their denial and refusal, is a decision of the scientific community, often shaped by the existing tradition, but is not always a self-contained and objective scientific process based on scientific knowledge. This understanding that the development of the natural sciences can be determined by social factors is particularly important in shaping the response of the legal system to the changing environment which we understand with the help of the natural sciences. This allows the legal system to take a more cautious and critical look at the environment – which may be required to assess the consistency of the commercial exploitation of biotechnological inventions on the basis of Art. 53(a) EPC from the perspective of the biomedical sciences.

567 Krygier, 'Law as Tradition' (n 509) 240.
568 Marshall Clagett, *The Science of Mechanics in the Middle Ages* (The University of Wisconsin Press 1959) xix.
569 John M Ziman, *Public knowledge: an essay concerning the social dimension of science* (Cambridge University Press 1968) 9.
570 Shils, *Tradition* (n 499) 22.

2.3. Preliminary Conclusion

Although it is difficult to find a definition of the term 'biomedical sciences', it can be argued that this scientific field essentially covers the spheres of science falling under the categories of biology and medicine, and can be identified with life sciences or, where appropriate, with biomedicine. Biomedical sciences are also closely linked to biotechnology, which can be used in the field of biomedical sciences and evaluated on the basis of knowledge in this field. In view of the rapid advancement in science and technology, and the interconnections between different disciplines and branches, such a broad concept of biomedical sciences can be considered reasonable.

The natural sciences, including the biomedical sciences, can be perceived as phenomena encompassing both cumulative and non-cumulative development. This makes it possible to claim that tradition and revolution exist side by side in this field of science. Therefore, in the case of both normal natural sciences and scientific revolutions, the knowledge and assessment of the environment and its processes is influenced by the attitude of the scientific community, which is usually shaped by the existing traditions and may not always objectively reflect reality. This may encourage the European patent system to be more cautious about the knowledge provided by biomedical sciences and to make decisions only after a more careful assessment of the surrounding environment and its knowledge.

3. The Western Legal Tradition

3.1. The Importance of the Category 'Tradition' in a Legal System

In the previous chapter of this study, it was pointed out that traditionality is not always appreciated in Western intellectual thought. Traditional thinking is often contrasted with progressive and independent thinking, and traditional teaching methods with innovative methods, etc.[571] Also, traditional communities are often not considered to be dynamic, self-critical or rational, and discussions in Western societies show a clear dichotomy between modernity and tradition.[572] Nevertheless, this view, which in essence suggests that the modern Western world appeared out of nowhere and did not require many years of development, H. P. Glenn considers to be unfounded.[573] According to him, everyone is part of a certain tradition, and therefore both Western societies and Western law have their own traditions, which are directly recognised by the representatives of the legal tradition itself.[574]

The question of why it is crucial for lawyers to analyse and learn about their legal tradition is answered by the very nature of law. Scholarly literature indicates that tradition is present in almost every legal system, and is even its 'most important feature'.[575] Although modern predominantly positivist law is considered to be 'post-traditional law',[576] 'the fact that modern law also retains a relation to its past, to its history'[577] cannot be denied. This means that 'legal practices derive their necessary conceptual, normative and methodological resources, even their very possibility, from

571 Glenn, *Legal Traditions of the World* (n 42) 1.
572 H Patrick Glenn, 'A Concept of Legal Tradition' (2008) 34 Queen's Law Journal 427, 429.
573 ibid citing Charles Taylor, A Secular Age (Cambridge: Harvard University Press, 2007), Harold J Berman, Law and Revolution: The Formation of the Western Legal Tradition (Cambridge: Harvard University Press, 1983) at 112.
574 Glenn, *Legal Traditions of the World* (n 42) 3.
575 Krygier, 'Law as Tradition' (n 509) 239.
576 Kaarlo Tuori, 'The Law and its Traditions' (1989) 12 Scandinavian Political Studies 490, 494.
577 ibid.

the law's subsurface levels'.[578] Thus, human beings almost never look at a perceivable or an interpretable object without prejudice or predetermined intentions.[579] Tradition forms each person's self-consciousness, world view and aspirations, directs the ways and means of implementing them, and is also important for the relationship of the individual with the surrounding living and non-living environment.[580] This means that the perception of objects of reality is carried out through the help of 'conceptual and interpretative means provided by a specific tradition'.[581] Therefore, this category becomes important in every legal system.

M. Krygier points out that every tradition, including legal tradition,[582] consists of the elements discussed previously in this study:[583] (1) pastness, which means that the content of every tradition was formed, or is believed to have been formed, at a certain time in the past; (2) authoritative presence, which indicates that traditional practices, doctrines and convictions from the past did not remain there, but rather became important and have acquired a certain authority in the lives, thoughts or actions of the present participants in a certain tradition; (3) transmission, which means that a tradition is deliberately or unconsciously transmitted from one generation to the next, rather than being suddenly transferred from the past to the present without any link with the latter.[584] This scholar claims that law, more than most other traditions, is adapted to preserve and maintain these elements and to systematically rely on them.[585]

578 Tuori, 'The Law and its Traditions' (n 576) 494.

579 ibid 491. K. Tuori calls this the 'philosophical-hermeneutical concept of tradition' which indicates 'that all human acts of consciousness, all acts of understanding, interpretation and cognition are bound to tradition; we humans never approach the object of our cognition or interpretation with a *tabula rasa* consciousness but always through the conceptual and interpretative means provided by a specific tradition. "Tradition" in this sense is equivalent to the preconceptions ("pre-understanding") and prejudices which – as Gadamer emphasizes – are necessary in order for the process of understanding and interpretation to be launched. We draw this "preunderstanding" from the culture into which we have been "thrown", in which we have grown up and internalised our fundamental conceptions of the world.' (ibid 491-492).

580 Linas Baublys, *Antikinė teisingumo samprata ir jos įtaka Vakarų teisės tradicijai* (Mykolo Romerio universitetas 2005) 12.

581 Tuori, 'The Law and its Traditions' (n 576) 491.

582 Krygier, 'Law as Tradition' (n 509) 240.

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

584 Krygier, 'Law as Tradition' (n 509) 240.

585 ibid.

Each tradition consists of elements of the real or imaginary past.[586] This is a fundamental feature of any tradition, law being no exception, which makes the legal past of every legal system relevant to the legal present.[587] As with any complex tradition, law captures and preserves a set of well-established but often conflicting beliefs, opinions, values, decisions, myths or rituals.[588] The maintenance of the past in law is institutionalised: legal sources are recorded, grouped by type, matter of obligation, importance, etc., which the participants in the legal system must later take into account when interpreting the law and formulating their arguments.[589] Thus, any legal tradition can be said to be characterised by the past, which means that the current law is a heritage created through the input of many centuries and the contribution of many generations of people with non-consistent visions recognising competing values and different views of the world.[590] This heritage is comprised of particular legal mechanisms, procedures and norms that are employed by consecutive generations to solve the relevant questions.[591] Therefore, understanding a particular legal tradition, even one that encompasses conflicting views, can help in better comprehending the vision of the lawmakers of the past when seeking the answers to current legal problems.

However, law is traditional not only because of its past. It must have an authoritative presence.[592] It is precisely when the true or the imaginary past does not disappear without trace, but rather performs a normative or an authoritative role in relation to the values and convictions of its participants, including lawyers, that this element of tradition is considered to be fulfilled.[593] Nevertheless, the authoritative presence does not mean that today's lawyers must be experts in the legal system of the past and its application. F. W. Maitland argued that what is usually expected from a practising lawyer is not simply the knowledge of, for example, the law of the Middle Ages, but rather the knowledge of it interpreted by the

586 Krygier, 'Law as Tradition' (n 509) 240; Glenn, 'A Concept of Legal Tradition' (n 572) 430.
587 Krygier, 'Law as Tradition' (n 509) 240-241.
588 ibid 241.
589 ibid.
590 ibid 242.
591 Jevgenij Machovenko, 'Lietuvos viešosios teisės iki XVIII a. pabaigos istorijos tyrimų būklė ir perspektyvos' (2011) 79 Teisė 22, 26.
592 Krygier, 'Law as Tradition' (n 509) 245.
593 ibid 246.

contemporary courts in a way that is consistent with the facts of today.[594] According to M. Krygier, for lawyers, historical legal sources are important not for the purpose of revealing past events, but rather as authoritative material which may help in finding answers to current problems.[595] Thus, this authoritative presence determines the effect of the legal tradition, as a totality of elements from the past, when solving present legal issues.

Lastly, according to M. Krygier, tradition must be characterised by transmission. It is argued that traditions are dependent on real or imaginary continuity between the past and the present, which can be formalised or institutionalised, as for example in law or religion.[596] It is transmission that is connected with another important aspect of tradition, namely change. Authoritative interpreters in the field of law, for example, can strive to ensure that the interpretation of law would not diverge from the interpretation of the past. However, changes in tradition are inevitable,[597] even if they remain dependent on it.[598] Therefore, knowledge of a legal tradition is important for understanding how, over time, a specific legal system can react and change in response to new factual circumstances.

According to H. P. Glenn, as the participants in the legal system increasingly choose not to rely only on the legislation adopted by specific state-authorised entities, law is becoming more and more extensive, which encourages the search for a broad category allowing the organisation of both the different sources of law that are used and the relations among them.[599] This is why, according to the aforementioned scholar, knowledge about the legal tradition is essential, as it provides the measures to ensure a 'peaceful coexistence of different ideas and peoples'.[600] As indicated by L. Baublys, an understanding of a tradition provides us with methods for knowing the content of the existing law and the criteria for assessing it.[601] Also, according to H. P. Glenn, legal tradition is a certain basis allowing for the analysis of both positive law and the social norms that are outside

594 Krygier, 'Law as Tradition' (n 509) 248-249 citing The Collected Papers of Frederic William Maitland, ed. H. A. L. Fisher (Cambridge: Cambridge University Press), vol. 1, p. 491.
595 ibid 250.
596 ibid.
597 ibid 251-252.
598 ibid 254.
599 Glenn, 'A Concept of Legal Tradition' (n 572) 427.
600 ibid 444.
601 Baublys, *Antikinė teisingumo samprata ir jos įtaka Vakarų teisės tradicijai* (n 580) 13.

the boundaries of the law established by the state[602] and influence the legal system.

The latter aspect is especially important in the Western legal tradition, where, on the one hand, according to H. J. Berman, there is a prevailing belief that law is a special phenomenon, characterised by a certain relative autonomy, and can therefore be analytically distinguished from other spheres of social reality.[603] On the other hand, in this tradition, 'law is greatly influenced by religion, politics, morality and customs'.[604] That is why the Western legal tradition constantly raises the question of not only the relationship between the positive, state-established law and certain values beyond it, but also the connection between the latter and other areas of reality and their effect on the legal systems that belong to the Western legal tradition.

One example of the latter situation is the interpretation and application of Art. 53(a) EPC in deciding on the patenting of biotechnological inventions analysed in this study. In this situation, knowledge of the biomedical sciences influences the decisions made by the Office on the basis of Art. 53(a) of the Convention. However, even with this knowledge, biotechnological inventions are still regarded from the perspective of the Western legal tradition rather than in a neutral way.

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

Classifying legal traditions and legal families is a rather challenging task,[605] simply due to each person's own preconceptions concerning 'what is important in law or a legal system'.[606] As a result, there are a variety of classifications of legal traditions and families.[607] Thus, the exercise and results of distinguishing and defining the Western legal tradition should be accepted and treated with caution.

602 Glenn, 'A Concept of Legal Tradition' (n 572) 428.
603 Berman, *Teisė ir revoliucija: vakarų teisės tradicijos formavimasis* (n 41) 24.
604 ibid (translated from Lithuanian into English by the author of this study).
605 Goldman, *Globalisation and the Western Legal Tradition: Recurring Patterns of Law and Authority* (n 43) 3-4.
606 John W Head, *Great Legal Traditions* (Carolina Academic Press 2011) 11.
607 E.g. ibid 11-12.

Despite its multitude of meanings,[608] the word 'West' can be used to describe Western civilisation.[609] Nowadays, the latter term is often considered to encompass liberal, secular, capitalism- and market economy-oriented societies,[610] and from a geographical perspective, in some scholarly sources,[611] it is generally associated with Europe, including the United Kingdom and some of the countries that were part of the former British Empire.[612] According to H. J. Berman, Western civilisation has formed 'distinct "legal" institutions, values and concepts'[613] deliberately handed down from one generation to the next, resulting in a complex and broad phenomenon, i.e. the Western legal tradition.[614]

The above-mentioned scholar, while describing this legal tradition as originating in the 11th-12th century Gregorian Reform and the struggle for

608 Stevenson, *Oxford Dictionary of English* (n 459) 2016.

609 William H McNeil, 'What we mean by West' (1997) 41 Orbis 513, 513-514.

610 Gunther Hellmann and Benjamin Herborth, 'Introduction: Uses of the West' in Gunther Hellmann and Benjamin Herborth, *Uses of the West. Security and the Politics of Order* (Cambridge University Press 2017) 1-12, 2.

611 František Dvornik, 'Western and Eastern Traditions of Central Europe' (1947) 9 The Review of Politics 463- 481; Goldman, *Globalisation and the Western Legal Tradition: Recurring Patterns of Law and Authority* (n 43) 4; Hellmann and Herborth, 'Introduction: Uses of the West' (n 610) 1-2. The Western legal tradition may include countries with both (1) civil (continental) law systems and (2) common law systems (the United Kingdom (Scotland does not have a common law system), the United States, Canada, Australia and New Zealand) (Head, *Great Legal Traditions* (n 606) 12-13; H Patrick Glenn, 'Legal Traditions and *Legal Traditions*' (2007) 2 The Journal of Comparative Law 69, 85; Catherine Valcke, 'Comparative History and the Internal View of French, German, and English Private Law' (2006) 19 Canadian Journal of Law and Jurisprudence 133, 137). Despite the abundance of countries that are attributed to the Western legal tradition and the peculiarities of these two law systems, it is argued that both systems have long been influencing each other (Franz Wieacker and Edgar Bodenheimer, 'Foundations of European Legal Culture' (1990) 38 The American Journal of Comparative Law 1, 6-7). That is why the differences between them are much smaller than when compared to the Chinese, Islamic or Indian legal traditions (Wieacker and Bodenheimer, 'Foundations of European Legal Culture' (n 611) 4-5; Mark Van Hoecke and Mark Warrington, 'Legal Cultures, Legal Paradigms and Legal Doctrine: Towards a New Model for Comparative Law' (1998) 47 International and Comparative Law Quarterly 495, 502-503; Head, *Great Legal Traditions* (n 606) 12; Egidijus Kūris, 'Teismo precendentas kaip teisės šaltinis Lietuvoje: oficiali konstitucinė doktrina, teisinio mąstymo stereotipai ir kontraargumentai' (2009) 2 Jurisprudencija 131, 132). Therefore, it is reasonable to consider these two systems to be part of the Western legal tradition.

612 E.g. Australia, the United States, Canada and New Zealand.

613 Berman, *Teisė ir revoliucija: vakarų teisės tradicijos formavimasis* (n 41) 15.

614 ibid 16.

investiture, which were followed by the 'new canon law' and the formation of secular legal systems, argues that the analysed tradition 'refers to those nations, whose legal tradition originates from these events'.[615] According to him, it encompasses much of Europe, North and South America and even various other parts of the world.[616] Nevertheless, despite the attempts to define what 'West' is from a geographical point of view, scholarly literature suggests that this term may depend on the historical period[617] or the subject who uses this term,[618] meaning that although the '[g]eographical limits help in finding it [the West], eventually they change'.[619] However, H. J. Berman notes that the West is not just an idea, but also 'encompasses both a historical structure and a structure which has a history'.[620] Therefore, in this study, not the geographical boundaries of the Western legal tradition but the concept summarised by the aforementioned scholar is held to be the most important.

The concept of the analysed legal tradition provided by H. J. Berman covers a rather wide range of closely related features. In the Western legal tradition, according to the aforementioned scholar, it is possible to analytically distinguish law from other areas of social reality.[621] As a result, in this tradition, legal activities are entrusted to legal professionals,[622] who are trained in special educational institutions.[623] In the Western legal tradition, the law encompasses not only legal institutes, legal requirements, legal decisions, etc., but also legal science, which allows the analysis and evaluation of law.[624]

Moreover, in the Western legal tradition, law is perceived as a coherent, unified system,[625] which develops 'in time, from generation to generation, through the ages',[626] and whose viability is determined by the belief that it

615 Berman, *Teisė ir revoliucija: vakarų teisės tradicijos formavimasis* (n 41) 16.
616 ibid.
617 ibid.
618 ibid 17.
619 ibid (translated from Lithuanian into English by the author of this study).
620 ibid (translated from Lithuanian into English by the author of this study).
621 ibid 23-24.
622 ibid 24.
623 ibid.
624 ibid.
625 ibid 25-26.
626 ibid 25 (translated from Lithuanian into English by the author of this study).

has a continuous nature[627] and grows with the passing of the generations.[628] For H. J. Berman, there is an internal logic to this growth: 'in the Western legal tradition, it is assumed that change is not accidental, but emerges with a new interpretation of the past',[629] which means that law is characterised by its historicity.[630] According to the aforementioned scholar, historicity relates to the supremacy of law in relation to political authorities. This supremacy is manifested in the belief that in the West, since the 12th century, even under the rule of absolute monarchs, the law, until otherwise changed, constrained even the rulers.[631]

The Western legal tradition is also described as pluralistic, characterised by 'the coexistence and competition of different jurisdictions and different legal systems in the same society'.[632] This feature determined the complexity of the legal system and the competition among its different parts, but, according to H. J. Berman, it was also the factor which 'promoted the pluralism of Western political and economic life'.[633] The last feature of the Western legal tradition distinguished by H. J. Berman is the 'tension between reality and ideal',[634] which from time to time caused revolutions.[635]

Revolutions, according to the aforementioned scholar, are an important part of the understanding of the Western legal tradition. Indeed, the tradition analysed in this study emerged from a revolution[636] and was later interrupted by other revolutions,[637] during which the aforementioned characteristics arose. Thus, both the internal and external conflicts encouraging change are considered to be important factors that inspired new ideas and the formation of the Western legal tradition. On the one hand, over time,

627 Berman, *Teisė ir revoliucija: vakarų teisės tradicijos formavimasis* (n 41) 26.
628 ibid.
629 ibid (translated from Lithuanian into English by the author of this study).
630 ibid.
631 ibid.
632 ibid (translated from Lithuanian into English by the author of this study).
633 ibid 27 (translated from Lithuanian into English by the author of this study).
634 ibid (translated from Lithuanian into English by the author of this study).
635 ibid.
636 12th century Papal Revolution.
637 Berman, *Teisė ir revoliucija: vakarų teisės tradicijos formavimasis* (n 41) 15. According to H J Berman, the main revolutions are as follows: (1) the Papal Revolution of the 12th century; (2) the Lutheran Revolution in Germany; (3) the Anglo-Calvinist Revolution in England; (4) the Great French Revolution; (5) the American Revolution; (6) the Russian Revolution (Berman, 'The Western Legal Tradition in a Millennial Perspective: Past and Future' (n 103) 742-750).

the Western legal tradition was interrupted by revolutions, each of which, while seeking a new vision of justice, was aimed against the legal system then in existence, but on the other hand, this tradition survived the aforementioned revolutions, with their help renewed itself,[638] and continued to develop organically.[639]

Although revolutions are an important factor in the development of this tradition, bringing novelties, in reality all of the changes are a continuation of what has already happened in the past, because changes in the Western legal tradition do not happen accidentally, but rather by redefining the past for the needs of the present and the future.[640] The author of this study holds that such revolutions include both World Wars of the 20th century, when, according to H. J. Berman, on the one hand the identity of the Western legal tradition was at risk of being lost, but on the other hand there arose a possibility to create a partnership with the newly emerging world order.[641] In view of this, it is considered that the discussion of the concept of the modern Western legal tradition in this study is informed by the ideas that emerged after the Second World War, one of the most prominent of which is the emergence of an international system for the protection of human rights.

After that war, it was understood that, as long as the law is perceived merely as a system of orders issued by the competent entities to which society must unconditionally submit, and the value of human beings is not recognised, it would be impossible to achieve peace or justice in the world. The war showed the consequences of an absolute disregard for the value of human beings. That is why shortly afterwards, on 10 December 1948, the Universal Declaration of Human Rights[642] (the 'Declaration') was signed, announcing to the world that every human being is of value and

638 Berman, 'The Western Legal Tradition in a Millennial Perspective: Past and Future' (n 103) 750-751.

639 Harold J Berman, 'The Western legal tradition: The interaction of revolutionary innovation and evolutionary growth' in P Bernholz, M E Streit and R Vaubel (eds), *Political Competition, Innovation and Growth* (Springer 1998) 35-47, 39-40.

640 Berman, *Teisė ir revoliucija: vakarų teisės tradicijos formavimasis* (n 41) 26.

641 Berman, 'The Western Legal Tradition in a Millennial Perspective: Past and Future' (n 103) 751.

642 Universal Declaration of Human Rights (adopted 10 December 1948) UNGA Res 217 A(III) (Declaration).

that his/her life and dignity must be respected.[643] This document contains a list of human rights which, while not in fact universally accepted and applied throughout the world, lay down minimum conditions of respect for dignity of an individual.[644] Thus, in the mid-20th century, when the legal system became highly human-centred, the human person became a value giving meaning to any state and to the whole legal system, and dignity was recognised as the basis of human rights.[645]

Although the idea of the protection of human rights as universal rights is not considered exclusively Western,[646] according to the scholarly literature, the West was the first to modernise on this issue.[647] Also, despite the fact that the purpose of the Declaration was to reconcile different religious, economic and other views,[648] the concept of human rights, due to its particularly prominent role in the West, appears predominantly Western.[649]

643 E.g. Tade M Spranger, 'Case C-34/10, Oliver Brüstle v. Greenpeace e.V., Judgment of the Court (Grand Chamber) of 18 October 2011' (2012) 49 Common Market Law Review 1197, 1197.

644 Goldman, *Globalisation and the Western Legal Tradition: Recurring Patterns of Law and Authority* (n 43) 232 citing Upendra Baxi, The Future of Human Rights (New Delhi: Oxford University Press, 2nd edn, 2006) and William Twining, 'Human Rights: Southern Voices: Francis Deng, Abdullahi An-Na'im, Yash Ghai, and Upendra Baxi' (2006) 11 Review of Constitutional Studies 203–80.

645 The Preamble of the International Covenant on Civil and Political Rights establishes that 'rights derive from the inherent dignity of the human person' (International Covenant on Civil and Political Rights (adopted 16 December 1966, entered into force 23 March 1976) 999 UNTS 171 (ICCPR)), whereas the Preamble of the Declaration establishes that 'recognition of the inherent dignity and of the equal and inalienable rights of all members of the human family is the foundation of freedom, justice and peace in the world' (Declaration). One of the most recent examples is the Charter of Fundamental Rights of the European Union, in which human dignity is mentioned in the first provision, whereas the right to life and other rights are mentioned in the following provisions (Charter of Fundamental Rights of the European Union, OJ, 2016 C 202, p. 389, Articles 1 and 2 (EU Charter of Fundamental Rights)).

646 Arvind Sharma, *Are Human Rights Western?: A Contribution to the Dialogue of Civilizations* (Cambridge University Press 2005) 24; Darren J O'Byrne, *Human Rights in a Globalizing World* (Palgrave 2016) 110.

647 Goldman, *Globalisation and the Western Legal Tradition: Recurring Patterns of Law and Authority* (n 43) 234.

648 James V Spickard, 'The Origins of the Universal Declaration of Human Rights' (1999) <http://bulldog2.redlands.edu/fac/Spickard/OnlinePubs/OriginUDHR.pdf> accessed 30 May 2023.

649 Sharma, *Are Human Rights Western?: A Contribution to the Dialogue of Civilizations* (n 646) 145.

Meanwhile, in certain regions or countries that in the scholarly literature are referred to as 'non-Western', despite international legal acts, human rights are criticised and even rejected as culturally unacceptable.[650]

This prevalence of human rights, especially in countries of the Western legal tradition, can be attributed to the fact that the focus on the individual as a special creature[651] is not an entirely new phenomenon that emerged in the middle of the 20th century. The granting of a special status to the human being has long been a feature of this tradition, linked to Judeo-Christian philosophy, which the Western legal tradition itself has made into one of its predecessors.[652] The ideas presented by these religions indicate that a human being is created in the image of God, who has long been considered the basis of lawfulness in the Western legal tradition.[653]

Since the 12th century, Western civilisation has been partly characterised by individuals having rights that they could exercise not only in economic or social relations with other individuals, but also against the legislators.[654] Later, at the end of the 18th century, the ideas of the 'rights of a man' which the nation-states had to ensure emerged in the West.[655] It was through the influence of the above-mentioned religions and ideas that the human person acquired the status of a special creature in the Western philosophical, legal and political thought. For a long time, human behaviour had been

650 E.g. Goldman, *Globalisation and the Western Legal Tradition: Recurring Patterns of Law and Authority* (n 43) 232-233. It is believed that such critics emphasise duties, not rights; mutual trust rather than detailed rules; and mediation in disputes rather than formal court litigation procedures (Berman, 'The Western Legal Tradition in a Millennial Perspective: Past and Future' (n 103) 760 citing Raimundo Pannikar, *Is the Notion of Human Rights a Western Concept?,* 120 Diogenes 75 (1982)).

651 The fact that the human is a special being did not always mean that his/her rights and freedom were respected at all times in the Western legal tradition (see e.g. Goldman, *Globalisation and the Western Legal Tradition: Recurring Patterns of Law and Authority* (n 43) 233-234).

652 See further Berman, *Teisė ir revoliucija: vakarų teisės tradicijos formavimasis* (n 41) 17-18.

653 *The Bible. The Book of Genesis* <https://www.bible.com/bible/59/GEN.1.ESV> accessed 30 May 2023; Remi Brague, *Ekscentriškoji Europos tapatybė* (AIDAI 2001) 53. The connection between religion and law is particularly emphasised by H J Berman in his second book 'Law and Revolution, II. The Impact of the Protestant Reformations on the Western Legal Tradition' (Harold J Berman, *Law and Revolution, II. The Impact of the Protestant Reformations on the Western Legal Tradition* (Belknap Press 2003)).

654 Berman, 'The Western Legal Tradition in a Millennial Perspective: Past and Future' (n 103) 760.

655 ibid.

regulated by the immutable commands of God; however, now this function has essentially been taken over by human rights, which took on particular significance in the aftermath of the Second World War.[656]

The aspects discussed above illustrate the continuing development of the Western legal tradition as a coherent system. This means that, although revolutions are an important factor in shaping this tradition, the development of institutions in the West has always been steady, and 'every generation deliberately continued the work of previous generations'.[657] Thus, the development in this legal tradition is an organic process of growth,[658] which implies that, even in the course of a revolution, the Western legal tradition strives not to stray away from its roots. In this tradition, 'changes arise from a new interpretation of the past in response to the needs of the present and the future'.[659] Hence, from the perspective of the Western legal tradition, the emergence of a system for the protection of human rights corresponds to this organic growth, since the principles arising from ancient religions and subsequent ideas and the perception of the importance of the human being were adapted to the new situation that arose after the aforementioned war.

The human status currently prevailing in the legal systems of the Western legal tradition is very close to I. Kant's ideas of the 18th century stating that '[i]n the whole of creation everything one wants and over which one has any power can also be used *merely as means*; a human being alone, and with him every rational creature, is an *end in itself*: by virtue of the autonomy of his freedom he is the subject of the moral law, which is holy. Just because of this every will, even every person's own individual will directed to himself, is restricted to the condition of agreement with the *autonomy* of the rational being, that is to say, such a being is not to be subjected to any purpose that is not possible in accordance with a law that could arise from the will of the affected subject himself; hence this subject is to be used never merely as a means but as at the same time an end'.[660] It is argued in the scholarly literature that it is I. Kant's view of the

656 Goldman, *Globalisation and the Western Legal Tradition: Recurring Patterns of Law and Authority* (n 43) 227.

657 Linas Baublys and others, *Teisės teorijos įvadas* (Mes 2010) 27 (translated from Lithuanian into English by the author of this study).

658 Berman, *Teisė ir revoliucija: vakarų teisės tradicijos formavimasis* (n 41) 20.

659 ibid 26 (translated from Lithuanian into English by the author of this study).

660 Immanuel Kant, *Practical Philosophy* (Mary J Gregor ed and tr, Cambridge University Press 1999) 210.

individual that is the basis of the contemporary system of the protection of human rights reflected in the above-mentioned Declaration.[661] In the more than 70 years since the adoption of this document, numerous treaties, pacts and conventions have set out detailed parameters of the commitments in question and established values, among which human dignity and human rights are highly important.[662] The human being has become an element that embodies the politics of a country and its legal system. It has been recognised that each human being is a special value to be protected by the law and that the protection of human rights is essential to meet basic human needs. These standards have penetrated many areas of life, including the field of scientific research.[663]

This perspective on the human being, as a standard for evaluating the legal system, can be associated with deontological ethics, which holds that actions are considered good or bad, right or wrong, not because of their consequences, but in themselves.[664] This means that the purpose and consequences do not provide any value to the action, because it is important to follow the principle or the obligation itself. Consequently, at least from the perspective of the countries belonging to the Western legal tradition, a legal system which essentially denies human rights is not considered to be appropriate, and in especially extreme situations even its status as a legal

661 Catherine Dupre, 'Unlocking human dignity: towards a theory for the 21st century' (2009) 2 European Human Rights Law Review 190, 190.

662 E.g. Convention for the Protection of Human Rights and Fundamental Freedoms (adopted 4 November 1950) (European Convention on Human Rights, as amended), Articles 2-3 (European Convention on Human Rights); African Charter on Human and Peoples' Rights (adopted 27 June 1981, entered into force 21 October 1986) (1982) 21 ILM 58 Articles 4 and 5.

663 In 2001, at a meeting of ministers of science, Kōichirō Matsuura, the Director-General of the United Nations Educational, Scientific and Cultural Organization (UNESCO), stressed the need to protect human rights and human dignity from the misuse of science and technology (United Nations Educational, Scientific and Cultural Organization, 'Bioethics: International Implications' (proceedings of the Round Table of Ministers of Science, Paris, 22-23 October 2001) <https://unesdoc.unesco.org/ark:/48223/pf0000130976> accessed 30 May 2023, 2); Speech by Mr Philippe Séguin, President of the National Assembly of the French Republic (International Bioethics Committee: proceedings of the third session, v. I) <https://unesdoc.unesco.org/ark:/48223/pf0000105160> accessed 30 May 2023, 120. See also ICCPR, Art. 7; International Covenant on Economic, Social and Cultural Rights (adopted 16 December 1966, entered into force 3 January 1976) 993 UNTS 3, Art. 15.

664 Larry Alexander and Michael Moore, 'Deontological Ethics', *The Stanford Encyclopedia of Philosophy* (rev edn, 2020) <https://plato.stanford.edu/entries/ethics-deontological/> accessed 30 May 2023.

system may be questioned. The incorporation of human rights into a legal system[665] reveals one of the essential features of this tradition which has been proposed by H. J. Berman, i.e. autonomy.[666]

Nonetheless, religious, political or moral considerations may influence the adoption of certain human rights legislation. Also, not all human rights hold the same weight in all cases, which is why in certain situations they can collide with each other. In addition, with legal systems regulating interpersonal relations among human beings, other living and non-living objects from the surrounding world, to which the same standards cannot be applied as those applied to people, inevitably come into the sphere of legal regulation. In these situations, a deontological human status-based approach may not seem suitable for making a legal decision, and this process may be influenced by other spheres of reality, such as religion, politics, morality, economics, customs or scientific knowledge of the surrounding environment. Therefore, although the Western legal tradition is considered to be comparatively autonomous from other areas of social reality, the influence of the latter on the former is undeniable.[667]

This means that, in certain cases, the Western legal tradition, consistent with its fundamental values, also deems knowledge provided by other areas of reality to be important, and in turn capable of being used when forming 'fundamental agreements'.[668] In such situations, it may be necessary to take

665 Carl Aage Nørgaard, 'The Implementation of International Human Rights' Agreements within a Domestic Legal System' (UniDem, Warsaw, 19-21 May 1993) <https://www.venice.coe.int/webforms/documents/?pdf=CDL-STD(1993)005-e> accessed 30 May 2023. Human rights are considered to be international law and must be included in the national legal system (Danutė Jočienė, 'Įžanga' in Danutė Jočienė and Kęstutis Čilinskas (eds), *Žmogaus teisių problemos tarptautinėje ir Lietuvos Respublikos teisėje* (Eugrimas 2004) 6).

666 According to H J Berman, although religion, politics, morality and customs have a strong influence on law, it is possible to analytically distinguish it from these spheres of social reality. E.g. politics and morality may determine legislation, but in the Western legal tradition they are not treated as the law itself (Berman, *Teisė ir revoliucija: vakarų teisės tradicijos formavimasis* (n 41) 24).

667 ibid.

668 According to A MacIntyre, tradition is an argument that is continuous in time, in which certain fundamental agreements are set and updated through two types of conflicts: (1) conflicts with critics and enemies who do not belong to the tradition and reject all or essential parts of those agreements; and (2) internal interpretative debates, which are the basis for expressing the significance and logical basis of the essential agreements, and which help the tradition progress (MacIntyre, *Whose Justice, Which Rationality?* (n 500) 12).

into account arguments from other spheres of reality and the impact of these decisions on the surrounding environment when choosing an action strategy and making decisions. Naturally, the consequences of the decisions taken are weighed. In these often extreme cases, such as war, it can be difficult to treat a human being as an end in himself/herself;[669] it may be necessary to choose between protecting one person's life and saving the lives of hundreds. There are also situations where, for example, it is necessary to decide between other values which do not have the same status as a human being. When making decisions in these situations, especially if the consequences of decisions are important, the deontological approach may not be very practical.

In such cases, the philosophy of utilitarianism based on categories of 'pain' and 'pleasure',[670] which states that 'the greatest happiness of the greatest number should be the guiding principle of conduct'[671], may become relevant. Classical utilitarianism argues that actions are correct if they tend to increase happiness and wrong when they create the opposite of happiness; happiness here is understood as pleasure and the opposite of happiness as pain or the absence of pleasure.[672] This means that a decision will be based on the consequences it is likely to entail, and the most suitable option that brings the greatest benefit will be chosen.

The discussion above shows that decision-making in the legal systems of the Western legal tradition is accompanied both by deontology and utilitarianism. The existence in legal systems of the aforementioned two philosophical branches, the former of which relating to the suitability of decisions for the observance of certain principles and the latter to the assessment of the consequences in reality, reveals one of the characteristics of the Western legal tradition indicated by H. J. Berman: the tension between the ideal and reality, which is the factor that leads to revolutions renewing the legal tradition in question from time to time.[673]

Based on what has been analysed above, it is to be held that the protection of human rights currently plays a crucial role in the legal systems of the Western legal tradition. Although the latter was reinforced by an

669 Goldman, *Globalisation and the Western Legal Tradition: Recurring Patterns of Law and Authority* (n 43) 236.
670 Jeremy Bentham, *An introduction to the principles of morals and legislation* (London, 1789) 21.
671 Stevenson, *Oxford Dictionary of English* (n 459) 1959.
672 David Miller, 'Utilitarizmas', *Blackwell politinės minties enciklopedija* (2005) 591.
673 Berman, *Teisė ir revoliucija: vakarų teisės tradicijos formavimasis* (n 41) 27.

event that can be considered revolutionary, the Second World War, in the Western legal tradition the human person has always been treated as a special being, which demonstrates the continuity and organic growth of this legal tradition. The emphasis on the value of a human being in the legal system of the Western legal tradition can be related to deontological ethics, which indicates that actions are considered to be good or bad, right or wrong, not because of their consequences but because of their nature.

In a legal system forming part of this tradition, the deontological approach to decision-making is not always optimal, especially when the consequences of decisions play a key role. Despite the importance of the human being in this legal tradition, situations often arise where human rights have to be weighed against one another. There are also other values that do not have the same status as a human, but which nonetheless may need to be protected. Therefore, the utilitarian approach becomes relevant when the decision in question does not directly affect, or at least does not harm, human life and dignity. Based on this school of thought, decisions are made by assessing the consequences of actions, i.e. by taking into account the arguments and knowledge provided by other realms of reality. This situation reveals the relative autonomy of the legal systems belonging to the Western legal tradition.

The above-described concept of the Western legal tradition is illustrated by the situation in the European patent system: in the face of the ever-faster advancement in science and technology, this legal system is required to make decisions based on Art. 53(a) EPC regarding new objects and processes brought about by the development of biotechnology. This requires a closer look not only at the scientific, technological or even economic aspects involved, but also at the protection of human dignity, life and other important issues related to the physical and mental well-being of individuals. It is precisely in the decisions made in the European patent system that the aforementioned ethical theories (deontology and utilitarianism), which are prevalent in Western philosophy and form the basis for the tests and standards used in the case law of the EPO for the interpretation of Art. 53(a) EPC of the Convention, are evident.

3.3. The Situation in the Western Legal Tradition in the 21st Century

According to E. Shils, the existence of tradition is determined both by the limited ability to escape from it and the desire to continue and preserve it: a society retains most of what it inherits, not because it is fond of it, but because it understands that, without it, it might not survive.[674] Usually, societies cannot imagine a reliable substitute for what they have inherited, even if the existing tradition does not seem to be sufficiently adequate.[675] However, even if it is unavoidable, a particular tradition is not necessarily acceptable, and therefore its participants may try to change it according to their will.[676]

As the above-mentioned author states, there are both endogenous and exogenous factors that can prompt changes in a tradition. The former cause changes in a tradition which are implemented by those who are part of the tradition in question, and these changes are perceived as improvements.[677] These changes are not determined by exogenous circumstances, but are considered to be the result of the relationship between the tradition and its members.[678] The latter appear when the members of a particular tradition are influenced by other traditions which encourage this tradition to change.[679] These changes in one tradition can be influenced by the other's economic, political and/or military power, its efficiency and convenience, or its superior intellectual persuasiveness.[680]

Similar ideas were raised by A. MacIntyre, who pointed out that each tradition faces two types of conflict: internal and external.[681] According to this author, internal conflicts in a tradition lead to an 'epistemological crisis', which is defined as a situation in a tradition in which 'conflicts over rival answers to key questions can no longer be settled rationally'.[682] The signs of this crisis are as follows: (1) historically based beliefs are rejected; (2) methods and arguments, which so far have been used to

674 Shils, *Tradition* (n 499) 213.
675 ibid.
676 ibid.
677 ibid.
678 ibid.
679 ibid 240.
680 ibid.
681 MacIntyre, *Whose Justice, Which Rationality?* (n 500) 12.
682 ibid 362. According to A MacIntyre, the rationality of a tradition lies in its development, which consists of certain stages (ibid 354-356).

achieve rational progress, reveal discrepancies, inconsistencies and new problems; (3) measures within the framework of a specific tradition seem to be inadequate to resolve these problems.[683]

According to H. J. Berman, the Second World War provided a temporary rise that lasted until the end of the 1950s, allowing the Western nations to understand that they are capable of both collective action and individual sacrifice in pursuit of common traditional goals.[684] However, despite the optimistic ideas presented by F. Fukuyama at the end of the 1980s about the triumph of the West and its ideas,[685] it is now recognised in the legal[686] and philosophical[687] literature, as well as in the media,[688] that the Western world is facing a crisis.

Although it is extremely difficult to fully agree on and to define the scale of this crisis, the political, international security and trade problems that the West is currently facing are hard to deny. One example that can be mentioned is the current human rights situation, which gives grounds for concern about the future.[689] This view is based on the infamous human rights violations in response to terrorism threats,[690] the temporary restraints of human rights during the economic crisis[691] or other emergencies,[692] as well

683 MacIntyre, *Whose Justice, Which Rationality?* (n 500) 362.

684 Harold J Berman, *Faith and Order. The Reconciliation of Law and Religion* (Scholars Press 1993) 2.

685 Francis Fukuyama, 'The End of History?' [1989] The National Interest 3, 4.

686 See e.g. Roger Brownsword, 'Human Rights – What Hope? Human Dignity – What Scope?' in Søren Holm and Jennifer Gunning (eds), *Ethics, Law and Society*, vol 1 (1st edn, Routledge 2005) 189-209.

687 See e.g. Claude Levi-Strauss, *Antropologija modernaus pasaulio problemų akistatoje* (Žara 2011); Topi Heikkerö, 'The Fate of Western Civilization: G. H. von Wright's Reflections on Science, Technology, and Global Society' (2004) 24 Bulletin of Science, Technology & Society 156, 157.

688 See e.g. Martin Jacques, 'The Death of Neoliberalism and the Crisis in Western Politics' *The Guardian* (London, 21 August 2016) <https://www.theguardian.com/commentisfree/2016/aug/21/death-of-neoliberalism-crisis-in-western-politics> accessed 30 May 2023; Herborth and Hellmann, 'Introduction: Uses of the West' (n 610) 3.

689 Roger Brownsword, 'Human Rights – What Hope? Human Dignity – What Scope?' (n 686) 189-209.

690 See e.g. Alfonsas Vaišvila, 'Terorizmas ir kova su terorizmu – dvi grėsmės žmogaus teisėms' (2005) 68 Jurisprudencija 11, 11.

691 Egidijus Kūris, 'Ekonominė krizė ir teisinė sistema: įtampų triada' (2015) 94 Teisė 7, 10-12.

692 E.g. on the refugee crisis see Alison Smale and Melissa Eddy, 'Migrant Crisis Tests Core European Value: Open Borders' *The New York Times* (New York, 31 August

as military interventions happening in certain countries based on human rights violations.[693] The category of human dignity is also considered problematic. Despite its well-established position in international and European legal acts[694] as well as attempts to define its basic minimal content,[695] it is open to interpretation; consequently, to this day, it creates tension both within the legal systems and in their relationships with various spheres of reality, such as science or technology.

Other more permanent phenomena can also be alarming. One example is collateralism,[696] which is described as a situation where specialised international organisations (especially those promoting trade) prioritise the implementation of their functions, treating human rights as secondary aspects.[697] According to R. Brownsword, the EPOrg can be considered to be such a type of organisation.[698] Another example introduced by this author is incrementalism. The default position of this approach is to allow actions having a potential risk factor to be carried out, except where there is a real safety concern.[699] Also, by allowing certain actions, it is almost impossible to ban them later on, i.e. there is a tendency to move only forward.[700]

In the situations discussed above, human rights begin to lose their status. An increasing number of members of the Western legal tradition begin to perceive them as too abstract and therefore ineffective, weak and unable to withstand negative phenomena such as the economic crisis, or even, on the contrary, as an appropriate tool allowing strong states to influence weak ones. Different crises, as well as the changing social, technological

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2015) <http://www.nytimes.com/2015/09/01/world/europe/austria-migrant-crisis-truck.html> accessed 30 May 2023. See also Roger Brownsword, 'Human Rights – What Hope? Human Dignity – What Scope?' (n 686) 189-209.

693 O'Byrne, *Human Rights in a Globalizing World* (n 646) 109 and 147.

694 Van Overwalle, 'Human Rights' Limitations in Patent Law' (n 97) 243-244.

695 Christopher McCrudden, 'Human Dignity and Judicial Interpretation of Human Rights' (2008) 19 European Journal of International Law 655, 680.

696 The term was suggested by Professor S. Leader from Essex University (see Sheldon Leader, 'Collateralism' in Roger Brownsword, *Global Governance and the Search for Justice* (Hart Publishing 2005) 53-68).

697 Sheldon Leader, 'Trade and Human Rights II' in Patrick F J Macrory, Arthur E Appleton and Michael G Plummer, *The World Trade Organization: Legal, Economic and Political Analysis* (Springer New York 2005) 663-696, 683; Roger Brownsword, 'Human Rights – What Hope? Human Dignity – What Scope?' (n 686) 193.

698 Roger Brownsword 'Human Rights – What Hope? Human Dignity – What Scope?' (n 686) 194.

699 ibid 195.

700 ibid 194-195. For further threats to human rights, see ibid 189-209.

and economic environment of the 20th and 21st centuries, create a tendency towards striving for the goals of scientific and technological advancement, which encourages the employment of arguments based on utilitarianism in the process of decision-making, and not the protection of human life, as expected in the mid-20th century.

One example of the crisis of the Western legal tradition could be also the difficulties encountered in the interpretation and application of Art. 53(a) EPC in attempting to resolve issues related to the patenting of biotechnological inventions. In the absence of clarity in the interpretation and application of the above-mentioned provision of the Convention, the protection of legitimate expectations and legal certainty deteriorates. In this situation, it is not only support for the granting of exclusive rights to specific inventions that is diminishing, but also trust in the benefits of the whole patent system and its transparency in the eyes of creators, developers and users of inventions.

As A. MacIntyre points out, a tradition that is unable to overcome a crisis by itself may seek for answers in another tradition, simultaneously acknowledging its superiority.[701] The European patent law analysed in this study, as a part of the Western legal tradition, if unable to find answers concerning the patenting of biotechnological inventions, may use arguments based on knowledge of the biomedical sciences to interpret and apply the provisions of the Convention. Deciding on the basis of the above-mentioned EPC provision runs the risk that, even concerning human body-related inventions, instead of deontological ethics, a utilitarian approach can be employed. In the light of all this, both in the context of patenting of biotechnological inventions based on Art. 53(a) EPC and in other cases, it is important to understand in which circumstances the dominant approach will be the deontological one and when the utilitarian one will prevail, as well as what impact this will have on the development of the Western legal tradition.

3.4. Preliminary Conclusion

Despite the fact that traditionality is not always viewed favourably, the category 'tradition' is important in every legal system, including those belonging to the Western legal tradition. Knowledge of a particular legal tradition makes it possible to understand how objects and processes are

701 MacIntyre, *Whose Justice, Which Rationality?* (n 500) 364-365.

valued and perceived within the legal system under that tradition, and to predict how, in the light of new circumstances, this system will respond and continue to evolve.

The Western legal tradition, having survived great turmoil in the first half of the 20th century, can be characterised by its attention to human life and human rights. The above-mentioned attitude towards the human being as a value is based on deontological ethics, which indicates that actions are considered good or bad, right or wrong, not by their consequences, but by themselves. However, in making decisions that do not adversely affect a human being, as well as in situations where different human rights compete with one another or with other non-human objects in the world, or where the consequences of decisions play a key role, utilitarianism becomes important.

The dynamics of the above-mentioned ethical theories employed in decision-making are determined by the relationship between the legal systems belonging to the Western legal tradition, based on their fundamental principles and values, and other spheres of reality, providing knowledge concerning the surrounding environment. This relationship is illustrated by situations in the European patent system in which, when making decisions on the granting of patents for biotechnological inventions under Art. 53(a) EPC, not only the principles and values of the Western legal tradition but also arguments based on the knowledge provided by the biomedical sciences are employed.

4. Morality and *Ordre Public*

4.1. The Concept of Morality and Ordre Public *in the Case Law of the European Patent Office*

One of the most common issues raised in the legal literature relating to Art. 53(a) EPC concerns the categories '*ordre public*' and 'morality' and the relationship between them in this legal provision.[702] In the Guidelines for Examination, these categories are treated as one and are not defined in any way.[703] Meanwhile, the EPO case law provides for different definitions and interpretations of these terms, and in respect of the category 'morality' has even stated that it is not a criterion which should be defined by the patent authorities.[704] In this situation, it is necessary to analyse the concepts of the above-mentioned categories and the relationship between them in the case law of the Office.

As discussed in this study, the first process in the European patent system in which the issue concerning patent granting for an invention on the basis of Art. 53(a) of the Convention was at issue arose when the Harvard Medical School sought to register a patent, the claims of which included the process of creating a genetically modified mouse used for research into cancer treatment.[705] In 1989, the EPO Examining Division rejected the patent application on the basis of Art. 53 (b) EPC.[706] As a result, the applicant lodged an appeal, which was further investigated in the *Onco-mouse/HARVARD* case, but this time also under Art. 53 (a) EPC.[707]

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702 See e.g. Warren-Jones, 'Finding a "Common Morality Codex" for Biotech – A Question of Substance' (n 116) 834; Liddell, 'Immorality and Patents: The Exclusion of Inventions Contrary to Ordre Public and Morality' (n 134) 147; Hellstadius, *A Quest for Clarity: Reconstructing Standards for the Patent Law Morality Exclusion* (n 6) 202-213.

703 Guidelines for Examination, March 2023 (n 63), pt A-III, 8.1. and pt G-II, 4.1.

704 *Euthanasia Compositions/MICHIGAN STATE UNIV* (n 54), para 6.12.

705 European Patent Application No. 85 304 490.7, published as No. 0 169 672.

706 *Harvard/Onco-Mouse* (n 75). See also 'European patents shall not be granted in respect of: [...] (b) plant or animal varieties or essentially biological processes for the production of plants or animals; this provision shall not apply to microbiological processes or the products thereof.' (EPC 1973, Art. 53(b)).

707 *Onco-Mouse* (n 80), para III.

During this process, the EPO Board of Appeal pointed out that the manipulation of mammal genes is definitely a problematic issue, especially when the activated oncogenes are injected in order to make the animal in question unusually sensitive to carcinogenic substances and other stimuli, which makes it more likely to develop tumours that inevitably lead to suffering.[708] In addition, according to the Board, there is a risk that, once released, genetically modified animals could cause irreversible damage to the environment.[709] As these aspects were not sufficiently analysed, the EPO Board of Appeal instructed the Examining Division to re-examine the case.[710] In this decision of the EPO Board of Appeal, *ordre public* and morality were treated as one and the same category, without mentioning any peculiarities or differences between them.

A similar approach was later shown in other EPO decisions on the patenting of inventions in the field of biotechnology and in other fields of biomedical sciences. The *Relaxin/HOWARD FLOREY INSTITUTE* case analysed an invention to develop a recombinant human relaxin[711] to alleviate complications associated with labour induction and caesarean section.[712] In this decision, the EPO Board of Appeal assessed the patent claims disputed by the opponents in relation to overall compliance with Art. 53(a) EPC, without any detailed analysis of the concept of morality or *ordre public*.[713] Although there was also no detailed description of the relationship between morality and *ordre public* or the content of each of them, it was concluded that Art. 53(a) of the Convention can be interpreted using Rules 23d and 23e[714] of the EPC Implementing Regulations. Finally, the Board indicated that the content of the EPC provision in question can be interpreted on the basis of Rule 23e(2)[715] of the EPC Implementing Regulations,

708 *Onco-Mouse* (n 80), para 5.
709 ibid.
710 ibid 22.
711 Relaxin is a hormone, secreted by the placenta in the terminal stages of pregnancy, that causes the cervix (neck) of the uterus to dilate and prepares the uterus for the action of oxytocin during labour (Jonathan Law and Elizabeth Martin, 'Relaxin', *Concise Medical Dictionary* (10th edn, 2020) <https://www.oxfordreference.com/display/10.1093/acref/9780198836612.001.0001/acref-9780198836612-e-8694?rskey=I3VMoj&result=10001> accessed 30 May 2023).
712 Sterckx and Cockbain, *Exclusions from Patentability, How Far Has the European Patent Office Eroded Boundaries?* (n 94) 271.
713 *Relaxin/HOWARD FLOREY INSTITUTE* (n 81), paras 4-9.
714 Currently EPC Implementing Regulations, r 28 and r 29.
715 Since 13 December 2007: EPC Implementing Regulations, r 29(2).

which provides a list[716] of inventions which, based on Art. 53(a) EPC, are considered patentable.

In the *Non-invasive localization/LELAND STANFORD* case, when deciding on the patenting of the eukaryotic cell detection process in a live non-human organism, the EPO Board of Appeal applied Rule 28(d)[717] of the EPC Implementing Regulations for the interpretation of Art. 53(a) EPC, as well as the weighing test which was previously used in the *Onco-mouse/HARVARD* case.[718] However, the concept of morality and *ordre public* as well as their relationship were not analysed in this decision.[719]

The European patent for the process of creating a genetically modified mouse[720] in the *Onco-mouse/HARVARD* case discussed above was eventually granted with certain modifications. However, oppositions concerning it were received from 17 subjects[721] and all were substantiated on the basis of Art. 53(a) of the Convention. In this way, a second case, *Transgenic animals/HARVARD*,[722] concerning the patentability of the invention in question was opened before the EPO. During this process, the Board changed its position on the relationship between *ordre public* and morality in analysing the same invention. In this case, unlike in the *Onco-mouse/HARVARD* case, *ordre public* and morality were considered as two separate categories which could together form one ground or separately two different grounds for opposing the patentability of a particular invention invoked in a certain procedure.[723] The aforementioned difference concerning the understanding and relationship between *ordre public* and morality in the *Onco-mouse/HARVARD* and *Transgenic animals/HARVARD* cases can be related to the *Plant cells/PLANT GENETIC SYSTEMS*[724] case, in which they were analysed as two distinct categories, each of them being given a different definition.[725]

716 *Relaxin/HOWARD FLOREY INSTITUTE* (n 81), paras 5-8.
717 Since 1 July 2017: EPC Implementing Regulations, r 28(1)(d).
718 *Non-invasive localization/LELAND STANFORD* (n 81), para 22.
719 ibid paras 13-24.
720 European Patent Application No. 85 304 490.7, published as No. 0 169 672.
721 *Transgenic animals/HARVARD* (n 80), para VI; Sterckx and Cockbain, *Exclusions from Patentability, How Far Has the European Patent Office Eroded Boundaries?* (n 94) 245.
722 *Transgenic animals/HARVARD* (n 80).
723 ibid para 10.2.
724 *Plant cells/PLANT GENETIC SYSTEMS* (n 22).
725 ibid paras 5-6.

In the EPO Board of Appeal decision concerning the *Plant cells/PLANT GENETIC SYSTEMS* case, morality was associated with 'the belief that some behaviour is right and acceptable whereas other behaviour is wrong, this belief being founded on the totality of the accepted norms which are deeply rooted in a particular culture'.[726] In the context of the European patent system, 'the culture in question is the culture inherent in European society and civilisation'.[727] Therefore, based on this provision, inventions that do not conform to this culture should not be patented. In the light of such interpretations, it can be argued that, in the *Plant cells/PLANT GENETIC SYSTEMS* case, the EPO Board of Appeal linked the category 'morality' to ethical rather than legal norms.

Meanwhile, concerning the term '*ordre public*' in the discussed case, the Board stated that this category involves the protection of the physical integrity of society as well as individuals belonging to it and the protection of environment.[728] Therefore, inventions whose exploitation is likely to violate public peace or social order (e.g. by using the invention to attempt a terrorist attack), or which could significantly harm the environment in general, cannot be patented.[729] This definition of *ordre public* allows it to be linked to legal norms.

In the context of the definitions given above, the EPO Board of Appeal considered respectively whether the use of the subject-matter claimed in the patent in suit[730] is likely to either (1) seriously harm the environment or (2) contradict the 'conventionally accepted standards of conduct of European culture'.[731] Having individually assessed the invention referred to in the patent claims – (1) processes controlling plant cell activity and the creation of herbicide-resistant plants and (2) herbicide resistant plants and cells – in relation to *ordre public* and morality, the Board stated that the commercial exploitation of the invention in question with regard to Art. 53(a) EPC was patentable.[732]

However, the position of the EPO Board of Appeal on *ordre public* and morality as two separate categories in the *Plant cells/PLANT GENETIC SYSTEMS* case was not confirmed by the further EPO case law. For

726 *Plant cells/PLANT GENETIC SYSTEMS* (n 22) para 6.
727 ibid.
728 ibid para 5.
729 ibid.
730 ibid para 14.
731 ibid paras 14 and 19.
732 ibid paras 17.2 and 19.

example, in the *Breast and Ovarian Cancer/UNIVERSITY OF UTAH* case, when deciding on the compliance with regard to Art. 53(a) of the Convention of an invention comprising the BRCA1 gene sequence and its mutations that may be used to diagnose a predisposition to breast or ovarian cancer,[733] the EPO analysed the commercial exploitation of this invention without separating the categories of *ordre public* and morality from each other.[734] The decision also indicated that, according to Rule 23e(2) of the EPC Implementing Regulations, which was in effect at that time,[735] the subject-matter of the invention described in the patent claims is not among the exceptions to patentability listed in Art. 53(a) EPC.[736]

Nevertheless, in the *Breast and Ovarian Cancer/UNIVERSITY OF UTAH* proceedings, an attempt to divide the arguments into legal and ethical ones, i.e. relating to *ordre public* and morality, is evident. The arguments that the patent applicant did not provide any information about the donors giving their informed and explicit consent for the commercial exploitation of cells and research results, as well as about signing a benefit-sharing agreement,[737] can be considered legal ones. This conclusion can be drawn because, in response to the arguments presented, the Board indicated that the EPC does not contain any provisions requiring the patent applicant to submit the consent form or the benefit-sharing agreement.[738] The definitions of *ordre public* and morality presented in the *Plant cells/PLANT GENETIC SYSTEMS* case allow for a conclusion to be drawn that the discussed arguments of the opponents in *Breast and Ovarian Cancer/UNIVERSITY OF UTAH* can be associated with *ordre public*. However, the EPO Board of Appeal did not choose to do that in this case.

Compliance with morality as mentioned in Art. 53(a) EPC in the *Breast and Ovarian Cancer/UNIVERSITY OF UTAH* case may be related to the

733 *Breast and Ovarian Cancer/UNIVERSITY OF UTAH* (n 22), para VII. The mutations of the BRCA1 gene increase the risk of breast cancer in women by about 60-85 per cent (up to 10 times) and the risk of ovarian cancer by about 40-60 per cent (approximately 30-40 times) compared to the general population (up to 80 years old). If a person has an increased risk of developing an oncological illness, certain characteristics of hereditary tumours, which may influence the nature and outcome of the treatment, should be considered during it. This allows the best course of treatment for each particular patient to be chosen.

734 ibid para 56.

735 Since 13 December 2007: EPC Implementing Regulations, r 29(2).

736 *Breast and Ovarian Cancer/UNIVERSITY OF UTAH* (n 22), para 56.

737 ibid paras 47.

738 ibid paras 48-49.

opponent's arguments regarding the socio-economic consequences of patent granting, which, according to the opponents, are related to ethical issues.[739] However, in this case, the EPO Board of Appeal did not further analyse the issue of compliance with ethics or morality. The Board found that the assessment of the exploitation of the invention itself, rather than the assessment of the exploitation of the patent, fell within the scope of Art. 53(a) EPC[740] and therefore rejected the opponent's arguments regarding the compliance of the exploitation of the patent with the provision in question. The EPO Board of Appeal also stated that the socio-economic implications of the exploitation of a patent cannot be assessed solely in relation to public health, since the consequences of the exploitation of a patent are always the same, i.e. the right to prevent competitors from using a specific invention,[741] and the fact that the national patent law of a Member State obliges them to assess the socio-economic or ethical aspects of patent granting is meaningless, because the regulations of national legal systems are not part of the European patent system.[742]

Therefore, the *Breast and Ovarian Cancer/UNIVERSITY OF UTAH* case did not take into account the interpretations of the content of *ordre public* and morality indicated in Art. 53(a) EPC that were presented in the *Plant cells/PLANT GENETIC SYSTEMS* case. Despite the fact that legal, ethical and socio-economic arguments were presented in the former case, the Board was not inclined to analyse them separately from the perspectives of *ordre public* or morality so as to provide a broader understanding of the content of each category in question.

However, in the *Euthanasia Compositions/MICHIGAN STATE UNIV.* case, where the patent claims encompassed a pharmaceutical composition, i.e. a solution intended to provoke death in lower mammals,[743] the exploitation of this invention, based on the decision in the *Plant cells/PLANT GENETIC SYSTEMS* case, was assessed separately with regard to both categories, i.e. *ordre public* and morality, emphasising that these are two different grounds for opposing the granting of a European patent.[744] The decision stated that mercy killing of animals is a normal part of veterinary

739 *Breast and Ovarian Cancer/UNIVERSITY OF UTAH* (n 22), para 52.
740 ibid para 53.
741 ibid.
742 ibid para 55.
743 *Euthanasia Compositions/MICHIGAN STATE UNIV* (n 54), para II.
744 ibid para 6.9.

practice, which, according to the EPO Board of Appeal, shows that this activity falls under the scope of *ordre public*.[745] The Board also indicated that there was no evidence presented that this type of veterinary practice could in any way disturb *ordre public* or public peace or result in harm to the environment.[746]

Meanwhile, morality, according to the EPO Board of Appeal, is based on ethical norms of behaviour that have become obligatory because of their universal acceptance.[747] In addition, the *Euthanasia Compositions/MICHIGAN STATE UNIV.* case discussed the concept of morality more broadly, indicating that morality is not a criterion which should be defined by patent granting authorities and that in the European culture there is no moral standard based on social, economic or religious principles.[748] However, following the decision in the *Plant cells/PLANT GENETIC SYSTEMS* case, the conclusion was drawn that morality is the basis for including non-legal, ethics-based norms into the legal framework.[749] Furthermore, the Board stated that the exploitation of an invention violates morality only if it is generally regarded as reprehensible by society or at least in commercial practice.[750] Having found none of the discussed violations, the EPO ruled that the patent in question was not in conflict with morality.[751] However, the *Euthanasia Compositions/MICHIGAN STATE UNIV.* case shows that the EPO Board of Appeal, following the decision in the *Plant cells/PLANT GENETIC SYSTEMS* case, applied Art. 53(a) EPC more broadly than in many other decisions, and assessed the exploitation of the invention in terms of both *ordre public* and morality.

In the context of the EPO case law discussed above, it is clear that, with the exception of a number of cases, *ordre public* and morality are not treated as two separate categories in the decisions of the Board. However, in those former few decisions, *ordre public* is perceived as covering the basic legal norms of a particular society, encompassing the security of the public and its members, environmental protection and physical human integrity, whereas morality is associated with other social norms (non-legal, but also very important to a certain society) which recognise proper or

745 *Euthanasia Compositions/MICHIGAN STATE UNIV* (n 54), para 6.10.
746 ibid para 6.11.
747 ibid para 6.12.
748 ibid.
749 ibid.
750 ibid.
751 ibid.

improper behaviour. Nevertheless, these exceptions are few in the EPO case law regarding the patenting of biotechnological inventions in the context of Art. 53(a) EPC. For this reason, in order to improve understanding of the concept of these categories and their relationship, further research into this question from the perspective of the Western legal tradition is needed.

4.2. The Role of Morality in the Western Legal Tradition

R. Dworkin describes the relationship between law and morality as a classical jurisprudential question, the answer to which has not been found for many centuries.[752] This legal philosopher has noted that the law-morality connection is traditionally understood as the relation between two sets of norms, in the context of which the main question is how these two systems of social norms are interconnected.[753] The analysis of this question in the Western legal tradition is aggravated by the legal pluralism[754] manifested in this tradition as one of its main features,[755] and by the differences between the methods of cognition[756] of law as a complex phenomenon, which are determined by the views of the researchers. Also, the fact that '[l]aw is a craft concerned with what *is not* law'[757] complicates its separation from other areas of social reality and allows it to be considered as a complex phenomenon. Therefore, the objective of defining what law is leads to possible answers *ad infinitum*,[758] as reflected by the definitions of law given in the different legal paradigms, which are largely determined by the way law relates to other areas of reality. Consequently, as there is no answer to the

752 Ronald Dworkin, *Justice for Hedgehogs* (Harvard University Press 2011) 400-401. The questions analysed in this subchapter are partially analysed in the article 'The Role of Morality in a Legal System in the Context of the Western Legal Tradition' by the author of this study (Jurgita Randakevičiūtė, 'Moralės vaidmuo teisinėje sistemoje Vakarų teisės tradicijos kontekste' (2016) 101 Teisė 145).

753 Dworkin, *Justice for Hedgehogs* (752) 401.

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

755 Berman, *Teisė ir revoliucija: vakarų teisės tradicijos formavimasis* (n 41) 26-27.

756 Ernestas Spruogis, 'Teisės aiškinimo probleminiai aspektai' (2006) 8 Jurisprudencija 56, 58.

757 Goldman, *Globalisation and the Western Legal Tradition: Recurring Patterns of Law and Authority* (n 43) 69.

758 ibid 5.

question 'What is law?',[759] a single definite answer to the role of morality in legal systems does not exist either. Despite this uncertain situation, it is agreed in the legal doctrine that it would be difficult to deny the influence of morality on law.[760]

Considering the above, in order to understand the concept of morality and its position from the perspective of the Western legal tradition, it is important to analyse this issue from different standpoints of various legal paradigms: legal positivism, the school of natural law and legal realism. The above-mentioned concepts of law and the works of their respective representatives are used in this study because each one of them emphasises an element important to any legal system in this legal tradition, i.e. the legal form, content or its actual functioning.[761]

4.2.1. The Role of Morality from the Perspective of the Paradigm of Legal Positivism

Although it is usual in the legal literature to analyse legal concepts by starting from the oldest, i.e. the concept of natural law,[762] in this study the paradigm of legal positivism, which is concerned with the legal form, will be discussed first. The use of the term 'positive' in law derives from the Latin word 'positus' and is used to describe works of deliberate human activity, as a contrast to what is not created but rather originates in the natural way of nature.[763] The rise of legal positivism is associated with the revolution in science and technology of the 18th and 19th centuries, which encouraged the

759 Herbert LA Hart, *Teisės samprata* (Pradai 1997) 43; William Twining, *General Jurisprudence* (Cambridge University Press 2012) 65; Vitalij Levičev, 'Teisėtyros metodologinio spektro analizė' (2015) 95 Teisė 100, 101-102.

760 See e.g. Hart, *Teisės samprata* (n 759) 393-394; Hans Kelsen, *Grynoji teisės teorija* (Eugrimas 2002) 87; Gediminas Mesonis ir Kazimieras Meilius, 'Moralės normos konstituciniuose teisiniuose santykiuose' (2002) 3 Jurisprudencija 5, 6.

761 Kūris, 'Grynoji teisės teorija, teisės sistema ir vertybės: normatyvizmo paradigmos iššūkis' (n 68) 24-26 (E Kūris argues that this is a 'simplified view', because, besides the main influential schools of jurisprudence there are many others, for example the historical and psychological schools of law, the law and economics doctrine, integration jurisprudence, etc.).

762 See e.g. Dalia Mikelėnienė and Mikelėnas Valentinas, *Teismo procesas: teisės aiškinimo ir taikymo aspektai* (Justitia 1999) 32-41; Kūris, 'Grynoji teisės teorija, teisės sistema ir vertybės: normatyvizmo paradigmos iššūkis' (n 68); Baublys and others, *Teisės teorijos įvadas* (n 657).

763 Darijus Beinoravičius, 'Teisės samprata kaip metodas' (2013) 75 LOGOS 43, 45.

perception of law 'as a set of certain objective laws subordinate to the same rules as the laws discovered in nature'.[764] In a general sense, the attitude of the paradigm of legal positivism towards law is reflected in J. Bentham's statement that law is the totality of signs expressing the sovereign will of the state, supported by a set of sanctions.[765]

The positivistic view of the relationship between law and values is illustrated by J. Austin, one of the classical positivists, who followed J. Bentham and sought to distinguish law from other social phenomena, especially morality,[766] claiming that '[t]he existence of law is one thing; its merit or demerit is another'.[767] This legal philosopher researched law as a form which exists on its own, independent of its content, and therefore, according to him, law is considered to be law simply because it exists, even if we are not fond of it.[768] According to J. Austin, the content of law and morality may coincide.[769] However, despite this, they are still two distinct categories, and moral rules can be regarded as positive law only when they impose legal duties and also sanctions for disobeying them exist.[770]

The above-mentioned ideas of classical positivism[771] were also developed by H. Kelsen. He acknowledged that, in addition to law, there exist various social norms that regulate human behaviour, one of which is morality.[772] H. Kelsen did not deny that morality could influence the content of law, but at the same time he did not agree that, in order to be regarded as law, a social order must conform to a certain moral standard, i.e. the 'minimal morality'.[773] The idea that law must be moral in nature and that an immoral social order cannot be regarded as a legal order, according to this legal philosopher, 'presupposes an absolute moral order, that is, one that is

764 Vaidotas A Vaičaitis, *Hermeneutinė teisės samprata ir konstitucija* (Justitia 2009) 29.
765 Kūris, 'Grynoji teisės teorija, teisės sistema ir vertybės: normatyvizmo paradigmos iššūkis' (n 68) 27.
766 Howard Davies and David Holdcroft, *Jurisprudence: Texts and Commentary* (Butterworths 1991) 16.
767 John Austin, *Austin: The Province of Jurisprudence Determined* (Wilfrid E Rumble ed, Cambridge University Press 1995) 157.
768 ibid.
769 ibid 138.
770 ibid 120 and 136-137.
771 James Penner and Emmanuel Melissaris, *McCoubrey & White's Textbook on Jurisprudence* (5th edn, OUP 2014) 40-58.
772 Kelsen, *Grynoji teisės teorija* (n 760) 83.
773 ibid 87.

valid at all times and places'.[774] However, in reality, a legal order can only correspond to the moral values of a particular group in society, which may be contrary to the beliefs of other groups that exist in that same society.[775] H. Kelsen also argued that law is constantly changing. Therefore, the legal order that was consistent with certain moral values at a particular time may, after a certain period of time, no longer be compatible with them.[776] Thus, based on this legal philosopher, the two discussed social orders may interact, but, because of the relative nature of the content of morality, it cannot be a criterion for the validity of a legal order.

According to H. L. A. Hart, the separation between legal and non-legal norms depends on the rule of recognition which determines the criteria for what can be considered law.[777] This legal philosopher argued that the validity of a legal system does not essentially depend on its compliance with any moral criteria, even if these criteria actually have an undeniable effect on its development.[778] Although H. L. A. Hart discussed the forms of the relationship between law and morality 'that very few positivist theorists would try to deny',[779] he also argued that the legal system does not have to comply with any particular norms of morality.[780] He stated that 'the failure to recognise unjust norms as being law would immensely simplify the variety of moral problems arising from these norms'[781] and it would not be possible to see the complexity and diversity of all the individually subtle

774 Kelsen, *Grynoji teisės teorija* (n 760) 89-90 (translated from Lithuanian into English by the author of this study).

775 ibid 89.

776 ibid.

777 Hart, *Teisės samprata* (n 759) 180-182. According to H L A Hart, the legal system is comprised of two types of rules: primary rules, which outline obligations and regulate the behaviour of the members of society, and secondary rules, which help in understanding the problems created by the primary rules – inefficiency, uncertainty and their static nature. Secondary rules of recognition compensate for the uncertainty of primary norms, secondary rules of change remedy their static behaviour, and secondary rules of adjudication deal with the inefficiency of the former.

778 ibid 303.

779 ibid 331. The forms of the relationship between law and morality are discussed in: ibid 322-337 (translated from Lithuanian into English by the author of this study).

780 Herbert L A Hart 'Positivism and the Separation of Law and Morals' (1958) 71 Harvard Law Review 593, 626; Hart, *Teisės samprata* (n 759) 303.

781 Hart, *Teisės samprata* (n 759) 336 (translated from Lithuanian into English by the author of this study).

and complex problems.[782] For this reason, he was inclined to consider even immoral legal norms as part of the law.

However, it is difficult for the representatives and supporters of legal positivism to strictly separate themselves from all the requirements related to values. This situation is also reflected in the references to morality in national and international legislation,[783] court decisions[784] and the analysis of the works of legal philosophers who belong to the paradigm of legal positivism.[785] Under discussion is also the *Grundnorm*, i.e. the 'basic norm' proposed by H. Kelsen, which is the basis for the validity of all other legal norms and at the same time of the entire legal system. It is not clear what requirements this norm must conform to and what its content is. Moreover, despite the allegedly strict structure of the positive legal system, this basic norm still faces the typical legal problem of the 'inherent groundlessness of law'.[786] According to H. Kelsen, it is not positive; it is simply presumed.[787] This situation allows for the emergence of ideas that equate the basic

782 Hart, *Teisės samprata* (n 759) 337.

783 See e.g. art 1.81, ch IV; pt II; Book 1 of the Civil Code of the Republic of Lithuania: 'A transaction that is contrary to public order or norms of good morals shall be null and void'; pt 2 of art 3.5, ch I; pt I; Book 3 of the Civil Code of the Republic of Lithuania: 'In exercising their family rights and performing their duties, persons must comply with the laws, respect the rules of their community life as well as the principles of good morality and act in good faith'; pt 2 of art 1.2, ch I; pt I; Book 3 of the Civil Code of the Republic of Lithuania rules that 'No civil rights may be limited, except in the cases established by laws, or on the basis of a court judgment made in accordance with laws, where such limitation is necessary to protect public order, the principles of good morals, likewise the health and life of people, property of persons, their rights and lawful interests' (Civil Code of the Republic of Lithuania (*Lietuvos Respublikos civilinis kodeksas*). *Valstybės žinios (Official Gazette)*, 2000, No. VIII-1864). In addition, Art. 53(a) EPC states that European patents are not granted to inventions the commercial exploitation of which would be against *ordre public* or morality (EPC, Art. 53(a)).

784 According to H L A Hart, judges are obliged to apply not just one important principle of morality when making decisions where the law does not have a clear answer, but to choose from a variety of moral values. In such cases, judges use comparison and balancing, which are typically employed in the cases where justice has to be brought to a situation of competing interests. H L A Hart indicates that this method of decision-making is often referred to as 'moral' (Hart, *Teisės samprata* (n 759) 328). See also Spruogis, 'Teisės aiškinimo probleminiai aspektai' (n 756).

785 Spruogis, 'Teisės aiškinimo probleminiai aspektai' (n 756) 57.

786 Vaičaitis, *Hermeneutinė teisės samprata ir konstitucija* (n 764) 31 (translated from Lithuanian into English by the author of this study).

787 Kelsen, *Grynoji teisės teorija* (n 760) 191.

norm to the 'higher' legal order postulated by natural law, which H. Kelsen categorically contradicts in his later works.[788]

H. L. A. Hart's rule of recognition, which helps to decide what is considered right and wrong in a certain society, is also relevant in this context. It defines 'legal sources and the relationships of superiority and subordination that exist among them'.[789] However, despite its importance, this category remains undefined: '[i]n a modern legal system [...] the rule of recognition is correspondingly more complex: the criteria for identifying the law are multiple and commonly include a written constitution, enactment by a legislature, and judicial precedents'.[790] In addition, in the 'Post Scriptum', H. L. A. Hart acknowledges that 'as criteria of legal validity, the rule of recognition may incorporate conformity with moral principles or substantive values'.[791] This approach further complicates the separation of positive law from morality.

The doubts around legal positivism grew significantly during the Second World War. This is illustrated by the change of position of G. Radbruch, who until 1933 was considered to be a proponent of the paradigm of legal positivism.[792] At the end of the war, this legal philosopher argued that the conflict between justice and security should be resolved in such a way that the law established by the legislator would be prioritised, even when its content is incorrect and inapplicable, except in those cases when the opposition between the positive law and justice reaches such an unbearable degree that the legislation, as unjust law, destroys justice.[793] Therefore, in the case of radical injustice, according to G. Radbruch, positive law must give way to justice. Hence, since the middle of the 20th century, at least in the countries of the Western legal tradition, legal criteria postulated in legal positivism are no longer the only ones to be considered when making decisions about the status of a system of social norms as a legal order.

The above-mentioned change, and the fact that it is difficult for legal positivism to remain rigid and to separate itself from criteria related to

788 Herbert L A Hart, 'On the Basic Norm' (1959) 47 California Law Review 107, 109.
789 Hart, *Teisės samprata* (n 759) 409 (translated from Lithuanian into English by the author of this study).
790 ibid 189 (translated from Lithuanian into English by the author of this study).
791 ibid 388 (translated from Lithuanian into English by the author of this study).
792 Baublys and others, *Teisės teorijos įvadas* (n 657) 138.
793 Gustav Radbruch, 'Statutory Lawlessness and Supra-Statutory Law' (2006) 26 Oxford Journal of Legal Studies 1, 7.

values, are reflected in the emergence of soft positivism[794] alongside the discussed hard positivism. The former form of positivism indicates that, although not necessarily, there is a possibility for moral arguments to become a criterion allowing social norms to be attributed to a legal system.[795] This view is also shared by H. L. A. Hart's followers J. Coleman, W. J. Waluchow and M. Kramer, who further developed the ideas of soft positivism and argued that legal systems exist in which the criteria of legal validity include moral principles.[796] Thus, even though there are opponents of the position discussed (J. Raz, A. Marmor, S. Shapiro),[797] the representatives of the paradigm of legal positivism are not able to completely erase the doubts concerning the recognition of certain 'higher' values, including that of morality, and their influence on recognising social norms as legal norms.

Considering the above, it can be concluded that, during its whole period of existence, legal positivism placed a greater or lesser emphasis on the formal features of the Western legal system. Precisely this legal paradigm helps in maintaining one of its characteristics indicated by H. J. Berman: the possibility to analytically separate law from religion, politics, morality and customs.[798] This allows it to be argued that, despite the above-mentioned return to the ideas of the school of natural law in the middle of the 20th century, the legal positivism-based approach to legal system remains important. Nevertheless, in the legal system that belongs to the Western legal tradition, even if the importance of the concept of formally defined social norms is accepted, other non-legal means may sometimes be employed in the interpretation and application of law.[799] Therefore, in order to fully reveal the role of morality in the legal system in the context of the Western legal tradition, it is important to analyse other legal paradigms that belong to this tradition and emphasise other elements of the legal system, i.e. its content and functioning.

794 Spruogis, 'Teisės aiškinimo probleminiai aspektai' (n 756) 57; Matthew H Kramer, *Where Law and Morality Meet* (OUP 2008) 2-3.
795 Kramer, *Where Law and Morality Meet* (n 794) 2.
796 Kenneth Eimar Himma, 'Inclusive Legal Positivism' in Jules Coleman and Scott Shapiro, *The Oxford Handbook of Jurisprudence and Philosophy of Law* (OUP 2002) 125, 125.
797 ibid.
798 Berman, *Teisė ir revoliucija: vakarų teisės tradicijos formavimasis* (n 41) 24.
799 See e.g. Spruogis, 'Teisės aiškinimo probleminiai aspektai' (n 756) 59.

4.2.2. The Role of Morality from the Perspective of the School of Natural Law

The paradigm of natural law indicates that the status of a system of social norms as a legal system does not depend only on whether its norms are determined by a particular procedure, but also on additional factors that arise outside a particular legal system.[800] The origins of this legal concept lie in the works of Greek philosophers.[801] Later, the concept in question was further developed in ancient Roman jurisprudence, where the ideal natural law was called *ius naturale* and was regarded as the basis of the functioning law. Actually, however, the latter was often unable to satisfy the requirements of justice, and therefore it was necessary to turn to natural law, the purpose of which was to correct the imperfections of the legal system in force.[802] This philosophy, born in the era of classical antiquity, had a great influence on Western legal thought, where conflicts between 'what really is' and 'what should be' arise, or as H. J. Berman puts it, a tension between reality and the ideal exists.[803]

The idea of natural law was further developed by the representatives of medieval Christian philosophy, the most prominent of whom were Saint Augustine and Saint Thomas Aquinas. The former lived during a period of important historical change and understood the foundations of the ancient Roman law, but as a Christian he attributed higher power to the order established by God, in which primordial rationality lies, rather than to secular laws.[804] This philosopher emphasised that people must obey the positive laws only insofar as they follow the eternal law, which was understood as created by God and designed to rule righteously and properly manage all affairs.[805] Saint Thomas Aquinas also grouped laws into the categories of right and wrong, and stated that each law created by people has as much legal basis as the extent to which it is derived from the natural law, and if it somehow differs from the latter, it is not a law, but rather a distortion of law.[806] Hence, in contrast to the representatives of

800 Ian McLeod, *Legal Theory* (3rd edn, Palgrave Maccmillan 2005) 19.
801 Baublys and others, *Teisės teorijos įvadas* (n 657) 81-82.
802 Beinoravičius, 'Teisės samprata kaip metodas' (n 763) 44.
803 Berman, *Teisė ir revoliucija: vakarų teisės tradicijos formavimasis* (n 41) 26.
804 Bronislovas Kuzmickas, *Filosofijos istorijos apybraižos* (Mykolas Romeris University 2012) 47-48.
805 Baublys and others, *Teisės teorijos įvadas* (n 657) 85.
806 ibid 102.

legal positivism, according to Saint Augustine and Saint Thomas Aquinas, positive laws must conform to a certain standard of justice that is derived from the will of God.

Later, in the 17th century, H. Grotius, who was still influenced by the ideas of natural law but was already looking through the prism of the dawning positivism,[807] sought to separate law from theology, arguing that natural law is based on rationality rather than on the existence of God.[808] These ideas, as well as those that emerged a little later during the Enlightenment, encouraged the secularisation of law and thus strengthened the central government of the state, at the same time eradicating the religion-based concept of natural law.[809] During the French Revolution, there was a transition from the school of natural law to the school of rationalism, which was based on the dominance of reason and sought to create law on new foundations, eliminating the element of morality.[810] In the second half of the 19th century, these factors contributed to the strengthening of the role of the state in legal ideology and prompted the creation of the paradigm of legal positivism.[811]

However, despite the changes discussed above, 'every time there is a disappointment related to positive law [...] [there is a] turn to the more "righteous" natural law'.[812] It was after the wars of the 20th century that the shift to the ideas of natural law occurred.[813] These ideas encouraged 'the pursuit of humanity and justice in positive law, prompted the consolidation and defence of the individual's economic freedom, and exerted enormous influence on constitutionalism and the development of democracy, as well as laid the foundations for more just international law'.[814] Currently, in the Western legal tradition, the secular, reason-based doctrine of natural law is

807 Justinas Žilinskas, '„Teisingo karo" doktrina ir jos atspindžiai mūsų dienomis' (2012) 19 Jurisprudencija 1201, 1206.

808 Brian Z Tamanaha, *General Jurisprudence of Law and Society* (OUP 2001) 21.

809 Beinoravičius, 'Teisės samprata kaip metodas' (n 763) 45.

810 ibid 44-45.

811 ibid 45.

812 Kūris, 'Grynoji teisės teorija, teisės sistema ir vertybės: normatyvizmo paradigmos iššūkis' (n 68) 24. The shift from legal positivism to the paradigm of Natural law, which happened at the end of the Second World War, is discussed in Chapter '4.2.1. The Role of Morality from the Perspective of the Paradigm of Legal Positivism'.

813 Max Lyles, *A Call for Scientific Purity: Axel Hägerström's Critique of Legal Science* (Institutet för Rättshistorisk Forskning 2006) 639.

814 Kūris, 'Grynoji teisės teorija, teisės sistema ir vertybės: normatyvizmo paradigmos iššūkis' (n 68) 24.

considered to be the basis of the concept of natural rights, which was later realised in positivist law in the form of human rights.[815] The Declaration[816] and the European Convention for the Protection of Human Rights and Fundamental Freedoms[817] are examples of legal positivism's return to the ideas of natural law. According to E. Kūris, although the attempt to define the origins of natural law 'ends up in speculations, the validity of which cannot be proven empirically',[818] today it is hard to imagine the refutation of human rights, at least in the countries that belong to the Western legal tradition.

The absence of agreement on the origin and content of natural law is one of the factors prompting the representatives of contemporary law to seek alternative criteria of morality that would impose different requirements on legal systems. L. Fuller argued that law must meet certain formal requirements, namely eight principles[819] called the 'internal morality of law',[820] rather than requirements of content. This 'internal morality of law' differs from the classical natural law in that it does not cover all aspects of the moral life of mankind[821] and is neutral in relation to most ethical problems.[822] However, the departure from the above eight principles, according to this legal philosopher, is a violation of the dignity of the person as a responsible subject.[823] Although L. Fuller did not concentrate on the content of law as much as the other representatives of the school of natural law by emphasising specific values that must be reflected in the legal system, according to him, the inability to ensure at least one of the

815 C Fred Alford, *From Aquinas to International Human Rights* (Palgrave Macmillan 2010) 2.
816 Declaration.
817 European Convention on Human Rights.
818 Kūris, 'Grynoji teisės teorija, teisės sistema ir vertybės: normatyvizmo paradigmos iššūkis' (n 68) 24.
819 (1) generality; (2) promulgation (the accessibility of law to the addressee); (3) non-retroactivity (general requirements of retroactive law); (4) intelligibility and clarity; (5) non-contradiction; (6) possibility of compliance; (7) constancy (avoidance of frequent change); (8) congruence (matching of official rules and actions) (Lon L Fuller, *The Morality of Law* (Yale University Press 1964) 46-91).
820 ibid 46.
821 ibid 96.
822 ibid 162.
823 ibid.

aforementioned principles shows that certain orders cannot be regarded as legal in general.[824]

Another representative of the contemporary school of natural law, J. Finnis, did not look for the source of natural law in metaphysics or in human nature, but argued that its origin are irreducible, unquestionable and obvious basic goods that are necessary for human prosperity.[825] The latter legal philosopher did not fully agree with the point of view of the representatives of the classical school of natural law, who claimed that a system cannot be considered a legal system if it does not comply with the aforementioned principles of natural law. J. Finnis stated that even unjust law can still be legally valid, or legally binding in the narrow sense,[826] if it meets certain requirements.[827] Thus, according to him, compliance with a certain higher order is a criterion for assessing the legal system and not a criterion of its status *per se*.

Considering everything discussed above, the change in the role of natural law as a 'higher' law is evident. Numerous ancient and medieval ideas show that natural principles and morality manifest themselves as factors declaring positive law invalid if its content does not meet certain natural law-based standards. Meanwhile, in the modern natural law theories, the morality of law is evaluated in the light of more formal criteria, whereas the 'higher' law acts as a standard for assessing the positive law. However, the incompatibility of the latter with the former does not always invalidate the positive legal system. Despite the clear awareness that a legal system must be characterised by formal features emphasised in the light of the paradigm of legal positivism, the value-based criteria originating in the concept of natural law remain important, even if they do not determine the status of the whole social order as a legal system. This suggests that the role of morality in the Western legal tradition is real and significant.

824 Lon L Fuller, *The Morality of Law* (Yale University Press 1964) 39.

825 Basic goods are the following: (1) life, (2) knowledge, (3) play, (4) aesthetic experience, (5) sociability (friendship), (6) practical reasonableness, (7) 'religion' (John Finnis, *Natural Law and Natural Rights* (OUP 1980) 59, 86-89).

826 ibid 360-361.

827 Requirements: (1) emanates from a legally authorised source; (2) will in fact be enforced by courts and/or other officials, and/or (3) is commonly spoken of as a law like other laws (ibid).

4.2.3. The Role of Morality in the Paradigm of Legal Realism

Defining legal realism is not an easy task, due to the absence of a standard unifying all of the directions of this legal concept.[828] This situation is influenced by the fact that it is not a very systematic legal paradigm, and also holds a sceptical view on generalisations.[829] In the most general sense, this is a direction of legal theory that is not interested in the content or the form of law,[830] but rather in its functions, operation and effects which occur in society.[831] There are two streams of legal realism: (1) American legal realism, which analysed case law, and (2) Scandinavian legal realism, which analysed fundamental legal concepts such as the concept of law, the concept of rights, the concept of the rule of law, etc.[832] According to American legal realism, law is what judges do when settling disputes,[833] whereas the Scandinavian realists claimed that law does not exist at all, and even if it does, its only purpose is factual or social benefit.[834]

According to O. W. Holmes Jr., who is the most prominent representative of American legal realism, when deciding whether certain laws can be applied, it is necessary to discuss such matters as 'the felt necessities of the time, the prevalent moral and political theories, intuitions of public policy, avowed or unconscious, even the prejudices which judges share with their fellow-men'.[835] The American legal realists, much like the legal positivists,

828 Mauro Zamboni, 'Legal Realisms and the Dilemma of the Relationship of Contemporary Law and Politics' <http://www.scandinavianlaw.se/pdf/48-34.pdf> accessed 30 May 2023; Wilfrid E Rumble, 'Legal Positivism of John Austin and the Realist Movement in American Jurisprudence' (1981) 66 Cornell Law Review 986, 987.

829 Harry W Jones, 'Law and Morality in the Perspective of Legal Realism' (1961) 61 Columbia Law Review 799, 809.

830 Kūris, 'Grynoji teisės teorija, teisės sistema ir vertybės: normatyvizmo paradigmos iššūkis' (n 68) 25.

831 Rumble, 'Legal Positivism of John Austin and the Realist Movement in American Jurisprudence' (n 828) 1001 citing Yntema, *Jurisprudence on Parade*, 39 MICH. L. Rev. 1154, 1164 (1941).

832 Torben Spaak, 'Naturalism in Scandinavian and American Realism: Similarities and Differences' in Matthias Dahlberg (ed), *Uppsala-Minnesota Colloquium: Law, Culture and Values* (Iustus förlag 2009) 33-83, 34.

833 Kūris, 'Grynoji teisės teorija, teisės sistema ir vertybės: normatyvizmo paradigmos iššūkis' (n 68) 25.

834 Baublys and others, *Teisės teorijos įvadas* (n 657) 185.

835 Oliver W Holmes, *The Common Law* (Belknap Press of Harvard University Press 1963) 5.

sought to separate law and morality from one another,[836] but at the same time acknowledged the influence of morality on the legal system.[837] As a result, according to the American legal realists, a decision of a court can also be based on arguments that arise from what 'should be'.

However, the American legal realists perceive this 'should be' more broadly than the legal positivists. According to the former, a court's decision which is based on arguments arising from the analysis of what 'should be' does not necessarily always exclusively refer to the principles of morality, but also to policy arguments or personal preferences.[838] In view of this, it is to be held that legal realism is not satisfied with only a formal analysis of concepts of legal positivism, but in the decision-making it is concerned with the practical result of legal procedure, rather than only with the internal doctrinal consistency in the positivist legal structure.

According to the Scandinavian realists, law is neither eternal principles nor an obligation imposed by the ruler to behave in a certain way in a particular situation. They argue that the true meaning of law, if it indeed exists, can only be found empirically or scientifically, through observation of the functioning of society.[839] This definition suggests that Scandinavian realism denies the ideas of the aforementioned paradigms, i.e. legal positivism and the school of natural law.[840] A. Hägerström, who was the pioneer of Scandinavian realism, sought to demonstrate that the categories of legal order (rights, duties, transfer of rights and validity) are partly superstitious beliefs, myths, fictions, magic or confusion.[841] He also denied the existence of values and moral norms *per se*, and argued that these categories merely exist in the minds of human beings.[842]

836 Rumble, 'Legal Positivism of John Austin and the Realist Movement in American Jurisprudence' (n 828) 1006.

837 Oliver W Holmes, 'The Path of Law' <http://moglen.law.columbia.edu/LCS/palaw.pdf> accessed 30 May 2023.

838 Rumble, 'Legal Positivism of John Austin and the Realist Movement in American Jurisprudence' (n 828) 1010.

839 Baublys and others, *Teisės teorijos įvadas* (n 657) 181.

840 For example, this was done by A Hägerström (see Bjarup J, 'The Philosophy of Scandinavian Realism' (2005) 18 Ratio Juris 1, 6).

841 Herbet L A Hart, 'Scandinavian Realism' (1959) 17 The Cambridge Law Journal 233, 233.

842 Baublys and others, *Teisės teorijos įvadas* (n 657) 181. This position was later supported by the representatives of Critical Legal Studies, who indicated that there is no single objectively appropriate moral position underpinning the legal system (John Eekelaar, 'What is 'critical' family law?' (1989) 105 Law Quarterly Review 244, 244).

A. Hägerström's ideas were continued by K. Olivecrona, who also disagreed with the idea that law originated from the 'higher' order, or that it was ordered by the sovereign. According to him, the binding power of law is nothing more than an idea in the minds of the people,[843] and the content of law and its change are influenced not by morality, but rather by the self-interest of individuals.[844] Much like K. Olivecrona, A. Ross emphasised the psychological nature of law, suggesting that consideration should be given to the way legal norms affect the real behaviour of individuals, rather than just looking at the law as a command of a sovereign.[845] This legal philosopher also argued that law and morality are essentially separate systems of social norms, but there is always the possibility that moral norms will affect legal practice, especially in situations not regulated or insufficiently regulated by law or when the law simply cannot provide an answer.[846]

Hence, despite the difficulties in finding common ground between the ideas of legal realism, both analysed branches agree that 'the roots of law lie in its practice'.[847] Therefore, the issues concerning the form and content of law, emphasised by the schools of legal positivism and natural law, are important to legal realism only insofar as they are related to the actual functioning of law in society. Concerning the role of morality in the legal system, the Scandinavian legal realists deny its impact on the legal system more strictly than the representatives of American legal realism. The latter understand the concept of 'should be' more broadly than the legal positivists and, alongside morality, include arguments arising in other areas of social reality. However, both streams of legal realism agree, at least on a certain level, that internal convictions may be important in interpreting the content of legal norms, which means that morality has a certain role in the legal system in the context of the Western legal tradition.

843 Davies and Holdcroft, *Jurisprudence: Texts and Commentary* (n 766) 427.
844 Gregory S Alexander, 'Comparing the Two Legal Realisms-American and Scandinavian' (2002) 50 The American Journal of Comparative Law 131, 159.
845 Baublys and others, *Teisės teorijos įvadas* (n 657) 184.
846 Cornelis V Maris, *Critique of the Empiricist Explanation of Morality* (Kluwer-Deventer 1981) 210.
847 Baublys and others, *Teisės teorijos įvadas* (n 657) 185.

4.2.4. The Role of Morality in the Western Legal Tradition and its Significance for the European Patent System

The legal paradigms discussed above present different views on the role of morality in the legal system that belongs to the Western legal tradition. This situation is considered to be an important element of the constant debate taking place in this legal tradition concerning law and its continuous and interrupted relationship with other areas of social reality.[848]

Legal positivism, which emphasises the formal concept of law, states that morality does not play any role in the positivist legal system, even if it affects the development of the positive legal norms. According to H. Kelsen, moral norms can only be transformed into positive legal norms if the law itself delegates 'certain metalegal norms, such as morality or justice'.[849] This legal philosopher argued that only those moral norms that have already undergone a certain formal procedure of becoming a part of the positive legal system – after which they are understood to be no longer moral but rather legal norms – can be considered as part of the legal system. Therefore, according to this legal paradigm, morality norms influence the content of legal norms before they become a part of the positive law, but after a legal system or a legal norm is formed on the basis of morality norms, morality loses any role it had in the legal system because morality becomes a legal norm. This means that in legal positivism, the role of morality as a category of ethics does not exist in the context of the Western legal tradition.

In the light of the discussed approach of legal positivism, it can be concluded that morality as a category of ethics[850] does not exist when applying and interpreting Art. 53(a) EPC. In the provision in question, morality has already been transformed into a norm of positive law and has become a part of the positivist European patent system. Therefore, in accordance with Art. 53(a) of the Convention, a decision concerning the patentability of a particular invention should not result from the arguments outside this legal framework, including morality.

However, in order to apply the said provision, it is necessary to interpret the content of the term 'morality', which inevitably leads to analysis of the

848 William Twining, *Globalisation and Legal Theory* (Cambridge University Press 2000) 244.

849 Kelsen, *Grynoji teisės teorija* (n 760) 280-281 (translated from Lithuanian into English by the author of this study).

850 According to ibid 83.

concept of the category in question. In this case, according to H. Kelsen, the legal norms are interpreted in two possible ways: (1) by the law enforcement body; or (2) by the private individual and, especially, by legal science.[851] During the processes of interpretation by a law enforcement body, 'the applicable law is merely a framework in which there are several different possible options'.[852] Therefore, H. Kelsen disagrees with the traditional approach in jurisprudence which states that 'a law applicable in a certain case can only provide *one* correct solution'.[853] Similarly, in the case of interpretation in legal science, which involves a purely cognitive identification of the meaning of legal norms,[854] it is possible to 'reveal all possible meanings of a legal norm and not more'.[855] Therefore, according to H. Kelsen, in every case of interpretation, there are several possible answers to questions concerning exactly what may happen when evaluating commercial exploitation of an invention with regard to Art. 53(a) EPC.

The above considerations show that, when a norm becomes part of the legal system, as in the case of Art. 53(a) of the Convention, a representative of legal positivism, even if he/she denies the role of morality as a category of ethics in the legal system, is forced to analyse the meaning of the category 'morality' as a part of the positivist legal system. In this case, the said category, even when it is included in the EPC and is a part of the positive law,[856] remains rather abstract in terms of its content. In such situations, it may not be sufficient to merely consider what is written, or to analyse the system of positive legal norms and their interrelationships, but it may also be necessary to make an assessment based on certain values. This means that, even from the perspective of positive law, in interpreting and applying Art. 53(a) EPC, it may be necessary to rely on moral norms prevailing in a society or even personal values, in addition to the norms existing in the positivist legal system.

According to the ideas of H. Kelsen, such a solution, despite the fact that it is based on moral convictions, is, if it falls within the framework of the positivist legal system, considered a legal act[857] which is in line with the existing positive law. Thus, even when seeking to eliminate morality from

851 Kelsen, *Grynoji teisės teorija* (n 760) 277.
852 ibid 279 (translated from Lithuanian into English by the author of this study).
853 ibid (translated from Lithuanian into English by the author of this study).
854 ibid 281.
855 ibid 282 (translated from Lithuanian into English by the author of this study).
856 Being in the 'framework' of positivist law (ibid 279).
857 ibid.

the legal system and deny its role in it, in the case of interpretation of abstract legal norms, as in Art. 53(a) EPC, the legal positivists are still forced to employ subjective personal or socially accepted and widespread values. Therefore, in the analysis of such norms as Art. 53(a) of the Convention, the role of morality in the legal system is difficult to deny.

Representatives of the school of natural law acknowledge that, along with the positivist legal system created by human beings, there also exists a certain 'higher' order to which the content of the former must correspond. Therefore, particular value-based standards, including morality, can be the criteria both for assessing a legal system and acknowledging it as legal.[858] Despite the absolutely identical positivist law,[859] the fact that the effect of values is extremely evident in the case of controversial legal issues shows that morality, even if it is relative, can play an important role in the legal system in the context of the Western legal tradition.

According to the paradigm of natural law, when employing the criteria of value, a direct reference to morality as provided in Art. 53(a) EPC is not necessary for the interpretation of the positive legal norms. However, such reference allows an analysis that focuses on value beliefs and does not hide behind legal arguments that are usually used with the intention of providing the legal system with more predictability and stability. Hence, in the case of the interpretation and application of Art. 53(a) of the Convention, it becomes possible to openly discuss morality as a criterion for making decisions.

Nevertheless, in this case, the difficulties coming from the concept of natural law are evident: differently than in legal positivism, even in the case of consistent argumentation leading to a rational solution from one perspective of a certain value position, that solution may be considered completely incorrect from the point of view of another. This difficult situation is caused by the fact that it is impossible to define universally acceptable standards of value applied in all cases, especially in a legal system that belongs to the Western legal tradition, which is characterised by pluralism.[860] Hence, even if the role of morality in the legal system is recognised, it is difficult to define it.

858 See e.g. Fuller, *The Morality of Law* (n 819) 39; Finnis, *Natural Law and Natural Rights* (n 825) 360-361.

859 Levičev, 'Teisėtyros metodologinio spektro analizė' (n 759) 101-102.

860 Berman, *Teisė ir revoliucija: vakarų teisės tradicijos formavimasis* (n 41) 26.

Often, from the point of view of the modern Western legal tradition, human rights are considered to be the expression of natural law in a positive legal system.[861] For this reason, from the perspective of both legal positivism and the school of natural law, particular attention is paid to the interpretation of Art. 53(a) EPC in order to ensure the physical and spiritual well-being of the human being. From the position of legal positivism, this development of thought in the Western legal tradition encourages the creation of positivist legal norms that would reflect the attention to human interests. It can even be connected to the discussed forms of the relationship between morality and law mentioned by H. L. A. Hart which appear when law overlaps with certain moral beliefs that the positivist legal system must match.[862] On the other hand, human rights, embodying the contemporary ideas of natural law, promote the assessment of the positive law precisely from the point of view of their protection. Considering the above, the criteria related to the protection of human interests influence the analysis of Art. 53(a) EPC, both with the help of the positive legal norms embodying specific standards for the protection of human rights – or containing such categories as 'morality' – and from the perspective of natural law, where the positivist legal norms are evaluated.

American and Scandinavian legal realism, both of which emphasise the actual functioning of law, acknowledge the separation of law from morality, much like the paradigm of legal positivism. However, American legal realism indicates that morality can nonetheless affect the legal system,[863] and that the idea of 'should be', which the discussed branch associates with policy or personal choice, can influence legal decisions.[864] Although policy or personal choice cannot be fully equated with morality, it can be agreed that the approach of American legal realism to the role of morality or other arguments that are outside the legal framework is more in line

861 Kūris, 'Grynoji teisės teorija, teisės sistema ir vertybės: normatyvizmo paradigmos iššūkis' (n 68) 24; Goldman, *Globalisation and the Western Legal Tradition: Recurring Patterns of Law and Authority* (n 43) 227; Kai Man Kwan, 'Reflections on Contemporary Natural Law Theories and Their Relevance' [2012] CGST Journal 197, 203 citing Jacques Maritain, *The Rights of Man and Natural Law* (London: Geoffrey, 1944).

862 Hart, *Teisės samprata* (n 759) 322-337.

863 Holmes, 'The Path of Law' (n 837).

864 Rumble, 'Legal Positivism of John Austin and the Realist Movement in American Jurisprudence' (n 828) 1010 citing HLA Hart, The Concept of Law (1961), at 200-201.

with the concept of natural law than with the position of legal positivism.[865] However, unlike the school of natural law, representatives of legal realism indicated that the factors influencing legal decision-making are not only morality, but also psychological, political, economic, business or social criteria.[866] This means that in the paradigm of legal realism, the decision-making process of the courts is not only perceived as a formal process limited by the norms of positive law, but also as an activity in which it is necessary to consider what 'should be' in the context of morality as well as other fields of social reality.

Considering the above, it can be concluded that legal realism reveals how difficult the interpretation of Art. 53(a) EPC is. In the case of the interpretation of the aforementioned provision, this direction of legal realism would draw attention not only to the normative, i.e. legal and moral, aspects, but also to the arguments and objectives related to economic benefits or even progress in a certain scientific field. Although the norms of soft law, the Guidelines for Examination, state that the economic effects of granting or rejecting patents are not examined,[867] in reality, these aspects are crucial for patent systems. Economic arguments, in particular, are considered to be one of the key reasons for the creation of the patent system.[868] Hence, it can be understood that, in the interpretation of Art. 53(a) of the Convention from the perspective of legal realism, the meaning attributed to the category 'morality' may be determined by specific economic intentions. Therefore, from the point of view of legal realism, the role of morality, as well as of the arguments emerging from other areas of social reality, in interpreting this provision of European patent law cannot be denied.

In the light of the above, it can be held that a legal system in the context of the Western legal tradition is influenced by the totality of the paradigms emphasising the form, content and actual functioning of legal systems.

865 Jones, 'Law and Morality in the Perspective of Legal Realism' (n 829) 809.

866 Rumble, 'Legal Positivism of John Austin and the Realist Movement in American Jurisprudence' (n 828) 997 citing W. O. DOUGLAS, Education for the Law, in DEMOCRACY AND FINANCE: THE ADDRESSES AND PUBLIC STATEMENTS OF WILLIAM O. DOUGLAS AS MEMBER AND CHAIRMAN OF THE SECURITIES AND EXCHANGE COMMISSION 279 (J. Allen ed. 1969).

867 Guidelines for Examination, March 2023 (n 63), pt G-II, 4.1.3. However, there is unanimous agreement on the importance of the economic function of patents in patent law theory (see e.g. Hall and Harhoff, 'Recent Research on the Economics of Patents' (n 56)).

868 Hall and Harhoff, 'Recent Research on the Economics of Patents' (n 56).

These paradigms discussed above, which have interchanged between themselves[869] and opposed each other,[870] are important for understanding every modern legal system in the Western legal tradition. A significant part of this legal tradition is the relationship between a legal system and other areas of social reality, such as morality, as is the case with Art. 53(a) EPC. Each of these legal paradigms distinguishes an important dimension of the legal system belonging to the pluralist Western legal tradition and indicates that there is nothing in the said tradition in an absolutely pure form.

The analysis of the above-mentioned legal paradigms reveals a significant and actual role of morality in the legal system in the context of the Western legal tradition. Consequently, this means that in the modern legal system, values outside its framework are also important; however, their role depends on the perspective of each of these paradigms. On the one hand, especially from the practical point of view, this leads to a paradoxical situation where there are contradictory positions in the same legal tradition concerning the role of morality in the legal system. On the other hand, the differences in the legal paradigms make it possible to analyse the place of morality broadly by taking into consideration its various dimensions. Thus, in order to determine the role of morality in Art. 53(a) of the Convention, which belongs to the Western legal tradition, the positions of all the legal paradigms analysed in this study must be taken into account and perceived as equally important parts.

4.3. The Role of Ordre Public *in the Western Legal Tradition*

For a long time, countries had the freedom to refuse patents for inventions of certain technologies, such as chemistry or pharmaceuticals, and this was regarded as one of the most significant intellectual property rights-related barriers to trade.[871] However, following the adoption of the TRIPS Agree-

869 Berman, 'The Western legal tradition: The interaction of revolutionary innovation and evolutionary growth' (n 639) 43.

870 Tamanaha, *General Jurisprudence of Law and Society* (n 808) 8. Discusses legal positivism, the concept of Natural law and the historical school of law. It must be noted that Yntema linked legal realism to the historical school of law (Hessel E Yntema, 'Mr. Justice Holmes' View of Legal Science' (1931) 40 The Yale Law Review 696).

871 Pires de Carvalho, *The TRIPS Regime of Patent Rights* (n 29) 245.

ment, this discriminatory regime was abolished,[872] as the TRIPS Agreement obliged the contracting parties to issue patents for all patentable inventions, regardless of their technological field.[873] At the same time, this new regulation made it possible for the contracting parties to impose limited exceptions to patentability, one of which is the *ordre public*- and morality-based Article 27(2).[874]

The aforementioned exception in the TRIPS Agreement indicates that the members of the World Trade Organization (the 'WTO') 'may exclude from patentability inventions, the prevention within their territory of the commercial exploitation of which is necessary to protect *ordre public* or morality, including to protect human, animal or plant life or health or to avoid serious prejudice to the environment, provided that such exclusion is not made merely because the exploitation is prohibited by their law'.[875] According to the legal doctrine, this Art. 27(2) of the TRIPS Agreement means that inventions may be considered non-patentable 'based on a risk that their commercial exploitation within their territory could endanger *ordre public* or morality within the territory of the WTO Members concerned'.[876]

The terms '*ordre public*' and 'morality' for the discussed provision of the TRIPS Agreement were 'borrowed' from Art. 53(a) EPC on the recommendation of the European Community.[877] In Art. 53(a) EPC, not only is '*ordre public*' identified as one of the grounds for exceptions to patentability, but it is also stated that the EPO can interpret this category autonomously and does not need to take into account the national legal systems of the EPOrg Member States.[878] Legal doctrine states that *ordre public* as referred to in Art. 53(a) of the Convention is composed of 'ethically based constitutional or other rules, usually backed up by penal provisions, that reflect basic rules prevailing in society and trade'.[879]

872 Pires de Carvalho, *The TRIPS Regime of Patent Rights* (n 29) 245.
873 TRIPS Agreement, Art. 27(1).
874 Pires de Carvalho, *The TRIPS Regime of Patent Rights* (n 29) 247.
875 TRIPS Agreement, Art 27(2).
876 Gervais, *The TRIPS Agreement, Drafting History and Analysis* (n 37) 341.
877 Pires de Carvalho, *The TRIPS Regime of Patent Rights* (n 29) 297.
878 The second part of the sentence in Art. 53(a) indicates that 'such exploitation shall not be deemed to be so contrary merely because it is prohibited by law or regulation in some or all of the Contracting States.' (EPC, Art. 53 (a)).
879 Singer and Stauder, *The European Patent Convention. A Commentary* (n 125) 88.

According to D. Gervais, the negotiations concerning Part 5 of the TRIPS Agreement,[880] containing Art. 27(2) on patents, were the most difficult, because a consensus had to be reached concerning both the problems that exist in the Northern hemisphere and the disagreements between the South and the North.[881] Despite the fact that the mentioned author regards the result of these negotiations as positive in terms of extensiveness concerning Part 5 and describes it as 'impressive',[882] there exist different opinions in the legal literature, some of which indicate that the TRIPS Agreement more reflects an approach that is favourable for developed countries, which are most often Western.[883]

The purpose of this study is not to analyse in detail the question of which countries or interest groups were most favoured in negotiating the TRIPS Agreement. However, the fact that the industrialised Western states proposed the inclusion of intellectual property in the Uruguay Round of the General Agreement on Tariffs and Trade, which led to the establishment of the WTO and the adoption of the TRIPS Agreement,[884] allows the con-

880 TRIPS Agreement, Chapter 5: Patents.

881 Gervais, *The TRIPS Agreement, Drafting History and Analysis* (n 37) 336.

882 ibid 336-337. According to publicly available data of the World Intellectual Property Organization, 164 countries have signed the TRIPS Agreement to date (World Intellectual Property Organization, IP Treaties Collection, IP-related Multilateral Treaties, Contracting Parties/Signatories, Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS Agreement) <http://www.wipo.int/wipolex/en/other_treaties/parties.jsp?treaty_id=231&group_id=22> accessed 30 May 2023).

883 See e.g. Gana, 'Prospects For Developing Countries Under the TRIPs Agreement' (n 49) 746-757; L Danielle Tully, 'Prospects For Progress: The TRIPS Agreement and Developing Countries After the DOHA Conference' (2003) 26 Boston College International and Comparative Law Review 129, 134; Daniel J Gervais, 'Intellectual Property, Trade & Development: The State of Play' (2005) 74 Fordham Law Review 505, 508-509 citing Daniel Gervais, The TRIPS Agreement: Drafting History and Analysis (2d ed. 2003); Annette Kur, 'International Norm-Making in the Field of Intellectual Property: A Shift Towards Maximum Rules?' (2009) 1 WIPO Journal: Analysis And Debate Of Intellectual Property Issues 27, 28; Marianne Levin, 'The pendum keeps swinging – present discussions on and around the TRIPS Agreement' in Annette Kur (ed), *Intellectual Property Rights in a Fair World Trade System* (Edward Elgar Publishing 2011) 3-60, 15-16.

884 Annette Kur, 'International Norm-Making in the Field of Intellectual Property: A Shift Towards Maximum Rules' (International Conference on Innovation and Communication Law 2009) <http://www.ip.mpg.de/fileadmin/ipmpg/content/personen/annette_kur/madrid_08032.pdf> accessed 30 May 2023. Some sources highlight the role of the U.S. in pursuit of higher standards for the protection of intellectual property (e.g. Josef Drexl, 'The Concept of Trade-Relatedness of Intellectual Property Rights in Times of Post-TRIPS Bilateralism' in Hanns Ullrich

clusion that the latter agreement, including its Art. 27(2), to a high degree reflects the interests of the Western countries. In addition, as mentioned above, the term '*ordre public*' was itself proposed by the European Community on the basis of Art. 53(a) EPC,[885] which in this research is regarded as part of the Western legal tradition. Therefore, the analysis of Art. 27(2) of the TRIPS Agreement, as well as of the legal norms and the doctrine related to it, can be beneficial in understanding the concept '*ordre public*' and its significance in the Western legal tradition. The definition of this concept as provided in the scholarly literature is difficult to translate into English,[886] and thus it is even regarded as not having an English equivalent.[887]

The choice of the category '*ordre public*' shows that, from the very moment of the drafting of the Convention, the European patent system seeks to ensure that this term is perceived in the same way, even from the perspective of those legal systems whose national legal norms could define this category differently. This also confirms the EPO's objective to ensure the unity of the European patent system and its autonomy from the influence of national legal systems in construing the content of *ordre public*.

In the countries of civil law tradition, *ordre public* refers to imperative or *jus cogens*[888] legal provisions that cannot be changed by contract or restricted in any other way.[889] This particular concept of *ordre public* exists in the French legal system.[890] In the German translation of the EPC, the term '*öffentliche Ordnung*' is used. It exists in the German legal system, which is a part of the civil law tradition, and it can also be synonymous with the category '*ordre public*'.[891] Meanwhile, in the English legal system,

and others, *TRIPS plus 20. MPI Studies on Intellectual Property and Competition Law* (Springer Verlag 2016) 53-83, 60-61).

885 Pires de Carvalho, *The TRIPS Regime of Patent Rights* (n 29) 297.

886 UNCTAD-ICTSD, *Resource Book on TRIPS and Development* (Cambridge University Press 2005) 375.

887 Warren-Jones, 'Finding a "Common Morality Codex" for Biotech – A Question of Substance' (n 116) 641 citing Armitage & Davis, "Patents and Morality in Perspective" (Common Law Institute of Intellectual Property, London 1994), at 24.

888 In the legal doctrine, *jus cogens* is defined as 'the body of those general rules of law whose non-observance may affect the very essence of the legal system to which they belong to such an extent that the subject of law may not, under pain of absolute nullity, depart from them in virtue of particular agreements' (Ian Sinclair, *The Vienna Convention on the Law of Treaties* (Manchester University Press 1984) 203).

889 Michael Forde, 'The "Ordre Public" Exception and Adjudicative Jurisdiction Conventions' (1980) 29 The International and Comparative Law Quarterly 259, 259.

890 ibid.

891 Sinclair, *The Vienna Convention on the Law of Treaties* (n 888) 203.

which belongs to the common law tradition, this category is considered to be closest to the term 'public policy',[892] indicating that courts may refrain from following certain contracts if these 'contravene fundamental moral principles (*bonnes moeurs*, or *gute sitten*), or which would offend against some other overriding public interest'.[893]

Although the legal literature indicates that there is no consensus on the definition of the term '*ordre public*',[894] the aim of providing certain generalisations concerning it exists. For example, it is argued that there are two approaches to the category of '*ordre public*'.[895] One of them is broader and identifies this term as 'public order' or 'public policy', both of which include a particularly wide range of aspects.[896] This concept is associated with the common law system, for example the English system, and, despite being rather broad, it is considered to be less prone to change.[897]

Another, narrower understanding of this term indicates that *ordre public* includes 'fundaments from which one cannot derogate without endangering the institutions in a given society'[898] or that the term in question 'expresses concerns about matters threatening the social structures which tie a society together, i.e., matters that threaten the structure of civil society as such'[899]. In Art. 27(2) of the TRIPS Agreement, it is specified that *ordre public* may be associated with the protection of human, animal or plant life and health, as well as the prevention of serious damage to the environment.[900] Also, legal doctrine states that *ordre public* includes 'only the "major principles of the legal order",[901] for example, the inviolability of human dignity and the right to life, physical integrity and personal freedom'.[902]

The legal literature explains that, when drafting the TRIPS Agreement, the term '*ordre public*', proposed by the European Community, was chosen

892 Gervais, *The TRIPS Agreement, Drafting History and Analysis* (n 37) 343.
893 Forde, 'The "Ordre Public" Exception and Adjudicative Jurisdiction Conventions' (n 889) 259.
894 Hellstadius, *A Quest for Clarity: Reconstructing Standards for the Patent Law Morality Exclusion* (n 6) 161.
895 ibid 162.
896 ibid.
897 Sinclair, *The Vienna Convention on the Law of Treaties* (n 888) 204.
898 Gervais, *The TRIPS Agreement, Drafting History and Analysis* (n 37) 343.
899 UNCTAD-ICTSD, *Resource Book on TRIPS and Development* (n 886) 375.
900 TRIPS Agreement, Art. 27(2).
901 Straus, '*Ordre public* and morality issues in patent eligibility' (n 56) 22.
902 ibid.

instead of 'public order' or 'public policy', specifically because it has a more precise and narrower meaning.[903] Although this concept is regarded as being narrower, it is also considered to have more potential for change and development according to political, social and economic circumstances,[904] and is therefore reasonably considered to be evolutionary.[905]

Considering the above, it is possible to conclude that the category '*ordre public*' is associated with the legal norms and principles that are of fundamental importance to the existence and proper functioning of a particular society, its members and the surrounding environment. Attention to the human being and the protection of his/her essential interests, which is an important characteristic of every legal system that is a part of the modern Western legal tradition, falls within the scope of *ordre public* and takes an important place. Despite the fact that *ordre public* is first and foremost equated with the legal aspects of reality, it is able to evolve and adapt to changing circumstances of the environment. Consequently, its content can be shaped not only by the established legal rules and principles, but also by non-legal arguments. This reveals another feature of the Western legal tradition, i.e. the relative autonomy of law with regard to other areas of reality, and allows the conclusion that *ordre public*, which is primarily identified as legal norms and principles, may coincide with certain moral norms that are common in a society. In such cases, *ordre public* can be difficult to distinguish from morality in the legal systems of the Western legal tradition, as illustrated by the case law of the EPO Divisions with regard to interpreting and applying Art. 53(a) EPC.

4.4. Preliminary Conclusion

In the majority of EPO case law, morality and *ordre public* are treated as a single ground for opposing the grant of a patent on the basis of Art. 53(a) EPC. There are only a few decisions of the Office in which

903 Dan Leskien and Michael Flitner, *Intellectual Property Rights and Plant Genetic Resources: Options for a Sui Generis System* (International Plant Genetic Resources Institute 1997) 16; Straus, '*Ordre public* and morality issues in patent eligibility' (n 56) 22; Hellstadius, *A Quest for Clarity: Reconstructing Standards for the Patent Law Morality Exclusion* (n 6) 161 citing Correa, Carlos M, Trade Related Aspects of Intellectual Property Rights, A Commentary on the TRIPS Agreement, Oxford University Press 2007.

904 Sinclair, *The Vienna Convention on the Law of Treaties* (n 888) 204.

905 Gervais, *The TRIPS Agreement, Drafting History and Analysis* (n 37) 343.

these categories are distinguished, associating morality with non-legal behavioural standards recognised in a specific society and identifying *ordre public* with legal norms that are fundamental for the existence and proper functioning of a certain society.

Legal positivism and legal realism perceive morality as norms of conduct recognised by a society, or even subjective internal beliefs of an individual, that influence the creation, interpretation and application of legal norms. From the point of view of natural law, morality, regardless of its relative nature, can be identified with law or can be the basis for its evaluation. However, even in the legal paradigms that seek to strictly separate morality from law, there are situations where it is difficult to do so; thus, these two categories may overlap. At the same time, *ordre public* in the Western legal tradition is identified as legal norms and principles that are fundamental to the existence and proper functioning of a particular society and its members as well as the surrounding environment, but which, due to its ability to evolve and adapt to changing conditions by accepting arguments of a non-legal nature, may in some cases coincide with the moral standards.

In the Western legal tradition and in the EPO case law, it is difficult to distinguish morality and *ordre public* from each other. They can be treated as a single category, or they can be treated separately by identifying *ordre public* with legal norms and principles, and morality with non-legal standards of conduct. These difficulties regarding the separation of these analysed categories, both from the position of the Western legal tradition and from the perspective of the European patent system, reveal one of the main features of the Western legal tradition, i.e. the relative autonomy of law from other areas of social reality.

5. The Economic Function of Patents in the European Patent System

5.1. The Utilitarian Patent Law Theories and their Occurrence in the Field of Biomedical Sciences

As previously mentioned in this study, the term 'West' can be used to describe, among other things, market economy- and capitalism-oriented societies.[906] It means that in such societies, apart from the civil and political rights, economic and social rights providing individuals with the opportunity to achieve material well-being also hold an important place.[907] The importance of the aforementioned rights[908] is demonstrated in both international[909] and national[910] laws and regulations in force in the countries of the Western legal tradition.

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906 Herborth and Hellmann, 'Introduction: Uses of the West' (n 610) 2.

907 However, there is no complete agreement about economic and social rights among the states of the Western legal tradition. The ICCPR has not yet been ratified by the U.S., which, on the basis of the scholarly literature, is classified as belonging to the Western legal tradition.

908 Although human rights are regarded as indivisible in the legal doctrine, which denies the hierarchy of these rights, it is recognised that one human right is or may be given greater protection than others (e.g. Lijana Štarienė, 'Teisės į teisingą teismą, įtvirtintos Europos žmogaus teisių konvencijos 6 str., pobūdis, vieta ir apsaugos lygis kitų konvencijos teisių požiūriu' (2006) 10 Jurisprudencija 40, 41).

909 Declaration; European Convention on Human Rights; EU Charter of Fundamental Rights.

910 For example, see (1) Constitution of the Republic of Lithuania: ch I. The State of Lithuania; ch II. The Human Being and the State; ch III. Society and the State; ch IV. National Economy and Labour (Constitution of the Republic of Lithuania (*Lietuvos Respublikos Konstitucija*). *Valstybės žinios (Official Gazette)*, 1992, No. 33-1014); (2) 1949 Basic Law for the Federal Republic of Germany (German: *Grundgesetz für die Bundesrepublik Deutschland*): ch I "Basic Rights" (German: *Die Grundrechte*): Articles 1-19 cover rights related to protection of human dignity, as well as civil and political rights (Basic Law for the Federal Republic of Germany (*Grundgesetz für die Bundesrepublik Deutschland*) <https://www.bundestag.de/gg> accessed 30 May 2023); (3) 1978 Spanish Constitution (Spanish: *Constitución Española*): ch I discusses the model of state administration, the language, the flag, the minorities, etc., while ch II presents the list of fundamental rights and duties, as well as social and economic rights (Spanish Constitution (*Constitución Española*) <http://www.senado.es/constitu_i/index.html> accessed 30 May 2023).

One of the many means of implementing the economic rights and freedoms of individuals as well as promoting innovation and competition is the patent granting system,[911] which is based on both the doctrine of inalienable rights[912] and utilitarian theories.[913] From an economic point of view, a patent is a bargain between society and the inventor: through it, the state or its mandated regional organisations can normally grant an exclusive right with the possibility of preventing others from using a particular invention for 20 years.[914] Not only does this create an incentive to conduct scientific research and develop certain inventions, but it also obliges their disclosure to the public, as opposed to their being kept as trade secrets.[915] Thus, patents not only satisfy private interests, but also act in the interest of the public, as they seek to ensure social and economic well-being through the promotion of scientific and technological progress and competition.

Strengthening of cooperation among the European states regarding invention protection and creation of a common patent granting procedure are listed in the Convention as the main objectives of the European patent system.[916] However, according to E. van Zimmeren, the utilitarian aspects related to the granting of patents, which promote the development of inventions, their disclosure and the creation of social and economic well-being,

911 In addition to patents, there are other means, such as grants, prizes, subsidies and so on (see Guellec and van Pottelsberghe de la Potterie, *The Economics of the European Patent System* (n 7) 55-63).

912 For more on theories based on the Natural law doctrine, see 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). For more on intellectual property theories based on Natural law, see Ramūnas Birštonas and others, *Intelektinės nuosavybės teisė* (Registrų centras 2010) 28-31.

913 For more on the creation of patent systems, see Fritz Machlup, 'An Economic Review of the Patent System', Study of the Subcommittee on Patents, Trademarks, and Copyrights of the Committee on the Judiciary, United States Senate, 85th Cong., 2nd Sess., Study No. 15 (U.S. Government Printing Office 1958) 21-25; 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) 182.

914 TRIPS Agreement, Art. 33.

915 See e.g. Machlup, 'An Economic Review of the Patent System' (n 913) 21; Mazzoleni and Nelson, 'Economic Theories about the Benefits and Costs of Patents' (n 60) 1038; Clarissa Long, 'Patent signals' (2002) 69 University of Chicago Law Review 625, 626; Hall and Harhoff, 'Recent Research on the Economics of Patents' (n 56) 544-545; Heidi L Williams, 'How Do Patents Affect Research Investments?' (2017) 9 Annual Review of Economics 441, 445.

916 EPC, Preamble.

are also important objectives of the establishment of the European patent system.[917] There are several major patent granting theories discussed in the scholarly literature based on the utilitarian philosophy: (1) the reward theory, (2) the patent-induced theory, (3) the disclosure theory, and (4) the commercialisation theory.[918]

The reward theory claims that the inventor has the right to compensation for creating and disclosing an invention to the public.[919] According to F. Machlup, this compensation is embodied by a temporary exclusive right to a particular invention which is granted to the inventor and which is proportional to this invention's utility to society.[920] It is also the market power provided by a patent which creates for the owners of the patent an opportunity 'to recoup the fixed costs of their research investments'.[921] Otherwise, the failure to recover investments may diminish the inventors' desire to develop patentable innovative products or processes in the future.[922] The disadvantage of this theory is the fact that it is not always possible to compensate the most merited innovator, and even if the invention is efficiently exploited, the compensation and its amount depend on the commercial success of that particular innovation, which is determined by various factors.[923]

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917 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) 219-220 citing Danish Board of Technology et al. (2007), Policy options for the improvement of the European Parliament, STOA, IP/A/STOA/FWC/2005-28/SC16, available at http://www.europarl.europa.eu/stoa/publications/studies/stoa16_en.pdf, at pp. 33–4. Scholarly literature indicates that there are more utilitarian theories for justification of patent protection: e.g. (1) the prospect theory; (2) the rent dissipation theory; (3) the race-to-invent theory; (4) the portable fence theory. They are usually employed in order to correct the drawbacks of the main theories discussed in this research (ibid 204-212).

918 ibid 198-204.

919 ibid 198.

920 Machlup, 'An Economic Review of the Patent System' (n 913) 21.

921 Williams, 'How Do Patents Affect Research Investments?' (n 915) 441.

922 Yusing Ko, 'An Economic Analysis of Biotechnology Patent Protection' (1992) 102 The Yale Law Journal 777, 792 citing FREDERICK M. SCHERER, INDUSTRIAL MARKET STRUCTURE AND ECONOMIC PERFORMANCE 444 (2nd ed. 1980); William F. Baxter, Legal Restrictions on Exploitation of the Patent Monopoly: An Economic Analysis, 76 YALE L.J. 267, 268-69 (1966).

923 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) 199.

The patent-induced theory, which is closely related to the reward theory, differs from the latter in that, according to this theory, in order to be compensated for an invention, the inventor's motivation has to derive from the patent system, while the reward theory does not consider the motivation behind an invention to be an important factor.[924] Although this theory is considered to be the dominant one and receives the most support from economists, researchers and politicians, it does not explain the cases where inventions are created for reasons that are not related to the patent granting system.[925]

The disclosure theory, which F. Machlup describes as a bargain between the inventor and society when the former discloses secret information in exchange for the protection of exclusive industrial use,[926] is one of the most widespread patent law theories in economic scholarship.[927] Due to exclusive patent rights granted to the inventor, the information that can be used to create new inventions[928] is disclosed quickly and extensively, preventing the technological knowledge which would otherwise become a commercial secret from 'dying with the inventor',[929] and avoiding duplication of research.[930]

However, the disadvantages of this theory become apparent in certain situations. For example, it may be difficult to keep important information about an invention private for an extended period of time. Thus, it is doubtful whether commercial secrets can be kept even if the patent system does not exist. Due to this fact, there is a probability that, even without granting exclusive rights to an invention, important technological knowledge would nonetheless be disclosed to society, and therefore, if the patent system did not exist, little or nothing would be lost.[931] Meanwhile, an inventor who knows that the information about his/her innovation will not be disclosed

924 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) 199-200.
925 ibid 200.
926 Machlup, 'An Economic Review of the Patent System' (n 913) 21.
927 Hall and Harhoff, 'Recent Research on the Economics of Patents' (n 56) 549.
928 Williams, 'How Do Patents Affect Research Investments?' (n 915) 445.
929 Machlup, 'An Economic Review of the Patent System' (n 913) 21.
930 Ko, An Economic Analysis of Biotechnology Patent Protection (n 922) 792 citing FREDERICK M. SCHERER, INDUSTRIAL MARKET STRUCTURE AND ECONOMIC PERFORMANCE 440 (2nd ed. 1980); WARDS. BOWMAN, JR., PATENT AND ANTTRUST LAW 12-13 (1973).
931 Machlup, 'An Economic Review of the Patent System' (n 913) 24.

to society will not attempt to register a patent.[932] In this case, a patent application will most likely only be filed when the inventor understands that important information may be disclosed and used by competitors when products based on the invention begin to be sold. Another problem is that patents can be granted without the applicants providing sufficient information that could be applied by a specialist in a corresponding field.[933]

Commercialisation theory can be relevant for patenting inventions in their early development stages, when it is evident that further research is needed in order to make the invention applicable in practice.[934] Patents granted in these early stages guarantee economic prosperity for the patent owner, provided that further development of an invention is successful.[935] In such cases, patents can either be licensed to other subjects who will further develop or commercialise the invention, or used to attract venture capital investment – which is especially relevant for small businesses attempting to develop and commercialise their inventions independently.[936] However, according to F. Machlup, if an invention cannot be industrially applied, the invention development can be the stage in which the patent system may encourage the protection of information rather than its disclosure.[937] Therefore, commercialisation theory is not always suitable.

The scholarly literature indicates that patent granting theories, including those discussed above, often overlap or complement each other.[938] Therefore, it may be difficult to completely separate them from each other. Although each of them, formed in different circumstances and in different historical periods, has both advantages and disadvantages, as well as differently reflecting the peculiarities of research in specific sectors of technology, all of them have influenced the development of a patent system. Therefore,

932 Machlup, 'An Economic Review of the Patent System' (n 913) 24.

933 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) 203 citing MACHLUP, F, An Economic Review of the Patent System, Study of the Subcommittee on Patents, Trademarks, and Copyrights of the Committee on the Judiciary United States Senate, 1958, 85th Cong., 2nd Sess., *Study No. 15*, Washington, U.S. Government Printing Office, 32.

934 ibid 203.

935 ibid.

936 ibid 203-204.

937 Machlup, 'An Economic Review of the Patent System' (n 913) 24-25.

938 Mazzoleni and Nelson, 'Economic Theories about the Benefits and Costs of Patents' (n 60) 1034.

even those theories that have a context of emergence very different from the current one should not be ignored.[939]

However, in the context of the aforementioned theories, it can be stated that all of the patent systems share the common goal of promoting the emergence of innovation and the dissemination of the newest scientific and technological information, ensuring both private and public interests. Nevertheless, despite this objective, theoretical and empirical analysis presents ambiguous findings, both on the effectiveness of a patent system in encouraging the creation and development of inventions and on the disclosure of the latest scientific and technological information related to it.[940] Thus, as indicated by D. Burk and M. Lemley, although there is 'virtually unanimous agreement' that the aim of granting patents as exclusive rights is to encourage the development of innovation, opinions in the debate about the success of a patent system differ.[941]

Despite the above-mentioned discussions, there is a consensus in the scholarly literature that there is a causal link between patent granting and innovation in the field of biomedical sciences.[942] Therefore, unlike in other scientific and technological fields, the granting or the rejection of a patent application can influence the development of the field in question or the

939 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) 224.

940 Hall and Harhoff, 'Recent Research on the Economics of Patents' (n 56) 559.

941 Mark A Lemley and Dan L Burk, 'Policy Levers in Patent Law' (2003) 89 Virginia Law Review 1575, 1580-1581; Peukert, 'Intellectual property and development – narratives and their empirical validity' (n 49) 9.

942 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 Economic Activity, 783-831 and E. Mansfield (1986), 'Patents and Innovation: An Empirical Study', 32 Management Science, 173–81. See also Guellec and van Pottelsberghe de la Potterie, *The Economics of the European Patent System* (n 7) 67.

emergence of innovation in that field. Taking this into account, it must be held that Art. 53(a) EPC, which, as discussed before, is most often used to analyse the development of the patentability of biotechnological inventions, can influence further growth of the biomedical sciences as well as the related fields of science and technology. In view of this situation, in this study it is necessary to discuss the consequences of application of this particular provision of the Convention.

5.2. The Consequences of the Application of Article 53(a) of the European Patent Convention

According to the scholarly literature, the European patent system was one of the elements to embody a vision of a closer union between the European countries that were devastated after the Second World War.[943] This union was seen as a primary instrument in achieving the development of a single market and economic growth on the Old Continent.[944] Initially, the EPO operated as an institution, which, by granting patents, encouraged innovation and economic growth and, in this way, performed a market-shaping function.[945] However, later, due to scientific and technological progress, the Office started identifying situations in which the application of market forces to certain inventions could be harmful to the public,[946] and thus identifying inventions for which patents should not be issued. This can be illustrated by the intensified application of Art. 53(a) EPC with regard to biotechnological inventions in the 1980s.

Although, as discussed in this study,[947] the creation of a patent system serves as a means for disseminating the latest scientific and technological knowledge, in turn encouraging innovation by providing an economic benefit to the inventors, according to the EPO Guidelines and the case

943 Plomer, 'A Unitary Patent for a (Dis)United Europe: The Long Shadow of History' (n 137) 510.

944 ibid.

945 Parthasarathy, 'Co-producing knowledge and political legitimacy. Comparing life form patent controversies in Europe and the United States' (n 17) 76.

946 ibid.

947 See '5.1. The Utilitarian Patent Law Theories and their Occurrence in the Field of Biomedical Sciences'.

law of the EPO Boards of Appeal,[948] when interpreting and applying Art. 53(a) EPC, '[t]he EPO has not been vested with the task of taking into account the economic effects of the grant of patents in specific areas of technology and of restricting the field of patentable subject-matter accordingly'.[949] In addition, the said Guidelines and the case law of the EPO indicate that '[t]he standard to apply for an exception under Art. 53(a) is whether the commercial exploitation of the invention is contrary to "ordre public" or morality'.[950] For example, according to the case law of the EPO Boards of Appeal, in the context of Art. 53(a) of the Convention, 'negative social and economic effects' on patients[951] or farmers and traditional plant breeders are not evaluated as part of invention's commercial exploitation in accordance with *ordre public* and morality.[952] Therefore, when analysing whether an invention's commercial exploitation is in line with Art. 53(a) EPC, the EPO does not consider the economic effects of the granting of a patent.

Despite this rejection of the influence of economic arguments for the interpretation of Art. 53(a) EPC, as it has been discussed, in the field of biomedical sciences, the evaluation of the exploitation of an invention from the perspective of *ordre public* and morality may have an economic effect on the stakeholders who have a direct interest in a particular patent. This is confirmed by the scholarly literature[953] as well as by the fact that the Office

948 See e.g. Enlarged Board of Appeal (European Patent Office), *Transgenic plant/NOVARTIS II*, Decision of 20 December 1999, Case No. G 0001/98, ECLI:EP:BA:1999:G000198.19991220, para 3.9; *Breast and Ovarian Cancer/UNIVERSITY OF UTAH* (n 22), para 53.

949 Guidelines for Examination, March 2023 (n 63), pt G-II, 4.1.3.

950 *Transgenic plant/NOVARTIS II* (n 948), para X; *Breast and Ovarian Cancer/UNIVERSITY OF UTAH* (n 22), para 53; Guidelines for Examination, March 2023 (n 63), pt G-II, 4.1.3.

951 *Breast and Ovarian Cancer/UNIVERSITY OF UTAH* (n 22), para 52.

952 *Transgenic plant/NOVARTIS II* (n 948), para X, 13.

953 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

included the provisions of the Biotech Directive in the EPC Implementing Regulations in order to promote economic growth in Europe.[954] Taking this into account, the economic effect of the commercial exploitation of an invention must be considered in accordance with Art. 53(a) EPC.

A patent confers on its owner a temporary exclusive right to prevent third parties from exploiting the invention without the owner's permission. This potentially provides the patent owner, or other entities financially involved in the creation of an invention, with the opportunity to recover the investments incurred in its research and development.[955] Without the exclusive right to an invention, the owner of the patent would soon face competitors who could copy and sell the invention at a lower price, thus weakening the owner's position in the market.[956] In that case, inventors would have less incentive to invest in the development of new products or processes, or would simply keep the results secret,[957] which would have a negative impact on one of the most important aims of patenting, i.e. scientific and technological advancement. In Europe, this is especially relevant for small and medium-sized start-up companies, which are currently conducting the majority of research in the field of biotechnology. For them, patents are an important means of recovering their investment in research and development of innovations.[958]

The above-mentioned exclusive intellectual property rights, which strengthen the patent owners' position against their competitors and thus help innovators to stay on the market, are not the only reason why having patents is important. In the scholarly literature, another significant function

industrial research and development', 3 Brookings Papers on Economic Activity, 783-831 and E. Mansfield (1986), 'Patents and Innovation: An Empirical Study', 32 Management Science, 173–81.

954 Parthasarathy, 'Co-producing knowledge and political legitimacy. Comparing life form patent controversies in Europe and the United States' (n 17) 78.

955 Gitter, 'Led Astray by the Moral Compass: Incorporating Morality into European Union Biotechnology Patent Law' (n 95) 7.

956 ibid.

957 ibid 7-8.

958 ibid citing ERNST & YOUNG, EUROPEAN LIFE SCIENCES 98, at 11, tbl. 3 (1998); Third Report of the Committee on Legal Affairs and Citizens' Rights on the Commission Proposal for a Council Directive on the Legal Protection of Biotechnological Inventions, EUR. PARL. Doc. (COM 88 0496 final-C3-0036/89- SYN 159) 27 (1992).

that these rights perform is referred to as 'patent signalling'[959] or 'informational function'.[960] Two key elements of the 'patent signalling' function can be discerned: (1) dissemination of information related to technological aspects of an invention and its innovativeness that can help to identify its commercial potential; and (2) dissemination of information about the prospect of a certain invention becoming an economic good in a certain legal system.

The first element means that patents, as intellectual property rights, should be interpreted not only as providing legal protection against competitors and binding the inventor to disclose the relevant information to the public, but also as a means of attracting potential investors.[961] Empirical studies indicate that businesses that are patent owners or patent applicants are more likely to receive venture capital investments, and that they will receive such investments more quickly.[962]

This patent signalling aspect is considered to be especially important for start-ups as well as small and medium-sized businesses[963] operating in knowledge-intensive industry fields, which tend to have long research cycles and face unforeseeable, often difficult-to-solve scientific, technical and regulatory challenges[964] hindering the achievement of quick and defin-

959 See e.g. David H Hsu and Rosemarie H Ziedonis, 'Patents as quality signals for entrepreneurial ventures' [2008] Academy of Management Best Paper Proceedings 1, 6; Long, 'Patent signals' (n 915) 625; Mark Schankerman, 'Introduction' (2013) 61 Journal of Industrial Economics 471; Stefano Comino and Clara Graziano, 'How many patents does it take to signal innovation quality?' (2015) 43 International Journal of Industrial Organization 66, 66-68.

960 Dietmar Harhoff, 'The role of patents and licenses in securing external finance for innovation' (2009) 14 EIB Papers 74, 85.

961 Long, 'Patent signals' (n 915) 626.

962 See e.g. Ian C Macmillan, Robin Siegel and PN Subba Narasimha, 'Criteria Used by Venture Capitalists to Evaluate New Venture Proposals' (1985) 1 Journal of Business Venturing 119, 121-122; Comino and Graziano, 'How many patents does it take to signal innovation quality?' (n 959) 66-67 and 74.

963 Patent signalling function is more important to companies with less than 50 employees and with fewer financing restrictions (Dirk Czarnitzki, Bronwyn H Hall and Hanna Hottenrott, 'Patents as quality signals? The Implications for Financing Constraints on R&D' (2014) DICE DISCUSSION PAPER No 133 <https://www.dice.hhu.de/fileadmin/redaktion/Fakultaeten/Wirtschaftswissenschaftliche_Fakultaet/DICE/Discussion_Paper/133_Czarnitzki_Hall_Hottenrott.pdf> accessed 30 May 2023). See also Comino and Graziano, 'How many patents does it take to signal innovation quality?' (n 959) 66-67 and 74.

964 Hoenen and others, 'The diminishing signalling value of patents between early rounds of venture capital financing' (n 106) 981.

itive results. Biotechnology is one of these knowledge-intensive fields of industry.[965] Indeed, European patent applications are deemed to be important signals by German and British venture capital investors when considering investments in biotechnology businesses.[966]

Patents can perform this function because they require a considerable amount of time, finance and effort due to the strict substantive and procedural patentability requirements set out in legislation, including the necessity to present the information about the invention in a certain way in patents claims. Moreover, the patent offices' registry information, which is available to the public, is considered as an inexpensive and reliable way to ascertain the technological capabilities and achievements of a company in a certain field.[967] Therefore, potential investors who are familiar with the patenting process are able to evaluate the strengths and weaknesses[968] of a technology and its commercial potential.

Based on the above, it can be stated that patent ownership can indicate a company's potential to provide commercially valuable results[969] to investors, thus helping to tackle the asymmetry of information between patent owners and potential investors when the latter have little knowledge about the work and quality of the former.[970] Consequently, patents assist in filling this information gap, and in this way help in attracting investment which allows companies to continue their research and development.

However, the above-mentioned function of dissemination of information related to technological aspects of an invention cannot be considered as especially important in all cases. For example, despite being essential at the

965 Hoenen and others, 'The diminishing signalling value of patents between early rounds of venture capital financing' (n 106) 959-960.

966 Hall and Harhoff, 'Recent Research on the Economics of Patents' (n 56) 553 citing HAEUSSLER, C., HARHOFF, D., MUELLER, E. (2009) To be financed or not... the role of patents for venture capital financing. Mannheim, Germany: ZEW Discussion Paper, No. 09-003.

967 Hoenen and others, 'The diminishing signalling value of patents between early rounds of venture capital financing' (n 106) 958.

968 Harhoff, 'The role of patents and licenses in securing external finance for innovation' (n 960) 85.

969 Toby E Stuart, Ha Hoang and Ralph C Hybels, 'Interorganizational Endorsements and the Performance of Entrepreneurial Ventures' (1999) 44 Administrative Science Quarterly 315, 317.

970 Jerry X Cao and Po-Hsuan Hsu, 'The Role of Patents in Venture Capital Financing and Performance' <http://www.efmaefm.org/0EFMSYMPOSIUM/2011-Toronto/papers/Hsu.pdf> accessed 30 May 2023.

initial stage of financing a business, the patent signalling function is not as important in the later financing stages, when the information asymmetry between the patent owner and investors decreases.[971]

The second important element of the signalling function is the fact that the grant of a patent discloses information about the acceptance of a particular invention becoming an economic good in a certain legal system. This means that encouragement is not being given to the creation of inventions at any cost and with any resultant consequences. On the contrary, the patent system may strive for inventions to be socially beneficial and consistent 'with fair and just social organisation'.[972] Consequently, a patent is not only a means of disclosure of information about an invention, with potential economic benefits to its owner, but also a source of information about society's attitude towards a certain patented object as a commodity, as well as support for and encouragement of this approach.[973]

During the proceedings in the *Use of embryos/WARF*[974] case, the then-incumbent President of the EPO, A. Pompidou, stated that the European patent system is not morally neutral and emphasised that 'the granting of a patent invention is often perceived to be an official endorsement of or reward for a particular invention'.[975] This indicates that the EPO performs invention control not only from a technical perspective, evaluating an invention's novelty, inventive step and susceptibility to industrial application,[976] but also, in accordance with Art. 53(a) EPC, by considering its social acceptability as a commodity from the perspective of *ordre public* and/or morality. Only after assessing the compatibility of the commercial exploitation of an invention with regard to the aforementioned article does the EPO decide whether to grant a patent, in turn supporting the commercialisation of objects from a certain scientific or technological field.

971 See e.g. Kuhn, *The Essential Tension: Selected Studies in Scientific Tradition and Change* (n 104) 982; Czarnitzki, Hall and Hottenrott, 'Patents as quality signals? The Implications for Financing Constraints on R&D' (n 963).

972 Liddell, 'Immorality and Patents: The Exclusion of Inventions Contrary To Ordre Public and Morality' (n 134) 141.

973 Mark J Hanson, 'Biotechnology and Commodification within Health Care' (1999) 24 Journal of Medicine and Philosophy 267, 273.

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

975 Parthasarathy, 'Co-producing knowledge and political legitimacy. Comparing life form patent controversies in Europe and the United States' (n 17) 82 citing Pompidou, Alain (2006) "G2/06 Comments by the President of the European Office. EP 96903521.1-2401/0770125".

976 EPC, Art. 52(1).

Thus, even if the EPO does not analyse the economic consequences of the grant of a patent, the evaluation of an invention's commercial exploitation in the light of Art. 53(a) EPC – and, based on the aforementioned legal provision, the grant or rejection of a patent claim – can often carry consequences for inventors affecting the development of certain fields of science and technology, especially the biomedical sciences. This situation arises because the granting of a patent or the rejection of a patent application based on Art. 53(a) EPC indicates to society which subject-matter can be commercialised in the legal system in question by providing exclusive rights and which objects cannot become economic goods, i.e. commodities. Therefore, the granting of a patent signals the company's ability to develop not only innovative but also socially acceptable technologies.

In reference to the case law of the EPO Boards of Appeal analysed in this study[977] and Rule 28(1)(a), (b) and (c) of the EPC Implementing Regulations,[978] it can be concluded that, at least currently, according to Art. 53(a) EPC, inventions encompassing the human body at various stages of its development and formation, as well as actions related to the use of human embryos for commercial or industrial purposes, human cloning or modification of the germ line genetic identity, are not tolerated in the European patent system and should not be encouraged.[979] For the assessment of the commercial exploitation of these inventions, in the EPO case law, the rebuttable presumption test, which is based on deontological ethics and the abhorrence standard, is applied.[980] In this case, the benefits of using such an invention cannot lead to a favourable decision to grant a patent. Also, the EPO will tend to interpret the term 'commercial exploitation' broadly, by including the stages of creation and development of the invention, and in some cases even the fact of patenting itself.[981] Under

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

978 According to r 28(1)(a), (b) and (c), the following are non-patentable: (a) processes for cloning human beings; (b) processes for modifying the germ line genetic identity of human beings; (c) uses of human embryos for industrial or commercial purposes.

979 Kamperman Sanders A and others, 'Final Report of the Expert Group on Patent Law in the Field of Development and Importance of Biotechnology and Gene Technology' (n 58).

980 See '1.4.1. Tests for Application of Article 53(a) of the European Patent Convention', '1.4.2. The Standards for Applying Article 53(a) of the European Patent Convention' and '1.4.3. The Concept and Scope of the Term 'Commercial Exploitation''.

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

these circumstances, it is practically impossible under Art. 53(a) of the Convention to consider the commercial exploitation of such an invention to be appropriate and to grant a patent.

Nevertheless, the attitude of the Office is much more favourable with regard to the patenting of elements that are isolated from the human body or otherwise technically produced. Although, as analysed earlier in this research,[982] the listed elements are also subject to a deontological approach, Rule 29(2) of the EPC Implementing Regulations explicitly states that these objects, even if they are identical to the structures of natural elements, are patentable.[983] This means that patents granted for objects isolated from the human body, and covered by the aforementioned rule, are regarded favourably by the European patent system. In addition, inventions including animals or plants can also be patentable in the European patent system. In such cases, the Board often applies a weighing test based on utilitarianism and the standard of unacceptability.[984] In both cases, in principle, the term 'commercial exploitation' is interpreted restrictively by the EPO, limiting it to the likely commercial exploitation of the invention as defined in the patent application.[985]

The above-mentioned approach of the EPO illustrates the classification of values into intrinsic and extrinsic[986] which exists in the field of ethics. Certain things can be regarded as having an intrinsic value in themselves without serving a particular purpose, while others can be regarded as having extrinsic value if their use can help to achieve a certain objective.[987]

The above-discussed classification of inventions in the European patent system according to their intrinsic and extrinsic value allows us to accept the idea that values can be divided into market values and non-market values.[988] It is the latter group which can be attributed to a human being in the context of the Western legal tradition, meaning that it is impossible to

982 See '1.4. European Patent Office Case Law on Article 53(a) of the European Patent Convention'.
983 EPC Implementing Regulations, r 29(2).
984 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'.
985 See '1.4.3. The Concept and Scope of the Term 'Commercial Exploitation''.
986 David B Resnik, 'DNA Patents and Human Dignity' (2001) 29 Journal of Law, Medicine and Ethics 152, 155 citation from W. Frankena, *Ethics*, 2d ed. (Englewood Cliffs, New Jersey. Prentice-Hall, 1973).
987 ibid 155.
988 ibid 156.

assign economic value to him/her. However, despite the status of a fundamental value attributed to human beings, the question arises as to whether the said approach can always be maintained in the changing, dynamic and market economy-oriented Western legal tradition.

According to M. Radin, society tends to more or less attribute market terminology to different objects: (1) objects possessing market value are subject to commodification, (2) objects not possessing monetary or market value are regarded as non-commodified,[989] and (3) objects possessing a market value and a different non-monetary value are considered to be incompletely commodified.[990] In the context of the Western legal tradition, it seems that, ideally, every human being should be viewed as having value which cannot be defined using market terminology or assigned a price, i.e. commodified.

However, in Western society, where there is freedom of economic activity and strong market rhetoric, all objects have the potential to become completely or incompletely commodified.[991] For example, in the past, sporting activities were not treated as a commodity as they are nowadays: for a long time, athletes were amateurs and took part in competitions out of sportsmanship and personal enthusiasm, in order to improve their skill level, etc. Today, athletes and their activities are subjected to incomplete commodification.[992] This is illustrated by the fact that the majority are paid a salary for such physical activity, and may also be purchased or sold[993] on the market for athletes. Sports would become completely commodified if athletes and spectators were only interested in the financial compensation and did not place meaning on sportsmanship and other values.[994] Therefore, despite the status of a human being as a fundamental value in the Western legal tradition, in some cases, such as in their professional life, a human being can be considered a commodity.

In order to prevent the total commodification of certain values, including human beings, legislation is adopted through which incompletely commodified objects can be regulated and protected from losing their intrinsic and

989 Margaret Jane Radin, *Contested Commodities* (Harvard University Press 1996) 102-104.
990 ibid.
991 ibid 99.
992 Resnik, 'DNA Patents and Human Dignity' (n 986) 156.
993 ibid.
994 ibid.

non-market value.[995] Regulatory provisions of this type exist in healthcare, education, real estate, life and health insurance, politics, sports and other spheres of human activity where certain important values are incompletely commodified[996] and where, to a certain degree, market economy principles exist. Hence, in the Western legal tradition, a constant balancing between the protection of the status of the fundamental values and the assigning of an economic value to them takes place.

It is stated that, in the process of the development of a free market economy, society attributed a monetary value to more and more objects which were previously not regarded as having any economic value: gradually, such objects as land, domestic labour, nursing care, consultations, sports activities and military service were given economic value.[997] These processes were heavily influenced by scientific and technological advancement, which not only transformed the conventional understanding of the environment, but also allowed the environment to be modified. Just like the changes in the aforementioned fields, similar processes can be observed today in the field of biomedical sciences – which is not only where measures ensuring human well-being are being created and our understanding of the environment is quickly being changed, but which is also a multibillion industry seeking profit for its investors.[998] Thus, for this sector, the ownership of patents, potentially providing an opportunity to receive economic benefits, is of major importance.[999]

Currently, it is feared that too lenient patent granting for biotechnical inventions could turn human beings into commodities. For this reason, based on Art. 53(a) EPC, an *ex ante* control of the social desirability of an invention exists in the European patent system.[1000] Due to this exception, the European patent system shows its views towards the commercialisation of certain inventions by granting a patent or rejecting a patent application. This patentability exception discourages certain research and development in specific technological fields, because without a patent protecting an

995 Radin, *Contested Commodities* (n 989) 107-110.
996 Resnik, 'DNA Patents and Human Dignity' (n 986) 156.
997 ibid 161.
998 Hanson, 'Biotechnology and Commodification within Health Care' (n 973) 268.
999 See e.g. Hall and Harhoff, 'Recent Research on the Economics of Patents' (n 56) 552-553.
1000 Kamperman Sanders A and others, 'Final Report of the Expert Group on Patent Law in the Field of Development and Importance of Biotechnology and Gene Technology' (n 58).

invention, and having no exclusive right to it, the possibility of obtaining any economic benefit, i.e. a return on the investment in research and development, diminishes significantly.[1001] Hence, Art. 53(a) EPC is deemed to be an indirect tool which allows scientific research to be controlled without, as it is thought, restricting its freedom.[1002]

Due to the patent signalling function discussed above, it can be held that the approach of the EPO, based on the Western legal tradition, of regarding the patentability of the aforementioned biomedical inventions related to human beings and possibly violating their right to life as well as dignity as undesirable in the European patent system, may have significant consequences for this particular scientific field. Such a strict position of the European patent system, based on Art. 53(a) EPC, regarding the patenting of inventions related to the human body at various stages of its development and formation, as well as actions with regard to the use of human embryos for industrial and commercial purposes, human cloning or modification of the germ line genetic identity, resulting in the rejection of patents for such inventions, may reduce the investment in businesses operating in the sphere of biomedical research involving the said subject-matter. Low funding may lead to a decrease or a complete halt in the research in the aforementioned controversial fields in the territory where the European patent system is in force.

Therefore, on the one hand, the rejection of a patent application on the basis of Art. 53(a) EPC lowers the investment in research in the field of biomedical sciences and allows the protection of a human being – as a fundamental value in the Western legal tradition – from his/her transformation into an economic good, and subsequently from his/her full commodification. On the other hand, despite the fact that the rejection of a patent application does not take away the possibility of conducting controversial but not illegal research and development of technology related to it, the reduced potential economic benefits of biomedical research may still have a negative impact on progress in this field of science, which may inhibit the emergence of knowledge concerning human beings, their life and the formation of the whole human body. Thus, although further research is theoretically possible even without a patent, given the previously discussed

1001 Kamperman Sanders A and others, 'Final Report of the Expert Group on Patent Law in the Field of Development and Importance of Biotechnology and Gene Technology' (n 58).

1002 ibid.

importance of patent rights in the field of biomedical sciences, the emergence of new scientific knowledge and the change of attitude towards the human being based on it may be slower in the European patent system belonging to the Western legal tradition.

5.3. Preliminary Conclusion

Despite the discussions about the efficiency of the patent system, it is generally agreed in the scholarly literature that patents provide economic returns and stimulate innovation in the field of biomedical sciences. This means that the non-granting of a patent for an invention in this field of science, based on Art. 53(a) EPC, reduces the possibility of its commercialisation and hence the potential economic advantage for the patent holder. In view of this, there is a possibility that the research and development of inventions that will be regarded as non-patentable in the European patent system in terms of *ordre public* and/or morality will receive less investment. This will lead to slower progress in the biomedical sciences with regard to certain issues and will not encourage the growth of knowledge about the surrounding environment, its objects and the ongoing processes.

The aforementioned situation is likely to occur with regard to inventions encompassing the human body in its various stages of formation and development, actions related to the use of human embryos for commercial and industrial purposes, human cloning or processes for modifying the germ line genetic identity of human beings. Although the rejection of a patent application does not eliminate the right to perform sometimes even controversial but not prohibited research actions or create such technologies, the reduction of the potential economic benefits may decrease the activity in certain areas of biomedical research. Therefore, the emergence of new scientific knowledge – and, based on this knowledge, the change in the approach towards a human being and his/her development in the European patent system within the Western legal tradition – may be slower.

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.

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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

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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.

Conclusion

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

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

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

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

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

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

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

Definitions of Terms Used in the Study

Blastocyst	A mammalian blastula[1103] in which some differentiation of cells has occurred.[1104]
Deontology	A branch of ethics analysing the problem of obligation.[1105] According to deontological theory, actions are considered to be good or bad, right or wrong by themselves, whereas the consequences do not add any value to an action.[1106]
Ethics and morality	The term 'morality' (in French 'morale': 'morality', in Latin 'moralis': 'moral') derives from Latin and is associated with a certain manner, behaviour, order or custom.[1107] The term 'ethics' is derived from the Greek word 'ethos', which means moral characteristics or custom.[1108] Considering these meanings, it can be stated that, in the scholarly literature, the aforementioned terms are often used synonymously; however, their meanings are not identical.[1109] In general, morality is perceived as norms and principles that regulate people's behaviour,[1110] while ethics is understood as a science that investigates morality.[1111] The latter meanings are attributed to morality and ethics throughout this study.
Herbicide	A substance that is toxic to plants, used to destroy unwanted vegetation.[1112]

1103 A blastula is an animal embryo at the early stage of development when it is a hollow ball of cells (Stevenson, *Oxford Dictionary of English* (n 459) 177).
1104 Stevenson, *Oxford Dictionary of English* (n 459) 177.
1105 Vaitkevičiūtė (ed), *Tarptautinių žodžių žodynas* (n 69) 228.
1106 Anzenbacher, *Etikos įvadas* (n 310) 32.
1107 Bagley, 'The New Invention Creation Activity Boundary in Patent Law' (n 92) 596-597.
1108 ibid 597.
1109 ibid.
1110 Aldona Bendorienė and others (eds), 'Moralė', *Tarptautinių žodžių žodynas* (Alma Littera 2003) 495.
1111 Kelsen, *Grynoji teisės teorija* (n 760) 83.
1112 Stevenson, *Oxford Dictionary of English* (n 459) 819.

Natural sciences	A branch of science which deals with the physical world, for example, physics, chemistry, geology, biology. This is also understood as the branch of knowledge which deals with the study of the physical world.[1113] In this research, the term 'natural sciences' is used interchangeably with the term 'science'.
Parthenogenesis	Reproduction from an ovum without fertilisation, especially as a common process in some invertebrates and lower plants.[1114]
Phenotype	All the observable characteristics of an organism (for example, behaviour, biochemical properties, colour, shape, and size) resulting from the interaction of its genotype (the genetic structure of an organism) with the environment.[1115]
Utilitarianism	The philosophical and economic doctrine that the best social policy is the one that provides the most good for the greatest number of people; especially, an ethical theory that judges the rightness or wrongness of actions according to the pleasure they create or the pain they inflict and recommends whatever action creates the greatest good for the greatest number of people.[1116]
Xenogeneic	Relating to or involving tissues or cells belonging to individuals of different species.[1117]

1113 Stevenson, *Oxford Dictionary of English* (n 459) 1183.

1114 ibid 1294.

1115 'Genotype', *Encyclopædia Britannica* <https://www.britannica.com/science/genotype> accessed 30 May 2023. See also Stevenson, *Oxford Dictionary of English* (n 459) 1334.

1116 Bryan A Garner (ed), 'Utilitarianism', *Black's Law Dictionary* (9th edn, 2009) 1688. The doctrine of utilitarianism of Jeremy Bentham extended not only to humans but also to animals (see Bentham, *An introduction to the principles of morals and legislation* (n 670) 309). Thus, it is regarded as being the 'proposition that lies at the beginnings of utilitarian arguments for the ethical treatment of animals' (James E Crimmins, 'Jeremy Bentham', *The Stanford Encyclopedia of Philosophy* (rev edn, 2021) <https://plato.stanford.edu/entries/bentham/#LifWri> accessed 30 May 2023).

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