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Patenting human biological materials and data: balancing the reward of innovation with the *ordre public* and morality exception

Esra Demir* and Evert Stamhuis

Introduction

The patent system as a regulatory intervention of the state promotes the commercialization of a certain type of technology.¹ Upon grant, the patent holder acquires exclusive rights to the commercial use of a technical invention for a period of up to 20 years.² The focal point of the patenting process, which is a strictly technical process, is the question of whether the invention sufficiently fulfils the requirements for patentability to qualify for a limited monopoly.³ However, the patent system and its technical structure have been challenged by biotechnological inventions and their commercial application, and in particular, the debate on patentable material has become increasingly controversial.

Historically, patenting human genetic materials dates back to the 1980s, yet the legitimacy of patentability and commercialization of these materials and data are still under debate.⁴ On the one hand, it is often put forward, although not without opposition, that the role of patents in the field of biotechnology stimulates innovation and promotes biomedical research and scientific progress for the benefit of society and mankind.⁵ As the physical embodiment of information about human nature, these

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Abstract

- The availability of human biological materials and data plays a key role in promoting biotechnological innovations and conducting biomedical research. While the function of patent rights in promoting innovation is widely discussed, there are still overarching concerns in patenting human biological materials and data, including triggering commercialization and commodification of the human body, precluding affordable access to the products or services and inducing interest extraction by patent holders to recoup investments and make excessive profits.
- This article aims to analyse the extent to which the *ordre public* and morality exclusion can protect the human being whose bodily material has been taken and prevent legal and ethical exploitation.
- We argue that the concept of *ordre public* and morality needs to be modified, sparking a new governance approach to better protecting human beings in a patent system that is more participatory, accountable and transparent in patent assessment.

materials and technologies have a wide range of applications in biomedicine today, such as next-generation

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1 J Pila 'Adapting the *ordre public* and morality exclusion of European patent law to accommodate emerging technologies' (2020) 38 *Nature biotechnology* 555 at 557.

2 A Kur et al *European Intellectual Property Law: Text, Cases and Materials* (Edward Elgar Publishing Cheltenham, UK 2019) at 78–79; A McMahon 'Accounting for Ethical Considerations in the Licensing of Patented Biotechnologies and Health-Related Technologies: A Justification' in Naomi Hawkins (ed) *Patenting Biotechnological Innovation: Eligibility, Ethics, and Public Interest* (Edward Elgar Publishing Cheltenham, UK 2022) 163, 167.

3 Pila (n 1) 557.

4 JS Sherkow and HT Greely 'The history of patenting genetic material' (2015) 49 *Annual Review of Genetics* 161 at 165.

5 WN Price II 'Big Data, patents, and the future of medicine' (2016) 37 *Cardozo Law Review* 1401 at 1419; McMahon (n 2) 167.

sequencing, therapeutic companion diagnostics and prenatal diagnostics.⁶ On the other hand, numerous legal and ethical questions arise, putting the patentability issue on the public agenda.⁷ A clear answer must therefore be given to the question of whether patent rights can be granted on human biological material and data and, if so, to what extent safeguards to protect humans need to be in place. The goal is to arrive at a fair innovation atmosphere that balances patent rights with existing concerns such as the commodification and commercialization of the human body, fair and equitable access to technologies and so on.⁸ This topic is a matter of serious concerns that needs to be resolved as the number of patent applications related to human biological materials and data has steadily increased and continues to increase.⁹

This article aims to analyse the *ordre public* and morality exclusion in patent law to understand the extent to which such exclusion can protect the human being whose bodily material has been taken in the course of the R&D that led to the invention and thereby prevent legal and ethical exploitation. To this end, this article begins with an analysis of the patentability of human biological material and data under European patent law. It then analyses the *ordre public* and morality exclusion as a tool to prevent ethical and legal exploitation. Finally, it looks at the role of such exclusion in creating a balance between rewarding innovation and protecting human rights and values. Using legal doctrine, we argue that the concept of *ordre public* and morality needs to be modified and that there is a need for a new governance approach to better protect human beings in a patent system that is more participatory, accountable and transparent.

Patentability of human biomaterials and data in European patent law

In Europe, the patentability of human biological materials has been handled at the legislative level by the European Patent Convention (EPC) and Directive 98/44/EC on the legal protection of biotechnological inventions (Biotech

Directive).¹⁰ The EPC, accepted on 5 October 1973, provides the general provisions on substantive patent law on what are patentable inventions, the exceptions to patentability and further patentability criteria.¹¹ With biotechnological innovations on the rise in the last quarter of the 20th century, the patentability of certain inventions attracted public attention. As a result, the European Union (EU) started to get involved in the European patent area in order to ensure legal certainty around new (biotechnological) inventions.¹² Therefore, the Biotech Directive was approved by the European Parliament and of the Council on 6 July 1998. The aim of this Directive is to provide effective and harmonized protection on biotechnological innovations through patent law.¹³ With this Directive, the protection of the inventions related to biological materials and the living matter has been brought into the field of patent.¹⁴

With the Biotech Directive regulating and protecting sensitive issues related to genetic inventions such as gene patents and human embryonic stem cells patents, the discussion about the scope of patentability has been stimulated.¹⁵ For example, in 2005, the EU Parliament passed a resolution on patenting biotechnological inventions, calling on the Commission to revise the Biotech Directive to consider human germ cells, human stem cells, human embryos and gene sequences as unambiguously unpatentable subject matter.¹⁶ However, this call has remained unanswered to date.

The following subsections provide information on the general criteria for patentability in Europe and discuss the distinction between discovery and invention. These criteria play a crucial role in ensuring that the patent is granted on the basis of human ingenuity, and we will show further down that they are not available to absorb the concerns with ethics and human right that are central in this paper.

- 6 JS Sherkow and R Abbott 'Fortune and hindsight: gene patents' muted effect on medical practice' (2018) 126 *British Medical Bulletin* 37 at 40–41.
- 7 E Kica and N Groenendijk 'The European patent system: dealing with emerging technologies' (2011) 24 *Innovation: The European journal of social science research* 85 at 85.
- 8 D Matthews et al 'Balancing innovation, "Ordre Public" and morality in human germline editing: a call for more nuanced approaches in patent law' (2022) *European Journal of Health Law* 1 at 5.
- 9 E Bicudo et al 'Patent power in biomedical innovation: technology governance in biomodifying technologies' (2022) 25 *The Journal of World Intellectual Property* 473 at 477, <https://doi.org/10.1111/jwip.12237>.

- 10 B Salter 'Patents and morality: governing human embryonic stem cell science in Europe' (2009) *Global Biopolitics Research Group Report, London: King's College, Centre for Biomedicine and Society* 1 at 6; JC Lai 'Myriad genetics and the BRCA patents in Europe: The implications of the U.S. Supreme Court decision' (2015) 5 *UC Irvine Law Review* 1041 at 1044.
- 11 European Patent Convention (EPC), 1973EPC—2000EPC, 17th edition/November 2020. Available at <https://www.epo.org/law-practice/legal-texts/epc.html> (accessed 5 May 2022).
- 12 Kica and Groenendijk (n 7) 89–90.
- 13 Directive 98/44/EC of the European Parliament and of the Council of 6 July 1998 on the legal protection of biotechnological inventions. Available at <https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=celex%3A31998L0044> (accessed 22 April 2022).
- 14 Kica and Groenendijk (n 7) 86.
- 15 Ibid, 90.
- 16 Patents on Biotechnological Inventions—European Parliament Resolution on the Patenting of Biotechnological Inventions, P6_TA(2005)0407, 26 October 2005—Strasbourg. Available at https://www.europarl.europa.eu/doceo/document/TA-6-2005-0407_EN.pdf (accessed 5 May 2022).

General patentability criteria in European patent law

In general, patentability criteria have been handled by both the EPC and the Biotech Directive.¹⁷ According to Article 52 EPC and Article 3 Biotech Directive, European patents shall be granted for any inventions, in the field of technology, which are new, involve an inventive step and are capable of industrial applicability. To meet the requirement of novelty, the invention must not have previously been disclosed to the public. In other words, if the invention does not form part of the state of the art, it can be considered as new.¹⁸ To meet the requirement of inventiveness, the patent applicants must be able to show that the invention is not obvious to the skilled person, a person well-informed and experienced about the subject matter.¹⁹ To meet the requirement of industrial applicability, the invention may be considered as industrially applicable if it can be made or used in any kind of industry.²⁰ More specifically, the Biotech Directive states that inventions that meet aforementioned requirements shall be protected by patent law, even if they concern a product consisting of or containing biological material or a process for the production, processing or utilization of biological material.²¹

Discovery v invention

With respect to biotechnological inventions, identifying the distinction between discovery and invention is of great importance to ensure that the patent is granted on the basis of human ingenuity and not on the basis of nature itself.²² In general, discoveries are accepted as unpatentable because they are signified as a law of nature or product of nature that is found and described by researchers or scientists without a technical effect.²³

This rule is enshrined in Article 5 of the Biotech Directive. According to this provision,

The 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. 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, may constitute a patentable invention, even if the structure of that element is identical to that of a natural element. The industrial application of a sequence or a partial sequence of a gene must be disclosed in the patent application.²⁴

As can be seen, the mere discovery of the human body and bodily tissue such as gene sequence is excluded from patent protection.²⁵ Accordingly, when the subject matter of patent protection is abstract in nature (discoveries) or non-technical in nature (scientific theories or methods for performing mental acts), it cannot be considered as an invention.²⁶ Although, in theory, this distinction between discovery and invention looks clear, it may not be drawn clearly in the field of biotechnology.²⁷

In principle, a previously unrecognized substance found in nature is a mere discovery, so it is not patentable material. However, according to the EU patent law, the substance may be accepted as a patentable subject matter if the technicality is revealed. For example, as mentioned in the European Patent Office (EPO) Guideline, if a gene, discovered in nature, has a technical effect, that effect may be patentable, eg, the use thereof in gene therapy.²⁸ This issue is also clarified in the preamble of the Biotech Directive. According to Recital 21, the element isolated from the human body or produced is not excluded from the patentability. This is because these biomaterials are obtained by the technical processes used to identify, purify and classify them. Furthermore, the techniques used to reproduce them outside of the human body cannot be accomplished by nature itself.²⁹ Human gene sequences are considered as a patentable subject matter as long as they are isolated or produced by using a technical process.³⁰ However, non-isolated forms of

17 Kur et al (n 2) 155–156.

18 The EPC, Art 54; Nuffield Council on Bioethics, ‘The Ethics of Patenting DNA – a discussion paper’ [2002] 29.

19 The EPC, Art 56; Nuffield Council on Bioethics (n 18) 29.

20 The EPC, Art 57. The Board of Appeal of the EPO clarifies the disclosing of industrial applicability in haematopoietic receptor/ZYMOGENETICS. According to the Board, ‘the criterion of “industrial applicability” requires that a patent application describes its subject invention in sufficiently meaningful technical terms that it can be expected that the exclusive rights resulting from the grant of a patent will lead to some financial or other commercial benefit’. EPO: T 0898/05–3.3.08, Haematopoietic receptor/ZYMOGENETICS, Boards of Appeal of The European Patent Office (7 July 2006) at 12–13.

21 Biotech Directive, Art 3: ‘Inventions which are new, which involve an inventive step, and which are susceptible of industrial application shall be patentable even if they concern a product consisting of or containing biological material or a process by means of which biological material is produced, processed or used.’

22 Kur et al (n 2) 157; Guidelines for Examination at the EPO, March 2021. Available at https://www.epo.org/law-practice/legal-texts/html/guidelines/e/g_ii_3_1.htm (accessed 27 April 2022).

23 Kur et al (n 2) 157.

24 The Biotech Directive, Art 5 (emphasis added).

25 Lai (n 10) 1047.

26 I Huys et al ‘Gene and genetic diagnostic method patent claims: a comparison under current European and US patent law’ (2011) 19 *European Journal of Human Genetics*. 1104 at 1104.

27 Guidelines for Examination at the EPO, March 2021, Part G—Chapter II-3.1. Available at https://www.epo.org/law-practice/legal-texts/html/guidelines/e/g_ii_5_1.htm (accessed 27 April 2022).

28 Ibid.

29 Biotech Directive, recital 21 in the preamble at L 213/15.

30 Lai (n 10) 1047.

genes cannot be the subject matter of patent protection.³¹ Furthermore, again in the same text, it is stated that a mere DNA sequence without indication of a ‘function’ is not assessed to contain any technical information, but accepted as mere essence found in nature, so it is not a patentable subject matter.³² Therefore, technicality is an essential precondition in Europe for characterization as a patentable invention, and furthermore, the technical effect of the invention needs to be disclosed in the patent application.³³

In practice, one of the prominent cases related to drawing the line between discovery and invention involves the patents on BRCA genes, which have been hotly debated in both the EU and the USA. After the discovery in the 1990s of the precise location and sequence of two human genes, namely, BRCA1 and BRCA2, on chromosomes 17 and 13, mutations of which significantly increase the risk of breast and ovarian cancer, Myriad Genetic Inc. has been granted several patent rights. With this, Myriad has had exclusive rights to isolate an individual’s BRCA1 and BRCA2 genes and to synthetically create complementary DNA.³⁴ In Europe, between 2001 and 2004, the EPO granted patents to BRCA genes.³⁵ After obtaining patent rights, Myriad Genetic Inc. reached out to the European healthcare providers to suggest them licences. However, the licensing terms required that European healthcare providers send the DNA samples to Myriad’s laboratories rather than allowing licensees to perform the tests by themselves.³⁶ Therefore, the oppositions against the BRCA patents started to arise in Europe, in the early 2000s, and many scientists and laboratories filed oppositions against the EPO.³⁷

The grounds for these oppositions essentially focused on the question of whether it was a mere discovery and thus not an invention. In other words, it was a question of whether the general patentability criteria were met, particularly with regard to the requirements of inventive step and industrial applicability.³⁸ In addition, there were concerns about access to diagnostic tests at fair and reasonable prices and also about the difficulty of confirming test results and finding low-cost (alternative) tests,

given Myriad’s monopoly position in the market.³⁹ This has resulted in Myriad Genetics holding only a handful of very narrow patents in Europe.⁴⁰ Likewise, on 13 June 2013, the US Supreme Court held that a naturally occurring DNA segment is not patent-eligible material.⁴¹

The case of the BRCA genes shows the difficulty in drawing the distinction between discovery and invention in the patent procedure. In addition, given the current state of biotechnology and its impact on the function of identifying specific genes, it is increasingly difficult to meet general patentability requirements, in particular, the criteria of involving an inventive step and being susceptible to industrial application.⁴²

From the above, it can be concluded that the key question here is whether the subject matter is indeed an invention and not just a discovery.⁴³ However, the complexity of determining patentable subject matter creates legal uncertainty.⁴⁴ This issue remains particularly important because inventions involving human biological material and data have been the subject of ongoing patent disputes over the ownership of such technologies.⁴⁵ Therefore, it is important to analyse the protection mechanisms embedded in the normative framework against legal and ethical exploitation.

Ordre public and morality as an instrument to prevent ethical and legal exploitation

European law denies patent protection to inventions, the commercial exploitation of which would be contrary to *ordre public* or morality. In general, the aim of this requirement is to refuse patent protection to inventions that may provoke public disorder or cause offensive use, criminally or generally.⁴⁶ Considering the scientific and societal aspects of human biological materials and related data in current life, the full implementation of the patentability requirements is crucially important for the

31 J Pila, ‘Intellectual property rights and detached human body parts’ (2014) 40 *Journal of medical ethics* 27 at 27; Huys et al (n 26) 1105.

32 Biotech Directive, recital 23 in the preamble at L 213/15.

33 Huys et al (n 26) 1104.

34 US: *Association for Molecular Pathology v Myriad Genetics, Inc.*, [2013] 569 U.S. 576 at 4–5.

35 G Matthijs et al ‘The European BRCA patent oppositions and appeals: coloring inside the lines’ (2013) 31 *Nature biotechnology* 704 at 705; Lai (n 10), 1057–1062; Kica and Groenendijk (n 7) 91.

36 G Matthijs ‘The European opposition against the BRCA gene patents’ (2006) 5 *Familial Cancer* 95 at 97.

37 Matthijs et al (n 35) 704.

38 Matthijs et al (n 35) 709; Lai (n 10) 1062.

39 Matthijs et al (n 35) 705.

40 Lai (n 10) 1042.

41 *Association for Molecular Pathology v Myriad Genetics, Inc.* at 1; P Webber ‘The end of DNA patents in the United States?’ (2013) 23 *Expert Opinion on Therapeutic Patents* 1525. Although scenarios were written that the patents on the gene will expire after this decision of the court, empirical research on searching the impact of the *Myriad* case shows that the number of gene-related patents has continued to increase particularly in the USA and the EU. JG Kers et al ‘Trends in genetic patent applications: the commercialization of academic intellectual property’ (2014) 22 *European Journal of Human Genetics* 1155 at 1158.

42 This issue was also mentioned by the Nuffield Council on Bioethics at 36.

43 Lai (n 10) 1043.

44 Matthews et al (n 8) 5.

45 *Ibid.*, 7.

46 Kur et al (n 2), 160.

legality and legitimacy of biotechnological inventions and their industrial commercialization.⁴⁷

The requirement is embedded in EPC Article 53(a) and Biotech Directive Article 6(1). The Biotech Directive provides an illustrative list. According to Article 6(2), processes for cloning human beings, processes for modifying the germ line genetic identity of human beings, uses of human embryos for industrial or commercial purposes and processes for modifying the genetic identity of animals are explicitly deemed unpatentable.⁴⁸ The necessity of excluding from patentability innovations whose commercial exploitation offends against *ordre public* or morality is also highlighted in the preamble of the Biotech Directive.⁴⁹ As mentioned in Recital 38 of the Biotech Directive, processes, the use of which will be contrary to human dignity, are excluded from patentability, such as processes to produce chimeras from germ cells of humans.⁵⁰ In addition, Recital 39 has remarked that *ordre public* and morality correspond, in particular, to ethical or moral principles recognized in a Member State.⁵¹

The *ordre public* and morality exclusion in biotech patents has indeed been a subject of debate. One case illustrating this is the *Brüstle/Greenpeace* case.⁵² In this case, the dispute was about the patent obtained by Dr Brüstle over isolated and purified neural precursor cells processed for their production from embryonic stem cells and the use of neural precursor cells for the treatment of neural defects. This invention aimed at the treatment of damaged organs of patients suffering from diseases such as dementia, blindness and Parkinson's disease.⁵³ Greenpeace successfully challenged the invention by alleging that the patent at issue was invalid and unethical because it covered precursor cells obtained from human embryonic stem cells and processes to produce those precursor cells. Dr Brüstle appealed the decision.⁵⁴ The Court of Justice of the European Union (CJEU) stated that the resolution of the dispute depended on the interpretation of Article 6(2)(c) of the Biotech Directive, concerning the uses of human embryos for industrial or commercial purposes.⁵⁵ The discussion, therefore, centred on the

potential violation of *ordre public* and morality in biotechnology patents. The *Brüstle* case underlines the duties of patent officers and judges to assess the *ordre public* and morality compatibility of the inventions.⁵⁶

Indeed, the EPO is explicitly deemed to have dealt with ethical issues in a way that acted as a moral arbiter.⁵⁷ The *Relaxin* case is a well-known example demonstrating this reality.⁵⁸ During patent prosecution, the EPO Opposition Division, which examines and decides on the opposition claims, discussed the patent eligibility of the gene encoding *H2 relaxin*, a human protein that is only produced by the female body.⁵⁹ The EPO Opposition Division decided that human genes, obtained from the human body by using technical process, are not an exception to patentability. The Opposition Division clarified that patenting these genes does not mean patenting life and that human genes are just one of the many chemical materials/entities that participate in the biological process. Additionally, patenting human genes does not violate human dignity because the informed consent of individuals is obtained and it does not affect the individuals' right to self-determination because the relevant molecules are not affected by exploitation.⁶⁰ On appeal, the applicants⁶¹ claimed that the gene in question was naturally occurring in the female body, which cannot be the subject matter of patentability. According to the applicants' allegation, the subject of the patents was derived from the human body, and therefore, it was not patentable; the invention constituted a violation of the fundamental rights of the person due to the lack of informed consent.⁶² The Board of Appeal dismissed the appeal by using the Opposition Division's justification and held that the appellants' arguments related to *ordre public* or morality and discovery were answered by the current patent law.⁶³ In this case, the Appeal Board did not go beyond stating what the rule was and that the subject of the discussion did not violate the rule. However, the court could have given more explicit reasons for its decision, so that light would have been shed on what the decisive argument for upholding the patent was.

With cases beginning to emerge where the discussion of *ordre public* and morality was at issue, the EPO has

47 Pila (n 1), 557.

48 Biotech Directive, Art 6(2).

49 Biotech Directive, recital 37 in the preamble at L 213/16.

50 Biotech Directive, recital 38 in the preamble at L 213/16.

51 Biotech Directive, recital 39 in the preamble at L 213/16.

52 CJEU: Case C-34/10, *Brüstle v Greenpeace* [2011] Court of Justice of the European Union, I-9849.

53 *Brüstle v Greenpeace*, at I-9864; E Bonadio 'Biotech patents and morality after Brüstle' (2012) 34(7) *European Intellectual Property Review* 1 at 1 Available at <https://ssrn.com/abstract=2084207>.

54 *Brüstle v Greenpeace* (n 51), at I-9865; Bonadio, 'Biotech patents and morality after Brüstle' at 1.

55 *Brüstle v Greenpeace*, (n 51) at I-9865-9866.

56 Bonadio (n 53) 3.

57 Bonadio (n 53) 4.

58 EPO: T-0272/95-3.3.4, *Relaxin/Howard Florey Institute*, Boards of Appeal of the European Patent Office [2002].

59 Bonadio (n 53) 4.

60 *Relaxin/Howard Florey Institute*, at 2.

61 See opponents: Aglietta, Amendola et al, Fraktion der Grünen im EP Lannoye Paul-Fraktion der Grünen im EP.

62 *Relaxin/Howard Florey Institute*, at 10.

63 *Ibid*, at 11.

sought to clarify the meaning of these concepts on a case-by-case basis.⁶⁴ Although the argument of *ordre public* and morality has been contended only in a few cases,⁶⁵ the concepts of morality and *ordre public* are clarified by the case law of the Boards of Appeal. The concept of morality is explained by the Board⁶⁶ as being based on a belief that some behaviours are accepted as right, whereas others are accepted as wrong, and this belief represents the totality of the adopted norms that are rooted in one specific culture. Accordingly, inventions that are not in conformity with traditionally accepted standards will be excluded from patentability because of the infringement of morality.⁶⁷ The concept of *ordre public* was defined by the Board of Appeal encompassing the protection of public safety and the physical integrity of persons as part of society including the environment.⁶⁸ Hence, if inventions seriously harm public security, physical integrity or the environment, they are excluded from patentability as contrary to *ordre public*.⁶⁹

Given the aforementioned explanations, the *ordre public* and morality provisions undoubtedly provide a level of protection against possible legal and ethical exploitations. Indeed, the exemption of public policy and morality is included in Article 35 of the proposed regulation for the European health data space.⁷⁰ Accordingly, the development of products or services that may cause harm to individuals and society in general, including goods or services designed or modified in such a way as to be contrary to public policy or morality, will be prohibited.⁷¹ Although *ordre public* and morality statements are included in the normative framework and are the subject of discussion in patent evaluation systems, the understanding of these terms and their scope are not clear. The way the EPO defines the terms morality and public policy is not sufficient to regulate the challenges of contemporary technologies.⁷² In particular, there is no answer as to whether

violations of human rights and values, occurring in the R&D leading up to the patent application, fall within the scope of these terms. Moreover, given the difficulty of defining *ordre public* and morality, it remains unclear how the EPO can successfully prevent ethical and legal exploitation, particularly the inclusion of *ex ante* exploitative behaviour.⁷³ It reinforces the interpretative dominance of patent authorities and inventors over the patent system.⁷⁴ Indeed, critics refer to the main argument in this paper, which will be discussed in the section ‘the complexity of creating a balance between rewarding innovation and legal/ethical concerns’, where we will examine the role of such exclusion in striking a balance between rewarding innovation and protecting human rights and ethical values.

The complexity of creating a balance between rewarding innovation and legal/ethical concerns

Breakthrough innovations in the field of biotechnology, human biological materials and data play a pivotal role in today’s life, particularly in health care. These materials/technologies are called *good candidates* for patent protection in terms of meeting the patentability requirements.⁷⁵ However, there are overarching concerns when patenting human biological material and data, such as whether patent rights cause the commodification and commercialization of the human body, whether they prevent affordable access to the products or services and whether patent holders may engage in interest extraction to recoup investments and make excessive profits.⁷⁶ As such, the question of whether human biomaterial and related data should be treated as a product is a tightrope walk not only between promoting innovation and providing products with an appropriate liability standard but also preventing the commercialization of what becomes a living part of their bodies and may even consist of their own biomaterials. This is not an easy dilemma to solve.⁷⁷ Let us zoom in on a famous example.

Many people in the field of law and bioscience have heard of Henrietta Lacks, an African American woman diagnosed with cervical cancer disease in 1951.⁷⁸

64 Salter (n 10) 6.

65 S Soini et al ‘Patenting and licensing in genetic testing: ethical, legal and social issues’ (2008) 16 *European Journal of Human Genetic* S10 at S19.

66 T 0356/93 (Plant cells), Boards of Appeal of The European Patent Office [1995]. Available at <https://www.epo.org/law-practice/case-law-appeals/recent/t930356ex1.html> (accessed 2 July 2022).

67 Case Law of the Board of Appeal, Concept of ‘morality’ and ‘*ordre public*’. Available at https://www.epo.org/law-practice/legal-texts/html/caselaw/2019/e/clr_i_b_2_2_2_b.htm (accessed 2 June 2022).

68 T 0356/93 (Plant cells), at 5.

69 Concept of ‘morality’ and ‘*ordre public*’.

70 European Commission ‘Proposal for a REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL on the European Health Data Space’ COM(2022) 197 final, 3 May 2022 Available at https://eur-lex.europa.eu/resource.html?uri=cellar:dbfd8974-cb79-11ec-b6f4-01aa75ed71a1.0001.02/DOC_1&format=PDF (accessed 11 November 2022).

71 Proposed European Health Data Space, Art 35(e).

72 Pila (n 1) 555.

73 Salter (n 10) 6.

74 Pila (n 1) 555.

75 Ibid.

76 World Health Organization (WHO), ‘Ethics and Governance of Artificial Intelligence for Health’ [2021], at 93.

77 M Mourby et al ‘Biomodifying the “natural”: from adaptive regulation to adaptive societal governance’ (2022) 9 *Journal of Law and the Bioscience* lsac018 at 24, <https://doi.org/10.1093/jlb/lsac018>.

78 Johns Hopkins Medicine ‘The Legacy of Henrietta Lacks’ Available at www.hopkinsmedicine.org/henrietalacks/ (accessed 21 August 2022); M

Without her knowledge or consent, biological samples were taken from her body and cells were isolated, preserved and reproduced on a large scale.⁷⁹ To date, Lacks' cells, known by the first two letters of her name - HeLa cells - have played a role in almost 75 000 research studies.⁸⁰ Through the use of her cells, In Vitro Fertilisation was discovered, and with the help of her cells, the injectable polio vaccine was developed. Furthermore, HeLa cells continue to provide use in many research studies, such as the medication of Human Immunodeficiency Virus and Acquired Immunodeficiency Syndrome and recently the development of Coronavirus vaccines.⁸¹ HeLa cells, which have been the subject of more than 17 000 patents, also formed the basis of a multi-billion-dollar market.⁸² On 13 October 2021, 70 years after Lacks died, the World Health Organization conducted a ceremony and honoured her unknowing contribution to medicine and science.⁸³ The lack of consent on the side of Lacks appears not to have impeded the patentability of the inventions ever. This example shows how the human cell donor has been ignored for a very long time as an essential part of the mix of interests at stake. Consequently, an avenue for considering human rights and bioethical principles that favour the interests of donors, from the initial taking of the cells all the way to the final industrial exploitation of the R&D results, is worthy of attention. Given the conditions at the time of Henrietta Lacks' treatment (even DNA had not yet been discovered), it would of course not be fair to evaluate her case according to today's rights and principles. But that should not prevent us from looking at what is desirable now that we wish to better honour the position of the human subjects of today and tomorrow.

Today, there are still problems related to the application of legal and ethical rules when it comes to research on humans, especially on vulnerable populations.⁸⁴ For example, patent applications are filed by and granted to public and private actors, but private actors have a growing dominance in the field of biotechnological innovations that are seized from human biomaterials and

data.⁸⁵ It has been empirically shown in many European countries that the majority of patents invented in the academic field are owned by companies.⁸⁶ However, the current patent system is not designed for dealing with issues related to ethics, bioscience and law and therefore is found to be ill-equipped to provide sufficient protection to all parties that are involved in inventions related to human biological material and data.⁸⁷

Both the Henrietta Lacks example and the circumstances outlined in the previous paragraph have led to the observation that the consent of the donor is crucial, but does not serve to end all scrutiny. There are cases in which acting without consent is not illegal, but the further handling of the materials or data in the research over the years is not absolved from respecting the rights of the donor and her relatives. In addition, in asymmetrical power relations, a wall of signed consent forms should not provide cover from further scrutiny, in cases where there is sufficient ground for piercing that veil. Even consent that meets the standard of 'willingly and knowingly given' does not suffice as release from having to respect the rights of the donors in research practice.⁸⁸

This points us to our main argument. Although *ordre public* and morality provide a certain degree of protection, the scope of protection is still ambiguous and it remains unclear how the EPO can prevent ethical and legal exploitation, especially the involvement of *ex ante* exploitative behaviour. Therefore, this protection is highly dependent on the interpretative sovereignty of patent authorities and inventors over the patent system. In this context, the concept of *ordre public* and morality needs to be modified to develop a new governance approach for better protecting people in a patent system that is more participatory, accountable and transparent in patent assessment. Indeed, a real balance between innovation that rewards patent rights and fair and equitable access to technologies can be achieved through more participative, accountable and transparent patent systems.

Ahluwalia 'Genetic Privacy: we must learn from the story of Henrietta Lacks' [2020] *New Scientist*, Available at <https://www.newscientist.com/> (accessed 21 August 2022).

79 M Cramer 'Henrietta Lacks, Whose Cells Were Taken Without Her Consent, Is Honored by W.H.O.' *The New York Times*, 13 October 2021. Available at <https://www.nytimes.com/2021/10/13/science/henrietta-lacks-cells-who.html> (accessed 16 October 2022).

80 Ibid.

81 Cramer (n 79); Johns Hopkins Medicine (n 78); Ahluwalia (n 78).

82 Ahluwalia (n 78).

83 Cramer (n 79).

84 WHO, 'Ethics and Governance of Artificial Intelligence for Health', at 53.

85 Bicudo (n 77) 473.

86 F Lissoni 'Academic patenting in Europe: an overview of recent research and new perspectives' (2012) 34 *World Patent Information* 197 at 200, <https://doi.org/10.1016/j.wpi.2012.03.002>; C Martinez 'From Academic Inventing to University Patenting' (2018) WIPO Workshop on PCT Fee Reductions for Universities, at 10. Available at https://www.wipo.int/edocs/mdocs/pct/en/wipo_pct_uni_ge_18/wipo_pct_uni_ge_18_martinez.pdf (accessed 27 October 2022).

87 E Siew-Kuan Ng 'Immoral inventions - interaction between ethics and biotechnology patent law' (2010) 22 *SaClJ* 931 at 946.

88 K Hoeyer and LF Hogle 'Informed consent: the politics of intent and practice in medical research ethics' (2014) 43 *Annual Review of Anthropology* 347-362, <https://doi.org/10.1146/annurev-anthro-102313-030413>.

As analysed earlier in light of relevant literature and case law, it is expected, when patenting human genetic materials, that patent officers must give a decision on sensitive issues related to biomaterials and data. Therefore, to evaluate whether the subject matter of the patent application meets the requirements of patentability, the ethical and legal quality standards for biotechnological and genetic research should be considered in the patenting process. The exceptions to patentability based on *ordre public* and morality in the context of human biomaterial and data can be appreciated as the only avenue to pursue a balance between innovation and the protection of society's higher normative values.⁸⁹ To this end, the limits and scope of patentable subject matter need to be explored and tested, eg, with respect to patents on human biomaterials and data. It is also necessary to examine the extent to which the limitations set out in the exceptions to patentability apply, especially to *ordre public* and morality and to establish a coherent and consistent basis.⁹⁰ According to our understanding, the scope of morality and *ordre public* should be extended to comprise ethics and legal issues regarding the human research subjects/donors, and the meaning of these notions should be clarified to comprise anterior practices in the research. Following this, the ethical and legal compliance part of the patent application and decision-making process should be clearly disclosed. As stated by Pila, a precautionary and deliberative process that identifies the potential risks of patenting for morality and *ordre public* should be included.⁹¹ For our part, we see an advantage in

providing civil society organizations with a proven record in the discovery of gross violations of research standards a window into the deliberation of *ordre public* and morality.

Conclusion

This article aimed to analyse to what extent the *ordre public* and morality exclusion can protect the human being whose bodily material has been taken and prevent legal and ethical exploitation. In this context, we analysed the patentability of human biological material and data under European patent law, public policy and moral exclusion. The section on 'the complexity of creating a balance between rewarding innovation and legal/ethical concerns' discussed the role of such exclusion in creating a balance between rewarding innovation and protecting human rights and values.

Although exclusion from public policy and morality provides a certain degree of protection, the concept of these terms and their scope need to be modified. Moreover, as the current patent system has so far proven to be ill-equipped to consider legal, ethical and scientific issues, there is a need for a new governance approach to better protect human beings in patents that is more participatory, accountable and transparent in patent evaluation. This holds a better promise to incentivize research laboratories across the globe to adhere to the highest ethical standards, for fear of losing the opportunity to achieve a return on investment by way of commercializing patented (bio)technologies.

89 Matthews et al (n 8) 1.

90 N Hawkins 'Patents and Public Interest: A Multi-Faceted Approach' in Naomi Hawkins (ed) *Patenting Biotechnological Innovation: Eligibility, Ethics, and Public Interest* (Edward Elgar Publishing Cheltenham, UK 2022) 196, 202–203.

91 Pila (n 1) 557.