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.

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 Ethi*cs (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.