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 I.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.