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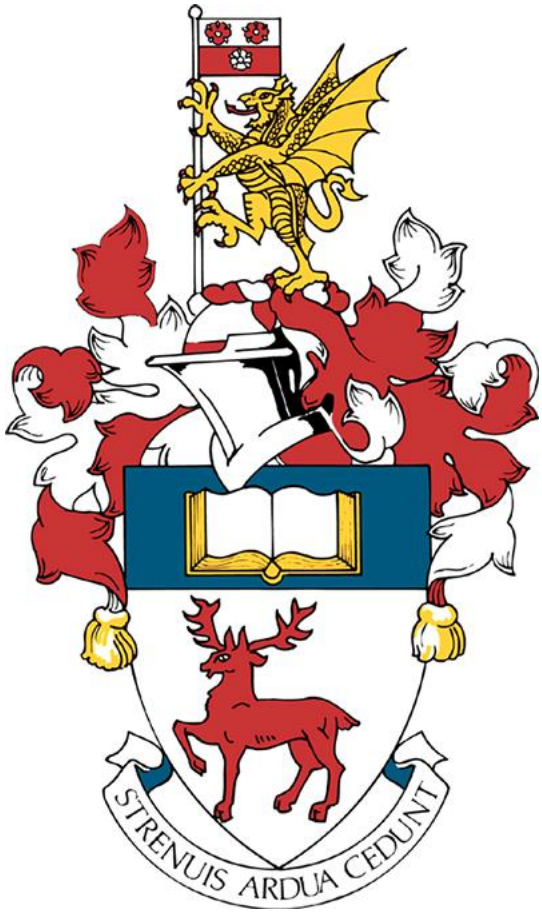

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The Editors also wish to thank all members of Southampton Law School who have aided in the creation of this volume.

Alex Patrick
Southampton Student Law Review, Editor-in-Chief
August 2021

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Foreword

It gives me great pleasure to write the foreword for the latest edition of the Southampton Student Law Review (SSLR). The SSLR fulfils an important pedagogical function by exposing students to the managerial and editorial aspects of a law journal and provides an opportunity for students to produce scholarship. The skills acquired in the process are beneficial for future solicitors and aspiring academics. The SSLR offers an important avenue for the dissemination of student's publications, displays their excellent research and gives recognition to the hard work of students. The value of the SSLR is therefore beyond reproach and it constitutes an integral facet of Southampton Law School's pursuit of research and teaching excellence. The target audience of this edition is students, alumni, practitioners and academics, and the accessibility of the journal through *HeinOnline* and the broad range of topics ensures that this edition will not merely gather dust in the virtual world. This edition covers the length and breadth of law. The first article by Skoutas discusses the human right to electricity access and the concomitant duties of business under international investment law. Mara proposes an amendment of the Mental Capacity Act to allow for a subjective declaration of future death, and Perves proposes legislation to regulate dermal fillers. Cole argues for the introduction of a comprehensive statute to govern the products, premises and practitioners involved in the administration of non-surgical cosmetics. The article of Achnioti critically examines the applicability of the common heritage of mankind principle to marine genetic resources in areas beyond national jurisdiction. Lastly, Burke assesses the Insurable Interest Bill's realisation of its overarching aim of updating the law surrounding the life and life-related insurable interest.

I hope that you will enjoy the latest edition of the SSLR!

Werner Scholtz
Head of School and Professor of Global Environmental Law
Southampton Law School

Keeping the Lights On: Businesses, Human Rights and Access to Electricity

*Apostolos Skoutas**

Abstract

The article explores the extent to which a right to electricity access may be found under international human rights law and critically evaluates the related duties of businesses regarding electricity access, under international investment law. The article also examines the relationship between the relevant human right and the business sector, as it is energy corporations, which are the actual providers of electricity. First, the arguments for the existence of a right to electricity in international law is critically evaluated. Then, the article raises the question of whether, considering international investment law, private actors should be deemed as duty-bearers of a human right to electricity access. The last section is concerned with the horizontal conception of a human right to electricity access. Specifically, the author argues over the existence of several horizontal dimensions of human rights duties and why from a policy argument, states may be reluctant to adopt legislation for imposing human rights duties to corporations.

"We will make electricity so cheap that only the rich will burn candles."
— Thomas A. Edison

Introduction

It is more than evident that electricity plays a vital role in our modern societies. Access to electricity has dominated our everyday lives, but also heavily influenced key economic policies worldwide, during the past decades.[1] These economic policies resulted in the liberalization of the energy market; a process still ongoing today in the European Union.[2] Recent data from the World Bank showcases that the percentage of people having access to electricity globally was increased from 76% to 88% in almost two decades.[3] The importance of universal electricity access is substantial to all countries and especially the developing ones, which are desperately in need of electricity investments for their economic, social and cultural growth.[4]

Despite the considerable progress towards universal electricity access, a human right to electricity access is rarely found in international law. Electricity access is key in combating energy poverty and influences directly the right to housing and development.[5] Critically, the

* *PhD Candidate (UoA), LLM in Maritime Law (dist) (University of Southampton), Lawyer (Athens).* I am very grateful to Professor Uta Kohl for the invaluable guidance and the smart and well thought comments on the essay. I would also like to thank Professor Constantine Antonopoulos for his kind words and encouragement when asked about the submission of the paper.

[1] Roger Fouquet, 'A brief history of energy' in Joanne Evans and Lester C. Hunt (eds) *International Handbook on the Economics of Energy* (EEP 2009) 10-11. Also see Dilip Ahuja and Marika Tatsutani, 'Sustainable energy for developing countries' (2009) 2 S.A.P.I.EN.S 1, 3.

[2] Fouquet (n 1) 14.

[3] See: The World Bank, 'Access to electricity (% of population)' <https://data.worldbank.org/indicator/EG.ELC.ACCS.ZS?end=2017&start=1990&view=chart> accessed 11 January 2021.

[4] Reinhard Madlener, 'The economics of energy in developing countries' in Joanne Evans and Lester C. Hunt (eds) *International Handbook on the Economics of Energy* (EEP 2009) 740.

[5] Lars Löfquist, 'Is there a universal human right to electricity?' (2020) 24 IJHR 711, 716.

need for universal electricity access is not only essential as a policy argument, but also important from the investment's law standpoint, since it is common for private energy corporations to proceed in investments in foreign electricity markets.[6] Until recently, human rights and investment law rarely interacted dynamically.[7] However, especially in the last decade, host-states have been arguing that foreign investors should be deprived of their investment law protection when their activities violate essential human rights obligations.[8] Thus, the existence of a human right to electricity access is especially relevant in the context of the horizontal conception of human rights under international investment law and to the nature of public utilities. This paper will examine firstly the extent to which a right to electricity access may be found under international human rights law, and then, whether businesses should be considered as duty-bearers of a human right to electricity access in international investment law.

1. The right to energy and electricity access

When approaching the idea of treating electricity as a basic human need, one could reasonably wonder: does a right to energy even exists, less alone electricity, in the international legal framework? Indeed, a right to energy is not included in major international conventions regarding human rights and is usually mentioned by scholars in the context of the right to an 'adequate standard of living' or 'as a necessity for people's economic and social development' in the context of a 'right to development'.[9]

A right to electricity does not exist *de lege lata*, in all but one international agreement, the Convention on the Elimination of All Forms of Discrimination against Women, [10] where it is mentioned that all women should enjoy adequate living conditions, 'including access to electricity'.[11] The treaty was concluded in 1979 and was ratified by 189 states, in an effort to combat women's poverty and gender discrimination.[12] The Convention is significant for the right to electricity access, since it links women's poverty with environmental and energy poverty issues, especially in developing countries.[13] One can understand that, since the right is mentioned in the CEDAW in the context of the right to an adequate standard of living, there is an absence of a convincing specific provision for a human right to electricity access and thus, 'the right to access to electricity is still in its infancy'.[14]

However, that does not mean that the right to electricity access does not exist, but probably that electricity access, much like energy, should be considered a derived right, i.e. a right

[6] Subhes C. Bhattacharyya, *Energy Economics Concepts, Issues, Markets and Governance* (Springer 2011) 495.
[7] Luke Eric Peterson, *Selected Developments in IIA Arbitration and Human Rights*. IIA Monitor No.2 (Geneva UNCTAD, 2009), UNCTAD/WEB/DIAE/IA/2009/7, 2-3.
[8] ibid.
[9] Gail Karlsson, 'A Human Rights Approach to Energy, Poverty and Gender Inequality' in Cindy Holder and David Reidy (eds) *Human Rights: The Hard Questions* (CUP 2013) 231.
[10] See Convention on the Elimination of All Forms of Discrimination against Women, (adopted 18 December 1979, entered into force Sept. 3, 1981) 1249 U.N.T.S. 13 (CEDAW).
[11] Article 14 of the CEDAW. Also, see Löfquist (n 5) 713.
[12] Ratifications: <https://treaties.un.org/doc/Publication/MTDSG/Volume%20I/Chapter%20IV/IV-8.en.pdf> accessed 1 May 2020.
[13] Karlsson (n 9) 235.
[14] Löfquist (n 5) 713.

based on other rights.[15] It is also worth mentioning that the abovementioned statement truly makes sense regarding the nature of electricity itself, as humans do not need *per se* the commodity of electricity, but foremost the goods and services it enables.[16] These services include modern medical treatment, educational aids, heating and most importantly, lighting. The nature of access to electricity as an implied right in the scope of other more fundamental and recognizable rights, can be proven variously in international law, as it will be seen below.

2. Access to Electricity as a derived right

When determining the right to electricity access as an implied derived right, one almost immediately focuses on the well-established right to an 'adequate standard of living', consisting among else and importantly for electricity, of the right to 'adequate housing'. Under Article 11 of the ICESCR,[17] state parties recognize the right of everyone to 'an adequate standard of living for himself and his family, including adequate … housing', which can be interpreted as requiring at least some basic level of energy usage.[18] The UN Committee on Economic, Social and Cultural Rights at a later stage elaborated the subject matter and highlighted the importance of electricity access and energy for the condition of adequate housing to be considered fulfilled, providing that 'all beneficiaries of the right to adequate housing should have sustainable access to natural and common resources' including 'energy for cooking, heating and lighting'.[19]

It is important to note that, apart from the ICESCR, numerous international conventions regulate the right to housing and therefore imply the right to electricity access,[20] such as the Convention on the Rights of Persons with Disabilities,[21] the European Social Charter,[22] and the Convention on the Rights of the Child.[23] One could also argue, that more rights in international human rights law could be considered as implying the right to electricity access, such as the right to health,[24] the right to the highest attainable standard of living and the right to development,[25] reinforcing the conclusion regarding the nature of electricity access as a

[15] See among others, Stephen Tully, 'The Human Right to Access Electricity' (2006) 19 The Electricity Journal 30, 38; Löfquist (n 5) 716.
[16] Tully (n 15) 33.
[17] See, International Covenant on Economic, Social and Cultural Rights, (adopted 16 December 1966, entered into force 3 January 1976) 993 UNTS 3 (ICESCR).
[18] Karlsson (n 9) 232. See also, Danwood Mzikenge Chirwa, 'Privatization and Freedom from Poverty', in Geraldine van Bueren (ed) *Freedom from poverty as a human right: law's duty to the poor* (UNESCO Publishing, 2010), 304.
[19] UN Committee on Economic, Social and Cultural Rights: *General Comment 4. The right to adequate housing* (Article 11, 1), of 1991 (United Nations: Document E/ E/1992/23), [8].
[20] Arturs Kucs, Zane Sedlova & Liene Pierhurovica, 'The Right to Housing: International, European and National Perspectives', (2008) 64/65 Cuadernos Constitucionales de la Cátedra Fadrique Furió Ceriol 101, 104.
[21] See Article 28 of the Convention on the Rights of Persons with Disabilities, (adopted 13 December 2006, entered into force 3 May 2018) 2515 UNTS 3.
[22] See Article 16 of the European Social Charter, (adopted 18 October 1961, entered into force 26 February 1962) 529 UNTS 89.
[23] See Article 27 of the Convention on the Rights of the Child, (adopted 20 November 1989, entered into force 2 September 1990) 1577 UNTS 3.
[24] Article 12 of the ICESCR.
[25] ibid 11, 1.

'derived right'.[26] Specifically, regarding the abovementioned rights, one could eagerly argue that electricity has clear environmental advantages (less pollution), than other energy sources and therefore should be considered as the highest standard.[27] It should be noted, that economic rights are 'progressive rights', meaning they cannot be enjoyed by citizens immediately, but they obligate the state to proceed in their eventual fulfilment.[28] Thus, although the right to access to electricity may exist on a derivative basis, its enjoyment will depend on the resources of the state.[29] This is a serious parameter to consider, taking into account that those who suffer more from the absence of electricity access are the citizens of developing countries.

Indeed, the industrialized countries recognized the importance of electricity access for social cohesion and implied its universal nature, by taking steps to achieve that all their citizens can enjoy electricity access.[30] Specifically, the EU has gradually but steadily recognized the need for universal access within its territory, by introducing the concept of the supplier of last resort.[31] This concept, which was relatively new when it was introduced (26 June 2003), aimed at ensuring the uninterrupted power supply of final customers, in the event of bankruptcy of their electricity supplier, until a new supplier may be identified.[32] Furthermore, newer EU law focuses especially on the universal protection of EU citizens regarding their right to electricity access, through a transparent and non-discriminatory way,[33] by expressly stating the need 'to achieve high standards of universal and public service in electricity supply, contributing to the protection of vulnerable customers'.[34] The above-mentioned EU driven policies should not be interpreted as obliging electricity suppliers to provide power in any event, even if customers are not willing or cannot pay their debts. They should be rather deemed as underlining the establishment of the right's universal nature and the treatment of electricity access as an essential service, like access to water, and not as a luxurious one.

Concerning electricity access as a human right, one should eventually address the elephant in the room: do humans really need electricity, for electricity to be considered a human right? The question can be put also in a different way: 'Why should people in country X not have the right to a similar standard of living as those who live in country Y?'.[35] There are two approaches to the above. The first one mainly focuses on the fact that someone could live a great life without the need for electricity access at all, as humans have done for centuries.[36] The second approach focuses on the context in which human rights should be interpreted

[26] Löfquist (n 5) 716.
[27] Tully (n 15) 31.
[28] H. Victor Conda, *A Handbook of International Human Rights Terminology* (2nd edn, University of Nebraska Press 2004) 207.
[29] ibid.
[30] Tully (n 15) 31-32.
[31] Directive 2003/54/EC of the European Parliament and of the Council of 26 June 2003 concerning common rules for the internal market in electricity and repealing Directive 96/92/EC, OJL 176, art. 3(3).
[32] Kim Talus, *EU Energy Law and Policy, A Critical Account*, (OUP, 2013), 211-212. See also, H. Knops, 'Securing Dutch Electricity Supply: Towards a Supplier of Last Resort?' in Martha M. Roggenkamp and Ulf Hammer (eds) *European Energy Law Report I* (Intersentia NV 2004) 253-254.
[33] Directive 2009/72/EC of the European Parliament and of the Council of 13 July 2009 concerning common rules for the internal market in electricity and repealing Directive 2003/54/EC, OJL 211, art. 36, 37.
[34] ibid, art. 36(h).
[35] Löfquist (n 5) 716-717.
[36] ibid.

globally.[37] Specifically, electricity seems to facilitate more options in modern society,[38] and importantly more quality options, such as modern medical treatment and the abolishment of most, otherwise time consuming activities. Considering the "progressive" nature of the right and reasonably expecting the rise of the percentage of people obtaining electricity access,[39] the best way arguably to interpret this derived right, is by considering the level of development of the state and the circumstances in which a violation arises. Therefore, it is more likely for a developed country to violate the right to electricity access in the context e.g. of the right to housing, than for a developing one.

3. The European Court of Human Rights – Cases regarding electricity access

The impact of the ECtHR in the development of human rights is no less than exceptional,[40] especially since the European Convention of Human Rights[41] is one of the few international conventions about the protection of human rights with its own judicial mechanism. Therefore, a proven connection between access to electricity and human rights should be considered as a decisive factor when considering the existence of a right to electricity access.

Article 3 of the ECHR provides the 'Prohibition of inhuman or degrading treatment'. There are two cases, namely *Modarca v Moldova*[42] and more recently *Pocasovschi and Mihaila v the Republic of Moldova and Russia*[43] that stipulate that the absence of (or even the unstable/periodical) electricity access should be considered as an inhuman condition. Both of these cases are concerned with prisoners that were deprived of a variety of different essential resources, including electricity access, during their imprisonment.

In *Modarca v Moldova*, 'water and electricity were only provided on a schedule and were unavailable for certain periods, including during the entire night'.[44] The court noted that, since the Government of Moldova did not refuse the allegations,[45] the conditions of the imprisonment (alongside other important deprivations and phenomena) constituted a violation of Article 3 of the ECHR. In *Pocasovschi and Mihaila v the Republic of Moldova and Russia*, insufficient access to water and electricity (sometimes only for two hours during the day)[46] resulted in the inability of the detainees to receive appropriate medical assistance or food of a sufficient standard, or maintain proper hygiene.[47] The ECtHR emphasized the connection between electricity access and Article 3 and noted 'that prolonged detention in

[37] ibid.
[38] ibid.
[39] See, James W. Coleman, 'Energy Market and Policy Revolutions: Regulatory Process and the Cost of Capital' in Klaus Mathis and Bruce R. Huber (eds) *Energy Law and Economics* (SIP 2018) 160.
[40] Merris Amos, 'The Value of the European Court of Human Rights to the United Kingdom' (2017) 28 EJIL 763, 766.
[41] See *Convention for the Protection of Human Rights and Fundamental Freedoms* (European Convention on Human Rights, as amended, adopted 4 November 1950, entered into force 3 September 1953) 213 UNTS 221 (ECHR).
[42] *Modarca v Moldova*, Application no. 14437/05 (ECtHR, 10 May 2007).
[43] *Pocasovschi and Mihaila v the Republic of Moldova and Russia*, Application no. 1089/09 (ECtHR, 29 May 2018).
[44] *Modarca v Moldova* [28].
[45] ibid [65].
[46] *Pocasovschi and Mihaila v the Republic of Moldova and Russia* [34].
[47] ibid [14].

conditions where access to water, electricity, food, warmth and medication is severely limited amounts to inhuman treatment under Article 3 of the Convention'.[48] The fact that these violations were committed in the prison context should not overshadow the findings of the Court regarding electricity access. Imprisonment should be considered a separate issue, since the wording of the findings seems to suggest that the Court treated electricity power as an essential commodity in general for the fulfilment of basic biological needs. Thus, access to electricity is recognized under European human rights law, seemingly almost as important as water (which is and will remain the primary universal human right), but also as a critical factor in determining other needs, such as health, cooking and warmth conditions.

4. Private actors: the duty-bearers of the human right to electricity access in international investment law?

International investment law contributes to energy issues, with international conventions such as the Energy Charter Treaty, for the market of energy investments.[49] Since electricity suppliers may consist of foreign corporations, given the liberalization of the electricity sector in many countries around the globe, the investments approach to the right to electricity access should not be disregarded. Even if in principle, foreign investors should be subject to the same domestic laws as national corporations, their advanced bargaining power, especially in developing countries, may lead to the domination of the local economy and their exclusion from certain legal obligations.[50] Thus, the existence of the human right to electricity access may prove critical in an investment dispute, even if investment law differs dramatically in its function and scope from human rights law. Recent cases displayed that international investment law is progressively relevant when discussing the accountability of private actors based on human rights obligations. Therefore, electricity access defences/arguments to investment claims based on human rights and the vertical conception of human rights that is founded in the investments law concept should be addressed.

First of all, do human rights apply to investment law disputes? There are several convincing discrete legal grounds that justify the applicability of human rights in international disputes: To begin with, human rights are part of international law that regulates all major investment treaties.[51] In the energy/electricity sector, for example, the ECT (Article 26, para. 6) provides that 'A tribunal … shall decide the issues in dispute in accordance with this Treaty and applicable rules and principles of international law'. Moreover, one should not forget the principle of systemic integration that is expressed by Article 31(3)(c) of the Vienna Convention on the Law of Treaties. One should be aware accordingly, that in interpreting a treaty, 'any relevant rules of international law applicable in the relations between the parties' must not be disregarded. Therefore, International Tribunals must examine provisions of

[48] ibid [62].
[49] Ernesto Bonafé and Andris Piebalgs, 'The New International Energy Charter: Sustainable Energy Transition' (2017) 33 Robert Schuman Centre for Advanced Studies: Policy Briefs 2.
[50] Melaku Geboye Desta, 'Sovereignty over natural resources and international investment law: The elusive search for equilibrium' in Stephan W. Schill, Christian J. Tams and Rainer Hofmann (eds), *International Investment Law and Development: Bridging the Gap* (EEP 2015) 227-229.
[51] Fabio Giuseppe Santacroce, 'The Applicability of Human Rights Law in International Investment Disputes' (2019) 34 (1) ICSID Review 136, 141.

human rights law, when applicable,[52] and human rights courts have the same obligation of examining applicable international investment law provisions likewise.[53]

Secondly, ICSID procedural rules, where most investment disputes are settled, but also other *fora* for the settlement of international investment disputes, contain provisions leaving applicable law to the discretion of the parties.[54] It is therefore likely that human rights and specifically the right to electricity access can be implied, when determining the applicable law, since the majority of states have ratified human rights treaties that regulate the right to housing. Investment treaties also provide *expressis verbis* (e.g. a separate human rights provision or 'In Accordance With Host State Law' clauses)[55] the application of human rights.[56] It can even be argued (although this approach has clearer disadvantages), that investment treaties imply the applicability of human rights, through investment treaty provisions that were founded on corresponding human rights provisions (e.g. the protection of property).[57] State parties committed to the protection of human rights have at least a clear obligation for abstaining from acts that could hinder the human rights regime, and it is not rare for an investment dispute to be litigated based on human rights, in a human rights court. It should be noted that one of the biggest awards for damages in the history of the ECtHR (EUR 1,866,104,634), was granted for a dispute that also arose under international investment law, regarding an energy company.[58]

According to the Guiding Principles on Business and Human Rights, the existence of indirect human rights duties of corporate actors is clear.[59] In *Urbaser v Argentina*,[60] it was held for the first time in international investment arbitration that a human rights counterclaim by a Host State could prove a decisive factor in determining the merits of the case.[61] Most importantly, it was also judged, although heavily criticized,[62] that international human rights law already provides for international human rights obligations of private actors.

In *Urbaser v Argentina*, the counterclaim of Argentina based on human rights law was quite aggressive, since it exceeded the demand of the claimants by dozens of millions.[63] Argentina argued that the investors had a well-recognized obligation to observe human rights, especially

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[52] *Rompetrol Group N.V. v Romania* (ICSID Case No. ARB/06/3, Award, 6 May 2013), [169].
[53] Vassilis P. Tzevelekos, 'The Use of Article 31(3)(C) of the VCLT in the Case Law of the ECtHR: An Effective Anti-Fragmentation Tool or a Selective Loophole for the Reinforcement of Human Rights Teleology?' (2010) 31(3) MJIL 621, 623.
[54] Santacroce (n 51) 141.
[55] See (detailed analysis) Ursula Kriebaum, 'Human Rights of the Population of the Host State in International Investment Arbitration' (2009) 10 JWIT 653.
[56] Bree Farrugia, 'The human right to water: defenses to investment treaty violations' (2015) 31 Arbitration International 261, 264-265.
[57] ibid.
[58] *Case of Oao Neftyanaya Kompaniya Yukos v Russia*, Application no. 14902/04 (ECtHR, 31 July 2014), see Judgment (just satisfaction).
[59] *Guiding Principles on Business and Human Rights, Implementing the United Nations "Protect, Respect and Remedy"* Framework - Developed by the Special Representative of the Secretary-General on the issue of human rights and transnational corporations and other business enterprises and endorsed by the Human Rights Council in its resolution 17/4 of 16 June 2011, 1.
[60] *Urbaser v Argentina* (8 December 2016, ICSID Case No. ARB/07/26).
[61] Patrick Abe, 'Counterclaims Based on International Human Rights Obligations of Investors in International Investment Arbitration' (2018) 1 BOL 61, 71-77.
[62] ibid.
[63] *Urbaser v Argentina* [1156 -1166], especially [1165].

considering the human right to water.[64] Even though the Tribunal rejected both the claimants' and the respondents' arguments,[65] it concluded that the reason Argentina's argument failed was not the absence of the obligation to observe human rights by multinational corporations. The counterclaim failed because, even if human rights law was applicable, since according to the Tribunal 'the BIT cannot be interpreted and applied in a vacuum',[66] the violation of the negative obligation was not enough to validate Argentina's argument.[67] That is because Argentina had a positive obligation to ensure access to water, whilst the corporations (i.e. Urbaser and CABB) were only obliged to abstain from acts that could hinder human rights.[68]

Urbaser v Argentina consists of evidence that in principle, private actors could be held accountable for violating human rights, especially considering the exploitation or the mismanagement of natural resources, such as water or those that generate electricity power. This accountability may lead to restrictions regarding the application of investment treaty protection.[69] The judgement may provide the key in unlocking the horizontal application of the right to access electricity within the international investment context. It is indeed rare that private actors must be considered as duty-bearers of human rights or international law more generally.[70] This raises the question, if a company could be held accountable for the violation of human rights obligations in an investment tribunal, does that mean that the "same" judgement could be "repeated" in private litigation? This remains an essential question that is rather difficult to answer, when considering the horizontal dimension of human rights and the many factors that should be considered. These include the jurisdiction and relevant domestic legislation, that may support the existence of indirect human rights obligations from private actors, especially considering those serving as public utilities.

5. The horizontal conception of a human right to electricity access

As deduced from the above, the narrow interpretation of international human rights law seems long gone, especially considering the immense economic power that many transnational corporations enjoy today.[71] This is especially true for non-state actors carrying out public functions (i.e. public utilities),[72] such as transportation or energy services, since besides their potentially vast economic prosperity, they address the public directly. Public utilities are usually heavily regulated businesses, charged with serving society, performing an essential public service.[73] Crucially, public utilities could consist of non-state actors that are fulfilling

[64] ibid [1161 -1163].
[65] ibid [1234].
[66] ibid [1200].
[67] ibid [1210].
[68] ibid.
[69] Farrugia (n 56) 266.
[70] C. G. Weeramantry, *Universalising International Law* (MNP 2004) 192.
[71] ibid. Also see, Ibrahim Kanalan, 'Horizontal Effect of Human Rights in the Era of Transnational Constellations: On the Accountability of Private Actors for Human Rights Violations' (2016) 7 EYIEL 423, 425 and Carlos Manuel Vázquez, 'Direct vs. Indirect Obligations of Corporations Under International Law' (2005) 43 CJTL 927, 932.
[72] Lottie Lane, 'The Horizontal Effect of International Human Rights Law in Practice, A Comparative Analysis of the General Comments and Jurisprudence of Selected United Nations Human Rights Treaty Monitoring Bodies' (2018) 5 EJCLG 5, 6.
[73] William Kline and Karl McDermott, 'Evolutionary stakeholder theory and public utility regulation' (2019) 124 BSR 283, 284-285.

obligations on behalf of the state.[74] Therefore, should a private actor, that mainly functions as a public utility (especially in regions where there is no competition and the company becomes a monopoly), be held accountable for human rights violations, such as the denial to access to electricity?

First of all, the horizontal approach of human rights is criticized[75] and even human rights scholars seem to disagree on the subject matter.[76] The votaries of expanding the human rights scope argue that the historical background for the adoption of human rights is irrelevant[77] and that it has become clear that multinational corporations have a corresponding large role to perform internationally and domestically, based on human rights obligations.[78] On the contrary, mainly "classical liberalists" support that the existing human rights framework does not constitute a sufficient solution to bind private actors into human rights duties and those UN related conventions were never meant to be interpreted that way.[79] However, these two approaches should be considered as the theoretical opposite extremes.[80] Arguably, the middle ground between the two notions is probably the more realistic approach to the subject matter. Human rights can become binding through the legal order of states and there are even human rights conventions (mainly of international criminal law)[81] that regulate private actors' duties to human rights requirements.[82] Therefore, one must address whether human rights violations should be confined 'through the current system of horizontal human rights law, under which most obligations of private actors are placed indirectly'.[83]

Accordingly, it is not a question of if private actors, namely those under a public function, are subject to human rights duties, but rather to which duties and under which conditions. Should e.g. an electricity company be liable in private litigation for breaching human rights duties, when interrupting the power supply due to non-resolving debts? The answer is likely to be negative, since human rights treaties that regulate the derived right to electricity access do not forbid electricity power to be treated as a commodity. On the contrary, an electricity company that serves as a public utility in a remote area is more likely to be held liable when it effectively deprives electricity access, e.g. due to the mismanagement of relevant resources, if the state enjoys a sufficient level of development.

Nevertheless, when contemplating if, under the existing human rights framework, a private company could be held accountable for failing to observe human rights in the – also crucial commercially – international investment context, *Urbaser v Argentina* proceeds in making a courageous step towards that direction. Even if the human rights framework is a cohesive and detailed body of law, its application to non-state actors should be considered rather incomplete at this stage, since human rights law does not particularly suit corporate

[74] Lane (n 72) 68.
[75] Kanalan (n 71) 425. Another interesting reason can be seen in Margaret E McGuinness Medellin, 'Norm Portals, and the Horizontal Integration of International Human Rights' (2006) 82 NDLR 755, 837.
[76] Jennifer C. Corrin, 'From Horizontal and Vertical to Lateral: Extending the Effect of Human Rights in Post-Colonial Legal Systems of the South Pacific' (2009) 58 ICLQ 31, 31-32.
[77] ibid.
[78] Weeramantry (n 70) 192.
[79] Corrin (n 76).
[80] ibid 33.
[81] John J Knox, 'Horizontal Human Rights Law' (2008) 102 AJIL 1, 27-28.
[82] Kanalan (n 71) 427.
[83] Knox (n 81) 47.

purposes.[84] If human rights duties are to be implemented to businesses via the existing human rights framework, a responsible balance must be achieved between outsourcing the state duties to businesses[85] and the effective protection of individuals. Considering all the above, there is a chance provided by recent developments in the international investment regime,[86] that a new investment architecture oriented towards sustainable development and the request for respecting human rights, will be adopted in the decade to come. This practice will steadily affect more directly private relationships[87] and may shape the boundaries of the human right to electricity access.

Conclusions

Electricity access maybe once considered the privilege of the global north, is established nowadays as one key attribute of human rights, implying the right's universal scope. Even if as a derived right in the modern framework, based most likely on the right to housing or the right to development, electricity access should be regarded as imposing obligations not only to states, but also to public utility corporations. The horizontal dimension of human rights, even if it is eventually rejected at private litigations by the courts, exists in Tribunal's decisions in the international investment context. From an electricity company's point of view, the consequences of the latter can only be deemed as formidable, since investors face the real prospect of dramatically losing a claim for failing to observe human rights. Additionally, their relevant duties will likely expand, as their power and the significance of essential services grows exponentially.

[84] ibid 40.
[85] ibid 2.
[86] 'Recent Developments in the International Investment Regime – IIA Issues Note' (UNCTAD, No. 1, May 2018) <https://unctad.org/en/PublicationsLibrary/diaepcbinf2018d1_en.pdf> accessed 1 May 2020, s.2.
[87] Lane (n 72) 87-88.

Law Reform Proposal: Personalized Declaration of Death

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Abstract

As medical sophistication has progressed, a growing portion of the population has, perhaps ironically, begun to question whether they would wish to be subject to some techniques of preserving life and whether they still believe that death is the worst-case scenario. However, securing a death that the patient may deem more dignified is a difficult and perhaps impossible task. This is because the law is systemically biased in favour of the preservation of life and seeks to impose a uniform definition of what death should mean to every individual.

The purpose of this paper is to propose a shift in the legal perception of death from that of the objective to the subjective. This paper proposes an amendment to the Mental Capacity Act that would bolster individual autonomy surrounding death and allow a capacitous patient to exercise a power similar to that of an Advance Directive. This directive would dictate the point at which the medical team will be permitted to harvest the organs of the patient and treat them as if they have died. A patient may define their future death as one of three previously recognized options: Brainstem Death, Cardiopulmonary Death, and a Permanent Vegetative State.

Introduction

The purpose of this paper is to propose a reform to the clinical process of diagnosing death that will ease the identification of the point at which death has occurred. To accomplish this, the power to define death must be taken from the medical practitioners and given to the autonomous patient. In operation, this power will be akin to that granted by the Mental Capacity Act 2005 (MCA) to provide an advance decision regarding the refusal of treatment.[1] However, the patient will have the power to define the state at which the medical team may be permitted to treat them as if they have already died, as opposed to the power to list the specific treatments they would refuse toward the possibility of a resultant death. This difference is slight but crucial.

In the United Kingdom, no statutory definition of death exists as of this writing.[2] Thusly, the determination and diagnosis of the death of a patient is a clinical decision to be made under many exterior influences. These include those such as: public perception; the religious leanings of not only the doctors themselves but also of the patient; and whether the patient is an organ donor. The potentially opposing nature of these differing views of death may be difficult to reconcile in an overarching manner. For instance, the declaration of Brainstem Death (BSD) as the medically accepted criteria for a death diagnosis has been met with backlash as the general public may be reluctant to accept the harvesting of organs from a patient whose heart is still beating.[3] Strict adherence to this Dead Donor Rule, the rule that prevents donors from being killed in order to obtain organs,[4] can lead to a damaging anoxic

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[1] Mental Capacity Act 2005, s 24.

[2] Emily Jackson, *Medical Law: Text, Cases and Materials* (5th edn, Oxford University Press 2019) 629.

[3] ibid.

[4] John A Robertson, 'Delimiting the Donor: The Dead Donor Rule' (1999) Hastings Centre Report 6, 6.

time between death and organ harvesting that can be detrimental to the quality of the organ and, consequently, the health of the transplant recipient.[5]

The scope of this report is to propose the power to self-define one's own death from previously accepted definitions. This reform proposal does not intend to alter the current state of death within the ambit of the Criminal Law nor does it intend to directly affect the prohibition upon medically assisted suicide. The proposed reform will operate in conjunction with the coming "opt-out" system of organ donation,[6] however, it will be an active decision to be made purposefully by those wishing to exercise the power and only by those with the capacity to do so under the MCA. The vulnerability of the incapacitous patients will be protected and the decision to diagnose and define death in such unfortunate cases will remain the duty of the medical practitioners. Equally, individuals who do not exercise the power to define death will be treated by the medical practitioners within the context of their case.

The proposed reform should be legally implemented through an Amendatory Bill to the MCA. This amendment should include the proposed power and the formalities of the patient-defined death declaration, which should be similar to those which govern an advance directive refusing life sustaining treatment.[7] However, these formalities should be bolstered to reflect the gravity of the decision. These formalities, the process of defining one's own death and the acceptable definitions of death will be detailed in Part 2. In order to contextualize the need for a reform of this nature, the ensuing section will outline the insufficiencies of the current law that is without such a method of defining death. Finally, the strength and applicability of the proposed reform to solve present issues will be explained.

1. The Current State of Law and Procedure

The Uncertain Evolution of "Death"

As medical sophistication has evolved, the notion of pinpointing the moment of death has become an increasingly arbitrary decision.[8] Early technological progress had begun to belittle the ideology, which was present before 1960, that death was signified entirely by the irreversible cessation of the patient's breathing and heartbeat.[9] What this cardiopulmonary criteria of death could not satisfy was the ability to bypass the natural functioning of the heart and lungs by ventilation and defibrillation. Therefore, the use of such instruments imposed a shift in the professional understanding of death.

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[5] Graeme Laurie, Shawn Harmon and Edward Dove, *Mason and McCall Smith's Law and Medical Ethics* (11th edn, Oxford University Press 2019) para 18.34.

[6] National Health Services, 'Organ Donation Law in England Is Changing: Pass It On' <https://www.organdonation.nhs.uk/uk-laws/organ-donation-law-in-england/?gclid=Cj0KCQjwj7v0BRDOARIsAGh37iocjr7oACe6y7y9Z3p10_v_lqJA817ndKUO2bO79ZBaiy5iL25bN-8aAnnBEALw_wcB> accessed 10 April 2020.

[7] Mental Capacity Act 2005, s 25(6).

[8] Henry K. Beecher, 'The New Definition of Death, some Opposing Viewpoints' (1971) 5 International Journal of Pharmacology 120, 120.

[9] David A. Jones, 'The UK Definition of Death' (The Linacre Centre, 2000) <http://www.lifeissues.net/writers/jon/jon_01death.html> accessed 13 April 2020.

Known in France as *comma depasse,*[10] a new clinical condition was recognized in patients who had suffered severe head trauma and required intensive care. These patients had lost all responsiveness, including the ability to breathe on their own. If the ventilator was removed, the patient would not be able to breathe spontaneously and they would very shortly die. This became known in the UK as the complete functional destruction of the brain.[11] However, the patient could not be considered dead at this stage, under the current understanding of death, because the fact of the matter was that the patient was still breathing, albeit mechanically. Therefore, through a series of publications by the Conference of the Medical Royal Colleges between 1976 and 1995, the first attempted recognition of BSD as death was suggested in that the 'irreversible loss of the capacity for consciousness, combined with the irreversible loss of the capacity to breathe should be regarded as the definition of death'.[12]

Nevertheless, a state of confusion and a reluctance to accept BSD as actual death persists, especially within the scope of public confidence toward the health care system. Despite the broadening of the concept of death to include those diagnosed as BSD, the cardiopulmonary standard remains the well-known, layman standard of death.[13] This is the point that allows the family to understand and begin to grieve their loss.[14] In fact, it is not uncommon for family members to believe that the medical staff would not operate to remove the patient's organs for transplantation until their heart had stopped beating, even after the diagnosis of BSD.[15] Successful organ transplantation is inextricably dependant on timing, as an organ's suitability for transplantation diminishes rapidly once respiration and oxygen supply to the organ ceases.[16] Therefore, the possibility of anoxic detriment to the organ appears to be a risk that should be avoided at all cost, given the increasing demand for life-saving organs, yet this risk is perpetuated by strictly adhering to the Dead Donor Rule as it is currently understood.

The perception of death is fickle and immensely subjective, rendering the creation of a definition that is satisfactory to all an impossible task. Take, for instance, a patient who has been rendered into a permanent vegetative state (PVS). The seminal jurisprudence in the United Kingdom regarding death and PVS is that of *Airedale National Health Service Trust v Bland*,[17] in which it was ruled that the care team of a victim of the Hillsborough disaster, which rendered him in a PVS state, would be permitted to withdraw life-sustaining treatment to procure a dignified death for the patient. As a PVS patient lacks the capacity to refuse treatment, the health team is forced to act in the best interests of that patient.[18] This is due to an important distinction between PVS and BSD patients. A diagnosis of BSD is reflective of an irreversible halt to brainstem function while the brainstem of PVS patients continue to operate, meaning they remain legally alive:

[10] ibid.
[11] ibid.
[12] ibid.
[13] John Lombard, 'Definition of death' (2012) 11 Hibernian LJ 63, 66.
[14] ibid.
[15] Seema K. Shah, 'A Narrative Review of the Empirical Evidence on Public Attitudes of Brain Death and Vital Organ Transplantation: The Need for Better Data to Inform Policy' (2015) 41 Journal of Medical Ethics 291, 296.
[16] Lombard (n 13) 65.
[17] [1993] AC 789.
[18] Mental Capacity Act 2005, s 1(5).

> I start with the simple fact that, in law, Anthony [Bland] is still alive. It is true that his condition is such that it can be described as a living death; but he is nevertheless still alive. This is because … doctors no longer associate death exclusively with breathing and heartbeat, and it has come to be accepted that death occurs when the brain, and in particular the brainstem, has been destroyed.[19]

This notion of "living death" has sparked academic debate arguing that death is more of a spiritual concept than previously regarded. As Tännsjö argues, 'we can now define death of a person as the point at which the person in question ceases to exist… If there is no consciousness at all, then there is no person at all'.[20] Under this ideology, the indicator of life and death is not the body but, rather, the controlling mind. It is the thoughts, feelings, attitudes and psychological character that make up the human life and, therefore, the death of the person may occur long before brainstem death or cardiopulmonary death.[21] In other words, once an individual's personality has died, and cognitive identity is irreversibly ceased, that individual should be eligible for organ donorship. However, again, firm rebuttal to this mentality is abundant and based primarily upon avoiding the broadening of the concept of death too widely under this utilitarian mindset; the worry that justifying the killing of ventilator-dependent patients could become the gateway into killing those who are not dependent on ventilation,[22] such as those in a PVS state or comatose patients. The need for the reform proposed in this paper is evident in the verve of this very rebuttal. Potts and Evans reject the argument that it is morally acceptable to harvest the organs of a patient who remains legally alive if the donorship benefits of those organs outweigh the harm done to the consenting patient/surrogate.[23] They reject this argument via three concerns: that the act of harvesting organs prior to cardiopulmonary death is unbefitting the doctor-patient relationship; that human beings are social creatures and individual autonomy is not a value that trumps the impact of the patient's death on others; and that patients who sign organ donor cards are not fully informed as to what they are permitting the medical team to do under the current legal scheme. With regard to the second argument, as will be noted in Section 4, the Supreme Court has recognized that the principle of autonomy has seen a strengthening throughout the jurisprudence on this topic and that the relinquishment of life may even be within the patient's best interest in certain circumstances.[24] This progress should not be reverted by providing for unrecognized interests of others, who are not dependents of the patient, especially when the patients themselves have professed their own wishes to the contrary. While it is entirely agreeable that lengthy and extensive information should be given to the patient who is contemplating end-of-life decision making, most pertinent to this paper is the first argument. Potts and Evans consider the harvesting of organs from BSD patients by the surgeons as an act of "killing" the patient: '[w]e believe that removing vital organs from a still living donor is the taking of innocent human life'.[25] This is because their criticism is centred upon their adherence to the objective, uniform sense of what constitutes death. If the

[19] *Bland* (n 17) 863.
[20] Torbjörn Tännsjö, 'Two Concepts of Death Reconciled' (1999) 2 Medicine, Health Care and Philosophy 41, 47.
[21] Julian Savulescu, 'Death, us and our bodies: personal reflections' (2003) 29 Journal of Medical Ethics 127, 157.
[22] Michael Potts and David W. Evans, 'Does it Matter That Organ Donors are not Dead? Ethical and Policy Implications' (2005) 31 Journal of Medical Ethics 406, 407.
[23] ibid 408.
[24] *An NHS Trust and others v Y (Intensive Care Society and others intervening)* [2019] AC 978, 1011.
[25] Potts and Evans (n 22) 407.

law accepts that death is subjective and allows the fully informed and capacitous patient to decide what state of health will constitute their own death, many moral and legal conundrums surrounding the harvesting of their organs at that point are harmonized. The doctor can no longer be said to have taken the life of the patient because the patient has both voluntarily and, under this reform, legally declared their life lost prior to the operation. This method would eliminate the risk of anoxic detriment to the organ. Therefore, this practice would respect the autonomy of the individual, ensure the highest likelihood of successful transplantation for the recipient and procure a dignified death for the deceased.

It is clear that the concept of death within the mind of the medically uninitiated has not evolved at the same pace and consistency in which the medical profession has come to perceive death. The crux of this issue is the subjectivity of death and the wavering sentimentality placed upon it between individuals. Some may believe people are dead after they take their last breath, while some may believe they should be considered dead when they have no hope of cognitive recovery. However, 'death must remain absolute; there is no place in medical jurisprudence for conditional phrases such as "at deaths door" or "as good as dead"'.[26] Therefore, the complexity of this issue is best alleviated through the implementation of a strengthened individual autonomy that allows one to decide what exactly will constitute one's own death.

The Principle of Autonomy: The Difficulty of Forward Thinking

The recognition of one's autonomy is caveated by a requirement of capacity. That is, for the purposes of this reform, only those who have the appropriate capacity are eligible to decide the treatment they wish to refuse even when this would be detrimental to their health. Section 1 of the MCA promotes and safeguards a patient's capacity by ensuring that patients are assumed to have capacity unless proven otherwise.[27] While this reform is intended to benefit only those who are deemed to have capacity, it is irrefutable that those who wish to utilize the proposed reform will at one point be rendered into a state of incapacity, thus it is necessary to criticise the current statutory difficulties patients experience when attempting to ensure their wishes regarding future treatment.

Patients are now recognized as 'persons holding rights, rather than as the passive recipients of the care of the medical profession'.[28] This sentiment, as well as the fact that this personal liberty is not limited to decisions that are objectively sensible, has been widely defended by the courts on several occasions:

> An adult patient who suffers from no mental incapacity has an absolute right to choose whether to consent to medical treatment, to refuse it or to choose one rather than another… This right of choice is not limited to decisions which others might regard as sensible.[29]

While a patient remains in a capacitous state, the patient's decision to refuse treatment:

[26] Laurie, Harmon and Dove (n 5) para 17.06.
[27] Mental Capacity Act 2005, s 1(2).
[28] *Montgomery v Lanarkshire Health Board* [2015] AC 1430, 1495.
[29] *Re T (adult refusal of treatment)* [1992] 4 All ER 649, 652.

> must be obeyed even, if on any objective view it is contrary to his best interest. A doctor has no right to proceed in the face of objection, even if it is plain to all, including the patient, that adverse consequences and even death will or may ensue.[30]

This position is also set out in the MCA in that 'a person is not to be treated as unable to make a decision merely because he makes an unwise decision'.[31] However, it is necessary to recognize that these statements and provisions are meant to assist the medical team when contemplating the treatment of a currently capacitous patient. When that individual subsequently loses such capacity, the medical team must then treat them in a way that conforms to the patient's 'best interests'.[32]

The criteria which assist in determining the patient's best interest are set out in section 4 of the MCA, and this provision dictates that the determination must not be motivated by a desire to bring about the patient's death.[33] While the inclusion of this provision is paramount for the protection of vulnerable people, it is possible that the provision grants a disproportionately subjective power to the decision-maker. To be clear, section 4 mandates that the decision-maker consider several circumstances and aspects of the patient's personality, such as their beliefs and values,[34] and the needs of possible dependants of the patient.[35] However, compliance with section 4 is satisfied if, having taken into account subsections 2 to 8, the decision-maker '*reasonably* believes that what he does or decides is in the best interests of the [patient]'.[36] The statute is silent with regard to what will reasonably satisfy a doctor's belief, however, the *Bolam*[37] test allows medical practitioners to act in accordance with the consensus and practice accepted by the general opinion held within the medical profession as to what care ought to be provided. Therefore, the *Bolam* test, in conjunction with General Medical Council guidance,[38] can frequently allow the medical staff to decide on methods which procure the continuation of life. This sustainment of life may be contrary to the patient's actual wishes and render them in a state that is undesirable:

> In an era of growing medical sophistication … many people are concerned that they should not be forced to linger on in old age or in states of physical or mental decrepitude which conflict with strongly held ideas of self and personal identity.[39]

Yet, there is very little recourse available for the families when the wishes of the patient are contradicted. This issue is even more concerning when the patient had indeed attempted to formalize their wishes through the use of an advance decision. An advance decision is a patient's written declaration to evidence their refusal of a specific treatment should they lose the capacity to make that refusal on a future date.[40] It is clear from the wording of the MCA

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[30] *Bland* (n 17) 891.
[31] Mental Capacity Act 2005, s 1(4).
[32] ibid s 1(5).
[33] ibid s 4(5).
[34] ibid s 4(6)(b).
[35] ibid s 4(7)(b).
[36] ibid s 4(9) (emphasis added).
[37] *Bolam v Friern Hospital Management Committee* [1957] 2 All ER 118.
[38] General Medical Council, 'Treatment and Care Towards the End of Life: Good Practice in Decision Making' (2010) 12.
[39] *Pretty v United Kingdom* (2002) 35 EHRR 1, 37.
[40] Mental Capacity Act 2005, s 24(1).

that an advance decision, in order to be valid, requires a nearly impossible level of care to be taken because the statute appears biased in favour of preserving life.[41] An advance decision must expressly state the specific treatment the patient wishes to refuse within the circumstances of his future health.[42] Therefore, in light of growing public reluctance toward mechanical maintenance, advance decisions may not protect patients from this maintenance the way they actually desire them to. To elaborate, consider the hypothetical man "B". B is very opposed to the idea and does not ever want to be kept alive through ventilation and artificial hydration in the event of life-threatening injury. He would wish to be allowed to die to save his family from his lengthened hospitalization. Therefore, he creates an advance decision stipulating that, in the event of serious head trauma, he has pre-emptively refused assisted ventilation, hydration, and nutrients. Years later, B's health deteriorates due to a degenerative neurological disease, rendering him unable to communicate. This is not the circumstance in which B had declared a refusal of treatment and his advance decision is not valid.[43] This is evidence of legislative bias, but consider also examples of judicial bias such as *A Local Health Authority v E*,[44] in which a severely anorexic woman sought to implement an advance directive to hasten death. Due to questionable capacity, E was forced to make two advance directives, the latter of which coming after it appeared that she had regained capacity (although doubts yet remain as to whether or not she had ever lost such capacity),[45] and she drafted this second directive with guidance from her Solicitor and Mental Health Advocate. Contrary to medical consensus, Jackson J ruled she was not capacitous at the relevant time primarily because no formal assessment of E's capacity had been performed.[46] The MCA does not impose a positive duty on the patient to prove their capacity beyond a reasonable doubt, quite the opposite; a presumption of capacity must be disproven. Therefore, in light of the contrary medical opinion, it appears a key influence on this ruling could have been a systemic bias favouring the preservation of life. Although this reform seeks to mandate an assessment of capacity, it is proportionate because the patient is dictating their actual death and not the general refusal of treatment. This requirement of an assessment will be specific to the proposed power and will not alter the presumption of capacity as it pertains to the rest of the MCA.

It is true that a decision-maker must contemplate the patient's past wishes and feelings, especially written statements made when the patient had capacity,[47] however, the decision-maker must be satisfied of the validity of the advance decision.[48] If they are not satisfied, a court may make a declaration as to the validity of the advance decision[49] and, until that ruling is made, the medical team is permitted to provide life-sustaining treatment in the interim.[50]

The current state of law is problematic because it does not adequately recognize that, for some, death is not perceived as the most undesirable outcome. The House of Lords had

[41] Laurie, Harmon and Dove (n 5) para 19.57.
[42] ibid.
[43] ibid s 25(4)(b).
[44] [2012] HRLR 29, [2012] EWHC 1639.
[45] Rob Heywood, 'Revisiting Advance Decision Making Under the Mental Capacity Act 2005: A Tale of Mixed Messages' (2015) 23 Medical Law Review 81, 91.
[46] *A Local Health Authority v E* (n 44) para 65.
[47] Mental Capacity Act 2005, s 4(6)(a).
[48] ibid s 26(2).
[49] ibid s 26(4)(a)-(c).
[50] ibid s 26(5).

recognized this fear of artificially sustained life and has even recognized that a right to determine the end of one's life is protected by their Article 8 ECHR right.[51] Nevertheless, if one wishes to choose a dignified death, they must do so legally within a counter-productive system that seeks to promote the sustainment of life.

The law is inevitably confused because it desires legal certainty and uniformity. As such, the law attempts to superimpose a constitution of what death *should* mean to every person. However, the concept of death is one that can never fit into one satisfactory definition. This is the concern that this reform seeks to resolve. Without a radical shift in the governance of a death declaration, this state of confusion will persist at vast expense to the NHS, the families of unfortunate patients, the judicial system, and the vulnerable individuals awaiting an organ.

2. The Reform

This reform will seek to bolster individual autonomy surrounding end of life decisions by altering the legal mentality from considering "what does death mean to all?" to "what does death mean to *you*?" As previously discussed, death has seen few operative definitions: cardiopulmonary death, BSD and the emerging "personality death" that is resultant of a PVS state. The reform will use these three possible definitions as a list of options for the individual patient to decide which best suits their beliefs. This reform should be implemented in law by an Amending Bill to the MCA, as matters involving Convention Rights and life-ending decision-making are widely regarded as only appropriately decided by Parliament.[52]

These declarations should be possible on three differing occasions:

a) During the informative risk consultation prior to invasive surgery,
b) Upon diagnosis of a degenerative disease/illness, and
c) A proactive, anticipatory declaration applicable to all future circumstances that may render the patient in their chosen state.

The first occasion is the most finite and specific declaration of death. When the patient declares their desired definition of death prior to an operation, that declaration will be applicable only to the outcome of that operation and will lapse upon successful post-op recovery.

Secondly, when a patient declares a future point of death upon diagnosis of illness, it must be the illness that has rendered them in their chosen state and will not be applicable to unforeseen injury, whether accidental or self-inflicted.

Lastly, the most substantial increase of individual autonomy is the ability to define death for all future circumstances, seen and unforeseen. Upon strengthening autonomy to this extent, this reform is careful to protect and further recognize the requirement of capacity. Therefore, the formality requirements for the implementation of this declarative power must be strong and strictly followed. For declarations made by individuals listed above in b (upon diagnosis

[51] *R (on the application of Pretty) v Director of Public Prosecutions* [2002] 1 All ER 1, 38.
[52] *R (on the application of Nicklinson and another) v Ministry of Justice* [2014] 3 All ER 843, 941.

of a degenerative disease/illness) and c (an anticipatory declaration), the formality requirements should be:

a) A formal assessment of capacity to be performed by a psychiatric expert,
b) The declaration of the individual's definition of death is written,
c) It is signed by the individual in the presence of at least two witnesses, at least one of whom is the individual's immediate next of kin or as closely related as possible,
d) The witnesses sign it in the presence of the individual,
e) A copy of this document is given to, signed and retained by the individual's Solicitor,
f) A copy of this document is given to, signed and retained by the individual's General Practitioner, and
g) The declaration will remain applicable for a period of nine years, upon which time the individual will have an additional twelve months to renew the declaration for another nine years. If the declaration is not renewed within this period, at the passing of twelve months, the declaration will lapse.

Some of these formalities will inherently not be possible for those who declare a definition of death prior to major surgery. Therefore, in lieu of the assessment of capacity, the minimum number of witnesses required in this situation is five: at least two next of kin, the Surgeon, the patient's General Practitioner and the patient's Solicitor. Three witnesses must sign in the presence of the patient and a copy of this must be sent to the General Practitioner and Solicitor prior to the commencement of the operation when possible.

The individual's declaration of death will remain ineffective until the individual has lost the capacity to make alternative direction. Revocation or alteration of the individual's death definition must be in writing unless communicated to all attesting witnesses in some fashion or vocalised at the hospital in the presence of at least one attesting witness while the patient is capacitous. Any declaration of an individual's definition of death will be void if:

a) It was declared prior to the enactment of relevant legislation,
    i. Including the implementing mechanism of this reform and any required legislation governing the "Opt-out" organ donation system.
b) The individual opts out of presumed consent organ donation, or
c) It becomes apparent to any attesting witness that the capacity of the patient/individual was lacking at the time of creation.

If the patient had declared their death criteria as that of PVS, a court may determine the validity of that declaration upon PVS diagnosis if uncertainty arises regarding the patient's capacity at the time of declaration. This uncertainty must be held by the medical team and corroborated by any attesting witness.

3. Justification

Without radical change to the status quo, a state of confusion over death will persist for many years to come, exacerbated by a multitude of conflicting sociopolitical concerns. These include concerns about advancing medical sophistication, a desire to adhere to the Dead

Donor Rule and, most importantly, public faith and perception. However, examining these concerns shows that, by implementing this reform, it is possible to reconcile these issues.

Firstly, it must be recognized that implementation of this reform will not abolish the Dead Donor Rule. Rather, it will define its parameters. The rule that organs may only be harvested once a person is dead is of utmost importance because its adherence promotes public trust in the transplantation system. It is for this reason that the only three options available to the public with which to define their death are previously recognized definitions of death. Whatever definition the patient chooses, they are to be treated as presently deceased when the state of their well-being arrives at that point. Therefore, the Dead Donor Rule is preserved.

It is important to note that the ideology that underpins this reform proposal has been present for many years. As Savulescu notes, '[a]t the very least, people should be allowed to complete advance directives that direct their organs be removed when their brain is severely damaged or they are permanently unconscious'.[53] As has been shown, advance directives are not effective mechanisms to protect individuals from a state of undesired medical maintenance with certainty. This is due to systemic bias and also because the validity of such an advance decision would require the foresight of an infinite number of circumstantial treatments which they wish to refuse.[54] To avoid this inadequacy, the political climate surrounding death and organ donation has now become suitable for individualized self-determination of death. Upon the arrival of the Opt-out system of organ donation, the ability to declare PVS as one's chosen death criteria will be available to all. Allowing the public to declare themselves as dead when they are rendered into a PVS state is the most controversial aspect of this reform policy because many unfortunate individuals in a PVS state may *live* unassisted for several years after diagnosis. However, upon the commencement of the presumed consent model of organ donation, the organs of an individual with this death criteria may be harvested at this stage, bringing their "living death" to an end and rendering the individual deceased within the past conventional sense. This is why individuals using this statutory power must not opt out of the presumed consent model.

In order to facilitate public faith in the transplantation system it is crucial that the autonomous patients themselves are tasked with defining their own death. Statutory definitions of death, like those found in the United States,[55] run the risk of expiration in light of the ever-evolving medical profession. Not only would this inevitable expiration frequently require the daunting task of statutory amendment,[56] but, if a great portion of the population disagreed with the definition imposed by law, the public may protest. For example, the definition may be seen as archaic because it allows PVS patients no release if they would not have wanted to be maintained in such a state or, conversely, it may be perceived as barbarically permitting the premature harvesting of organs from vulnerable living people.[57] The United Kingdom cannot risk a lessening of faith in the transplantation system which is already in an unsatisfactory state as nearly 50% of potential donors fail to become actual donors.[58] However, if individuals were

[53] Savulescu (n 21) 157.
[54] Laurie, Harmon and Dove (n 5) 19.55.
[55] Uniform Determination of Death Act 1981 (US).
[56] Lombard (n 13) 79.
[57] Laurie, Harmon and Dove (n 5) para 18.23.
[58] ibid para 18.44.

to be given more freedom over end of life decisions, then public confidence will likely rise, as indicated by recent polls regarding the demographic opinion of assisted dying.[59] Public distaste for any definition of death will be minimized should that definition be self-prescribed by the patients themselves because it is possible that a strong portion of the public would recognize the respect given to that patient's freedom of self-determination. This self-determination of death would be recognized as having no prospective implication on the life and death of the general public, as they may be free to choose a different definition. It is estimated that switching to a presumed consent model of organ donation would result in an increase in donation rates of up to 30%.[60] The possibility of further increase resultant of this reform is highly likely as participation in organ donorship may be perceived as a reasonable trade in exchange for heightened autonomy.

This reform represents an unprecedented bolstering of individual autonomy and one which is reflective of the increasing importance placed upon self-determination in the western world. As Robins JA of Canada stated, endorsed by Butler-Schloss LJ in the United Kingdom:[61]

> The right to determine what shall be done with one's own body is a fundamental right in our society… Free individual choice in matters affecting this right should … be accorded very high priority.[62]

Although, when death may result, society may be too quick to question one's capacity to exercise this right. One such argument is, in order for consent to be valid, the patient must be fully informed. Therefore, when a patient makes an advance decision refusing a future treatment, they are not fully informed as to what their actual desires *may* be at that future date and it is therefore dangerous to follow that decision.[63] To view autonomy as applicable only to the current moment of the patient's life is to rob them of the right of self-determination. In this debate, the competing principles are that of individual autonomy and the sanctity of life. Championing the sanctity of life is an honest and respectable concern, however, this principle has seen a weakening in recent decades, especially when the patient is PVS. Most recently, the Supreme Court held that, although we are to presume that a patient's best interests would have him remain alive, 'there may come a time when life has to be relinquished because that is in the best interests of the patient'.[64] Furthermore, when the two principles are in conflict, the House of Lords had made it adamantly clear that:

> the principle of the sanctity of life must yield to the principle of self-determination … Moreover, the same principle applies where the patient's refusal to give his consent has been expressed at an earlier date, before he became unconscious.[65]

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[59] Campaign for Dignity in Dying, 'Largest Ever Poll on Assisted Dying Finds Increase In Support to 84% of Britons' (2 April 2019) <https://www.dignityindying.org.uk/news/poll-assisted-dying-support-84-britons/> accessed 18 April 2020.
[60] Alberto Abadie and Sébastien Gay, 'The Impact of Presumed Consent Legislation on Cadaveric Organ Donation: A Cross-Country Study' (2006) 25 Journal of Health Economics 599, 610.
[61] *Re T* (n 29) 665.
[62] *Malette v Shulman* (1990) 72 OR (2d) 417, 432.
[63] Christopher James Ryan, 'Betting Your Life: An Argument Against Certain Advance Directives' (1996) 22 Journal of Medical Ethics 95, 97.
[64] *An NHS Trust* (n 24) 1011.
[65] *Bland* (n 17) 864.

This reform will therefore respect the Dead Donor Rule, albeit through a slightly altered perspective, promote respectful participation in organ donorship, and it will finally grant the public the true freedom of self-determination that they so unequivocally deserve.

Conclusion

As medical sophistication evolves, so too does public opinion over the question: what does it mean to be dead? As this evolution continues, it has become evident that it is inappropriate to dictate what the concept of death should mean to everyone and that decision should rest on the individual. For the sake of rationality, that discretion must not be unfettered, it must adhere to previously held concepts of death: cardiopulmonary death, brainstem death and the death of the cognitive individual in a permanent vegetative state.

Harmonizing the perception of death between the general public, the medical profession and the law can only be achieved by conceding the right to define death to the person who will experience it. The law is currently unable to adequately protect individuals from unwanted and undignified preservation beyond the point at which they deem their own lives lost. This is because the law too adamantly protects the sanctity of life and does not properly foster self-determination, to which the notion of sanctity must yield. By legally bolstering the principle of autonomy, the United Kingdom will enjoy increased public confidence, increased organ donation rates and an unclogged judicial system previously burdened by such upsetting and complicated cases.

The Regulation of Dermal Fillers in English Law

*Komal Pervez**

Abstract

This paper is an investigation of the inadequacy of the current lack of legal framework which regulates dermal fillers in English law. It covers issues relating to the supply of dermal fillers, in addition to the social factors which control their demand. This paper examines the current gap in legislation by evidencing the shortcomings of the existing approach, and by recommending a statutory scheme to remedy these deficiencies. It is focused on the tripart regulation of product, premises and practitioners. Further, it locates this discussion within the wider topic of the popularity and commodification of non-invasive cosmetic procedures and the exploitation of the most vulnerable sectors of society. This paper will conclude by outlining why legislative intervention is necessary to combat the physical and social harms of dermal fillers.

Introduction

Scope

Dermal fillers are non-invasive injectables, typically composed of hyaluronic acid, that fill lines, wrinkles, and add volume to the face.[1] This article is an investigation of the inadequacy of the legal procedures which regulate dermal fillers in English law. It covers issues relating to the supply of dermal fillers, in addition to the social factors which control their demand.

Dermal Fillers account for 9/10 cosmetic procedures, making up 75% of the market value of cosmetic interventions, a £2.27 billion industry.[2] The risks associated with dermal fillers are 'infection, lumpiness, filler moving away from the intended area and requiring surgery, scarring, blocked blood vessels, and even blindness'.[3] Despite this, there are no mechanisms for post market surveillance of fillers, no regulatory authority governing practitioners, and no mandatory registration of the premises which administer fillers.

It is widely recognised that the current law is unmethodical and full of gaps in protection; the lack of regulation of dermal fillers fails to keep up with the social and demographic factors which fuel their demand.[4] This lack of regulation has also failed to keep up with developments in the modern understanding of patient autonomy and informed consent. Because the administration of dermal fillers is at present not tied to legislation, this report articulates recommendations for statutory reform as a way to regulate fillers. Statutory redress will enable

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[1] NHS, 'Face and lip fillers (dermal fillers)' (16 July 2019) <https://www.nhs.uk/conditions/cosmetic-procedures/dermal-fillers/> accessed 1 April 2019.

[2] Department of Health, *Review of Cosmetic Interventions Final Report* (2013) 17.

[3] NHS, 'Face and lip fillers (dermal fillers)' (16 July 2019) <https://www.nhs.uk/conditions/cosmetic-procedures/dermal-fillers/> accessed 1 April 2019.

[4] NHS, 'Face and lip fillers (dermal fillers)' (16 July 2019) <https://www.nhs.uk/conditions/cosmetic-procedures/dermal-fillers/> accessed 1 April 2019; Save Face, 'Consumer Complaints Audit Report' (2018) <http://www.saveface.co.uk> accessed 1 April 2020; Department of Health, *Review of Cosmetic Interventions Final Report* (2013) 9.

consumers to make an informed choice to undergo non-invasive cosmetic interventions in a way that preserves patient autonomy. It is thus recommended that a statute governing the regulation of fillers in the UK incorporate the tripart management of product, premises, and practitioners, titled *The Non-surgical Cosmetic Interventions Act.*

History

Awareness of the shortcomings of the regulation governing cosmetic surgery was initiated by the PIP scandal, in which industrial grade silicone was used in breast implants sold by a French company. Upon the revelation of the gross insufficiencies in protection for patients of cosmetic interventions, there was a scramble to tighten the safety and regulation of cosmetic surgeries.[5] In England, the Department of Health created an expert group to develop guidance in the aftermath of the PIP scandal, and tasked Earl Howe to present the response to the Department and Medical and Health Products Regulation Authority (MHRA).[6] The process exposed serious flaws in the regulation of cosmetic interventions which included the widespread circulation of unsafe products on the market, improper information of the risks involved in procedures, difficulty in tracing people who were recipients of cosmetic interventions, and a lack of protection for vulnerable populations who felt pressured to have cosmetic procedures both invasive and non-invasive.[7]

In light of this, the Secretary of State for Health Andrew Lansely requested a review of the regulation of cosmetic practice in England.[8] Carried out by Bruce Keough, the review was aimed at ensuring better protection for patients, and was published by the Department of Health and Social Care in 2013.[9] The findings of this review emphasised dermal fillers as a 'crisis waiting to happen',[10] stating that '[a] person having a non-surgical procedure has no more protection and redress than someone buying a ballpoint pen or a toothbrush'.[11] Today, there is still limited protection through the law for individuals who receive dermal fillers.

Structure

This article will demonstrate that greater scrutiny of products, practitioners, and premises is needed to safeguard against the potential risks associated with dermal fillers. The structure of this report is as follows: Part 1 demonstrates the shortcomings of the current approach, Part 2 describes a statutory scheme to remedy these deficiencies, and Part 3 discusses why legislative intervention is necessary to combat the physical and social harms of dermal fillers.

Dermal fillers should not need a scandal to the magnitude of PIP to prompt a transformation of the existing legal landscape. This article is aimed at achieving the overarching objectives of

[5] Department of Health, *Review of Cosmetic Interventions Final Report* (2013) 9.
[6] ibid.
[7] ibid.
[8] ibid.
[9] Simon Withey, Nigel Mercer and Alex Woollard 'Five years after Keogh's review of regulation in the aesthetic sector, what has changed?' (2018) 7 JAN 271, 272.
[10] Department of Health, *Review of Cosmetic Interventions Final Report* (2013) 5.
[11] ibid 5.

The Keogh Report of high-quality care, an informed and empowered public, and accessible resolution and redress.[12]

1. Context and shortcomings of the existing approach

In England, the Care Standards Act 2000 covers invasive cosmetic surgery and laser treatment, and s 9 of the Health & Social Care Act 2008 includes a provision for cosmetic procedures. Both of these statutes do not extend to non-invasive cosmetic procedures. The limited regulation of cosmetic surgery is controlled by the Care Quality Commission (CQC), which recommends self-assessment as a way to monitor cosmetic practitioners, as opposed to a central regulatory body. Without a regulatory body to impose a standard of practice, there is an onus on patients to ask the right questions, check the speciality, knowledge, and qualifications of their practitioners, inquire about aftercare, and resist being pressured into immediate treatments.[13] The CQC does not regulate non-invasive cosmetic procedures. Accordingly, subcutaneous injections of products such as dermal fillers are outside of the CQC's ambit, excluding fillers from this, albeit limited, form of protection.

In 2013, The Keogh Report evidenced the problems with misleading advertisements, inappropriate marketing, and unsafe practices of non-invasive cosmetic interventions.[14] Additionally, it articulated that self-regulation, coupled with poor monitoring by the CQC was an inadequate safeguard for patients.[15] It also stated that previous attempts at regulation were futile because they were voluntary, rendering unscrupulous practitioners largely unaccountable under this regime.[16] Following this, Health Education England (HEE) were tasked with 'developing an appropriate accredited qualification for providers of non-surgical interventions',[17] and the *Cosmetic Surgery (minimum standards) Bill*,[18] which included targeted regulation of non-surgical cosmetic interventions, was introduced in parliament but ultimately failed to pass.

In 2014, there was a Government Response to The Keogh Report which contained 40 recommendations on how to improve and incorporate cosmetic regulations into law.[19] Additionally, in 2015 the HEE published a report on the necessary qualification requirements for those who were administering non-surgical interventions as well as guidance on the application of said requirements. This guidance covered different treatment modalities and levels of learning ranging from Level 4 foundation to Level 7 postgraduate, reflecting the level of speciality required in the procedures.[20] In 2015, there was also an attempted review on Aesthetic Surgery Services by the CEN titled Aesthetic surgery and Aesthetic Non-Surgical

[12] ibid 8.
[13] Melanie Latham, 'If it Ain't Broke, Don't Fix It: Scandals, 'Risk', and Cosmetic Surgery Regulation in the UK and France' (2014) 22 Med Law Rev 384, 396.
[14] ibid.
[15] ibid 396.
[16] Department of Health, *Review of Cosmetic Interventions Final Report* (2013) 5.
[17] ibid 21.
[18] Cosmetic Surgery (Minimum Standards) Bill (HC Bill 60).
[19] Department of Health, *Government Response to The Review of The Regulations of Cosmetic Interventions* (2014).
[20] Health Education England, *Part Two: Report on Implementation of Qualification Requirements for Cosmetic Procedures: Non-Surgical Cosmetic Interventions and Hair Restoration Surgery'* (2015) 5.

Medical Services, which was aimed at helping to improve quality, safety, and patient experience across Europe.[21] CEN 403 entailed a six-point tailored plan which included banning the advertisement of cosmetic procedures, re-classifying dermal fillers as medicines, a compulsory registration of practitioners managed by the CQC, mandatory safety-audits, and revalidation and mystery shopping in CE marking. This was ultimately postponed.[22]

In 2016, Guidance for Doctors Who Offer Cosmetic Interventions was introduced. Within this, cosmetic interventions were defined as any intervention, procedure, or treatment carried out with the primary aim of changing a patient's physical appearance.[23] This definition included surgical and non-surgical procedures, both invasive and non-invasive. This guidance suggested that doctors must consider the patient's psychological needs, be realistic about the outcomes of any intervention, and give patients time and information to make an informed decision.[24] Moreover, it was recommended that cosmetic practitioners must market services responsibly without making unjustifiable claims or articulating unreasonable results.[25] Additionally in 2016, the Royal College of Surgeons produced the Professional Standards for Cosmetic Surgery, which addressed 'key areas of risk identified for cosmetic surgery, including communication, consent, professional behaviours, and dealing with the psychologically vulnerable patient', as well as the standards expected of practitioners undertaking cosmetic procedures.[26] Finally, in 2017 Regulation EU 2017/745 classified dermal fillers as medical devices which mandated the CE mark of conformity.[27] EU 2017/745 obliges that medical products manufactured and distributed in the UK contain the CE mark of conformity, users ensure its presence before use, and that manufactures only supply to reputable users.

Despite attempts at reformation, as it stands, there is still insufficient protection and redress for patients who receive fillers, largely because the recommended reforms evidenced above were implemented on a voluntary basis. Accordingly, as demonstrated by a Consumer Complaint Audit Report by Save Face from 2017-2018, there were 934 patient complaints regarding unregistered practitioners, with 616 dermal filler related complaints.[28] Additionally, in regards to the quality of the treatment received, 213 patients complained of swelling and bruising, 156 patients reported lumps and nodules, 122 felt they looked worse than before, 89 reported uneven results, 27 patients complained of an infection, and 6 people reported vascular occlusion and impending necrosis.[29] Moreover, despite the RCS guidance for a

[21] European Committee for Standardization, 'CEN publishes standard on Aesthetic Surgery services' (2015) <https://www.cen.eu/news/brief-news/pages/news-2015-001.aspx> accessed 1 April 2020.
[22] BAPS, 'Surgeons put forward regulation proposal' (23 January 2012) <https://baaps.org.uk/media/press_releases/1458/surgeons_put_forward_regulation_proposal> accessed 1 May 2020.
[23] General Medical Council, 'Guidance for doctors who offer cosmetic interventions' (2016) <https://www.gmc-uk.org/-/media/documents/good-medical-practice---english-20200128_pdf-51527435.pdf?la=en&hash=DA1263358CCA88F298785FE2BD7610EB4EE9A530> accessed 1 April 2019.
[24] ibid.
[25] ibid.
[26] Royal College of Surgeons, 'Professional Standards for Cosmetic Surgery' (2016) <https://www.rcseng.ac.uk/standards-and-research/standards-and-guidance/service-standards/cosmetic-surgery/professional-standards-for-cosmetic-surgery/> accessed 5 April 2020.
[27] Regulation 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices [2017] OJ L 117/1.
[28] Save Face, 'Consumer Complaints Audit Report' (2018) <http://www.saveface.co.uk> accessed 1 April 2020.
[29] ibid.

partnership with patients, 226 patients complained that they were ignored by the person who treated them, 83% of patients had treatments that were carried out by non-health care practitioners, and 31% of the patients did not know the qualifications or training of their practitioner.[30]

Product

Though the classification of dermal fillers as medical devices is welcomed, most of the provisions of EU 2017/745 relate to the manufacturing and distribution of fillers, rather than those who administer said products. A CE mark of conformity still allows for 100+ products to be marketed in the UK, whereas in the USA the FDA has limited the number to six.[31] Moreover, CE marking provides limited protection for patients as even the PIP implants were CE marked.[32] Additionally, though EU 2017/45 requires that all products manufactured and distributed in the EU contain a CE mark, users engage in post market surveillance, and report adverse incidents, there is no framework to implement these guidelines. Additionally, EU 2017/45 is overseen by the MHRA whose remit is to ensure the safety of medicines and devices, rather than who those products are used by. Notably, while there is an implicit expectation that manufacturers will only supply to reputable users, there is no current legislative framework to implement this. Furthermore, it is unclear how the MHRA monitors post market surveillance and collects data on adverse events. This lack of regulation has dismal effects on the wellbeing of patients, as 84% of patients did not know what products were used on them and how they were sourced according to the Save Face Audit.[33] This audit also revealed that 5% of patients were injected with a different product to that paid for, and 30% of practitioners were believed to be purchasing products from the internet.

Practitioners

The current absence of a statutory register is a failed opportunity to harmonise standards across the cosmetic industry which is made up of varying levels of training, expertise, and experience.[34] As it stands, there are only voluntary databases for clinics, not practitioners.[35] This leaves the public vulnerable to unregistered practitioners who practice without accountability or standardized training, limiting protection from the law. There is no statutory rule governing who may administer fillers and no uniform licencing process. Consequently, the onus is still largely on patients to ensure compliance with good practices. Moreover, because practitioners compete for market share, a strong commercial competition has led to significant quality and safety concerns.[36] Accordingly, though guidance has been created by the GMC and the RSC, without the requirement of a mandatory register and a minimum standard of training, these recommendations are toothless and have a limited influence in

[30] ibid.
[31] Nigel Mercer, 'What has happened to clinical risk in aesthetic surgery since 2009?' (2013) 19 CR 34, 35.
[32] ibid.
[33] Save Face, 'Consumer Complaints Audit Report' (2018) <http://www.saveface.co.uk> accessed 1 April 2020.
[34] Withey, Mercer and Woollard (n 9) 273.
[35] BAPS, 'Surgeons put forward regulation proposal' (23 January 2012) <https://baaps.org.uk/media/press_releases/1458/surgeons_put_forward_regulation_proposal> accessed 1 May 2020.
[36] Nuffield Council on Bioethics, *Cosmetic Procedures: ethical issues* (2017) xx.

improved education or practice.[37] Moreover, since the government has maintained the advancement of registration to a regulatory body on a voluntary basis, there is no policing of practitioners who do not comply with the suggested standard; this unlike health-care practitioners who are accountable to their respected regulatory boards.

Premises

The CQC oversees hospitals and private clinics in England, however its remit only extends to hospitals and clinics which provide cosmetic surgery, rendering facilities offering non-surgical procedures unregulated.[38] As non-surgical providers are not required to register with the CQC, 'the locations where dermal fillers are administered, and the peripatetic nature of many practitioners leaves local authorities unaware of where fillers are being administered'.[39] In the Save Face audit, 33% of patients reported receiving injectable treatments in a domestic setting, 26% of patients were treated in beauty salons, 17% used mobile practitioners, 11% of people were given treatment at a party, 9% at hair salons, and 4% in training venues and conferences.[40] The unrestricted mobility of practitioners administering dermal fillers in almost any premises creates an unsafe environment for patients. Moreover, while local authority bodies, such as Environmental Health Officers (EHOs), can inspect premises such as beauty studios which often administer fillers, they lack the training and expertise to determine whether staff are adequately trained and do not have the power to impose sanctions.[41] Conclusively, because there is no statutory redress or national guidelines for the licencing of non-surgical outlets, policing by local authorities is limited, as is the protection of patients.[42]

2. Recommended Reform

In order to achieve meaningful control of dermal fillers, regulation must be statutorily mandated. It is recommended that a statute governing the regulation of fillers in the UK incorporate the tripart regulation of product, premises, and practitioners, titled *The Non-Surgical Cosmetic Interventions Act.*

Product

The establishment of a 'Filler Adverse Event Register' is recommended, as suggested by the British Association of Dermatologists (BAD), to collect data on high-risk fillers,[43] with a commitment to gather and publish long term-data. Adverse incidents will be reported to the

[37] Withey, Mercer and Woollard (n 9) 273.
[38] Nuffield Council on Bioethics, *Cosmetic Procedures: ethical issues* (2017) xx.
[39] Department of Health, *Review of Cosmetic Interventions Final Report* (2013) 24.
[40] Save Face, 'Consumer Complaints Audit Report' (2018) <http://www.saveface.co.uk> accessed 1 April 2020.
[41] Department of Health, *Review of Cosmetic Interventions Final Report* (2013) 24.
[42] ibid.
[43] 'British Association of Dermatologists Response to the Department of Health's Review of the Regulation of Cosmetic Interventions Call for Evidence' (British Association of Dermatologists, October 2012) <https://www.bad.org.uk/librarymedia/documents/Response_to_Sir_Bruce_Keogh_review_from_The_British_Association_of_Dermatologists-151012.pdf> accessed 20 April 2020.

MHRA by manufacturers, the public, and the private sector through this register. The establishment of a toll-free hotline where adverse reactions related to injectables are reported to the MHRA in corroboration with the CQC is also recommended. This is already within the ambit of the CQC, as the reporting of significant events is required from doctors as a part of their revalidation.[44] These recommendations will protect patients, by mandating safety testing and providing a legislative framework for post-market surveillance.[45] Additionally, it is recommended that the MHRA work alongside the NHS to improve the governance of injectables through an Injectables Officer Role.[46] The establishment of this role will improve and link the National Reporting & Learning System, thereby strengthening reporting quality.[47] This framework will encourage a transparent reporting culture and better control of dermal fillers. Furthermore, it will contribute to long-term data collection and publication through the MHRA,[48] whose general priorities include a reporting system to ensure patient safety.[49] These steps are necessary to proactively pursue the aims of EU 2017/745, which are post market surveillance and the collection and publication of long-term data on adverse events.

It is also recommended that dermal fillers be elevated to the status of medicinal products and be designated as prescription only medicines (POMs),[50] limiting prescription to doctors, dentists, and prescribing nurses.[51] To enable this, it is recommended that the CQC extend its remit to include non-surgical cosmetic interventions. This is justified as 'treatments which have the capacity to cause serious harm should come under the regulatory powers of the CQC'.[52] It is recommended that dermal fillers be administered on a prescription only basis with guidelines similar to those of Botox injections.[53] Like Botox, fillers should only be prescribed after a face to face meeting with a doctor, dentist, or a prescribing nurse, with liability on the prescriber to ensure an accurate account of medical history and consent.[54] Independent prescription by healthcare professionals is essential because it ensures the safe administration of fillers even when some of the responsibility is delegated.[55] Since only medical professionals can qualify as prescribers, this would significantly limit the current widespread availability of fillers to the masses.

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[44] Department of Health, *Review of Cosmetic Interventions Final Report* (2013) 14.
[45] Mercer (n 31) 36.
[46] Department of Health, *Government Response to the Review of The Regulations of Cosmetic Interventions* (2014) 14.
[47] ibid.
[48] Department of Health, *Review of Cosmetic Interventions Final Report* (2013) 14.
[49] Medicines & Healthcare products Regulatory Agency, 'About us' (2020) <https://www.gov.uk/government/organisations/medicines-and-healthcare-products-regulatory-agency/about#our-responsibilities> accessed 20 April 2020.
[50] Jackie Doyle-Price, Written answer: Plastic Surgery (29 April 2019) <https://www.parliament.uk/business/publications/written-questions-answers-statements/written-question/Commons/2019-04-23/246486/> accessed 1 April 2020; Lorna Jackson, 'Should beauty therapists be injecting dermal fillers and botulinum toxins?' (10 February 2017) <https://www.consultingroom.com/blog/557/should-beauty-therapists-be-injecting-dermal-fillers-&-botulinum-toxins?> accessed 1 April 2020.
[51] Mercer (n 31) 36.
[52] Peter Walsh, 'Clinical Risk' (2012) 18(2) Journal of Patient Safety and Risk Management 65.
[53] NHS, 'Botox injections' (2019) <https://www.nhs.uk/conditions/cosmetic-procedures/botox-injections/> accessed 1 April 2020.
[54] Health Education England, *Part One: Qualification requirements for delivery of cosmetic procedures: Non-surgical cosmetic interventions and hair restoration surgery* (2015) 34.
[55] ibid.

It is also recommended that this consultation include a psychological assessment, recognizing that cosmetic procedures constitute physical interventions for primarily psychological benefits.[56] Prescribers having training or access to psychological experts through a multidisciplinary network and professional peer support will strengthen their understanding of the suitability of fillers for a diverse group of patients.[57] A psychological consultation will ensure that patients are aware of risks, desired results, and achievability in a realistic way which will ensure that patients have the right information to make an informed decision.

Practitioners

All practitioners who administer dermal fillers should be uniformly trained to a minimum national standard and will be required to register with a regulatory body. This will be known as the United Kingdom Cosmetic Surgery Regulatory and Standards Authority (OffCos), as recommended by the *Minimum Standards Bill*.[58] OffCos, in partnership with the CQC, will be responsible for examining and certifying practitioners and premises.[59] Moreover, a requirement for OffCos certification will be appropriate indemnity insurance, so patients have legal redress in the case of adverse events.

In 2015, HEE published a report on the necessary qualification requirements for those who were administering non-surgical interventions, as well as guidance on the application of said requirements. It is recommended that these requirements be adhered to as the minimum national standard. As it stands, the CQC does not regulate non-surgical cosmetic interventions,[60] however training to a minimum standard would harmonise training codes enabling efficient regulation. It is recommended that those performing non-surgical cosmetic procedures be registered with the English Health Board and pay a fee for membership into OffCos. This will implement a method of policing standards giving the Health Board the authority to 'suspend operations, impose fines, strike professionals off the register, and refer cases to the police'.[61] This recommendation will echo Danish legislation for surgical and non-surgical interventions, which mandates that the Health Board has the authority to carry out such inspections. Additionally, it is recommended that cosmetic practitioners certified by OffCos enter a publicly available register. A publicly available register will provide an avenue for potential patients to make informed choices, through an easily accessible one-stop shop to find out the level of training, expertise, and experience of practitioners.[62]

The Keogh Report recommends that non-healthcare practitioners may preform cosmetic procedures under the supervision of appropriately trained health-care professionals.[63] It is recognised that without definition, "supervision" has the potential to be abused, and could form a two-tier level of service, 'one of good practice by health-care professionals available at premium price, and the other composed of non-health care practitioners at a cheaper cost but

[56] Nuffield Council on Bioethics, *Cosmetic Procedures: ethical issues* (2017) xxvi.
[57] ibid.
[58] Cosmetic Surgery (Minimum Standards) Bill (HC Bill 60).
[59] ibid.
[60] Department of Health, *Review of Cosmetic Interventions Final Report* (2013) 9.
[61] ibid 19.
[62] Creative Research, *Regulation of Cosmetic Interventions: Research among the General Public and* Practitioners (2013) 7.
[63] Department of Health, *Review of Cosmetic Interventions Final Report* (2013) 20.

greater health risk'.[64] It is recommended however, that as long as non-health care practitioners obtain level 7 HEE qualifications, they should be permitted to administer fillers under the supervision of a qualified health-care practitioner. Under this regime, non-health care practitioners administering fillers must work under an appropriately qualified prescriber, who approves and oversees all the dermal injections administered. This framework will ensure practitioners working under the delegation of a doctor, dentist, or nurse, have adequate supervision, since the prescribers will maintain residual responsibility for the welfare of patients.[65] Additionally, this will bring a standard of professionalism to the industry as prescribers will only want to supervise properly trained practitioners.[66]

It is recommended that current voluntary registries such as the Joint Council for Cosmetic Practitioners (JCCP) and the Cosmetic Standards Practice (CSP) collaborate with OffCos to achieve one uniform regulatory body and central register, as agreed upon by *The Government Response to the Review of the Regelation of Cosmetic Interventions*.[67] The current absence of a statutory register is a failed opportunity to harmonise standards across the cosmetic industry, which is made up of varying levels of training, expertise, and experience,[68] leaving the public vulnerable to unregistered practitioners who practice without accountability or standardized training, thereby giving them limiting protection from the law. The benefits of a single regulatory body will be increased transparency for patients, legal redress, and protection.

Premises

The mandatory licensing of private facilities that administer dermal fillers is recommended. Training of practitioners must include guidance that mandates that non-surgical procedures must be conducted from a safe premises with infection control and room safety.[69] Room safety should include operating from a safe and sanitary space in accordance with the minimum national standard. As articulated by *The Government response to the review of the regulation of cosmetic interventions*, those administering non-surgical cosmetic interventions should have clear guidance on what makes a safe premises and the responsibilities and upkeep involved in maintaining it.[70] It is recommended that these standards be adhered to as the minimum national standard, and that OffCos certification includes the obligation to abide by this defined standard of practice.[71]

In a study conducted among the public and practitioners, a female in her late twenties opted for a non-surgical cosmetic intervention because the premises were 'professional looking',

[64] Jackson (n 50).
[65] Health Education England, *Part One: Qualification requirements for delivery of cosmetic procedures: Non-surgical cosmetic interventions and hair restoration surgery* (2015) 34.
[66] Department of Health, *Review of Cosmetic Interventions Final Report* (2013) 8.
[67] Department of Health, *Government Response to the Review of The Regulations of Cosmetic Interventions* (2014) 12.
[68] Withey, Mercer and Woollard (n 9) 273.
[69] Department of Health, *Government Response to the Review of The Regulations of Cosmetic Interventions* (2014) 8.
[70] ibid 8.
[71] Ibid.

which she judged by walking past them.[72] As evidenced in this report, 'This was enough to reassure her – she did not feel it necessary to look into the qualifications of the person [...] because it was not an extreme procedure'.[73] The same study found that the appearance of clinics, the uniforms, and mannerisms of the staff were all used as 'proxy indicators of the level quality provided'.[74]

Mandating that the clinics which administer dermal fillers be licenced will demystify facilities operating under fancy monikers or the appearance of professionalism. It is recommended that premises which administer dermal fillers should have a licensing process similar to those of tattoo shops.[75] This will require registration on the mandatory national register through OffCos, in addition to the local council. Moreover, like tattoo licencing, practitioners will only be permitted to work where they are licenced. The conglomeration of monitoring through OffCos and local by-laws will ensure patients have ample protection. Local by-laws will regulate hygiene and cleanliness, while OffCos will control the quality of care provided, with jurisdiction to determine whether staff are properly trained and following standardized practice. The renewal of this license will ensure that practitioners are always up to date with the required standards. Moreover, once the license is obtained, it must be displayed in a prominent place to ensure that individuals are not fooled by outward appearances as indicators of the quality of treatment provided.

The licencing of non-medical facilities which provide non-surgical cosmetic procedures will echo a Scottish Law Reform proposal which recommends that businesses providing non-surgical cosmetic procedures be licensed.[76] Under this proposed reform, local EHOs will assess clinics against specified standards before granting a license.[77] Mandatory licencing of premises will include independent clinics which do not provide services as part of the NHS, with the term 'service' encompassing consultations, treatments, aftercare, and investigation.[78]

3. Controls on demand

As demonstrated by Lord Donaldson in *NHS Trust v T*,[79] the law allows 'a patient to make a decision for any reason, rational, or irrational'.[80] In *Re C*,[81] Thorpe J gives the best case for

[72] Creative Research, *Regulation of Cosmetic Interventions: Research among the General Public and* Practitioners (2013) 20.
[73] ibid.
[74] ibid 54.
[75] 'Tattoo, piercing and electrolysis licence (England and Wales)' (2020) <https://www.gov.uk/skin-piercing-and-tattooing> accessed 5 April 2020.
[76] Scottish Government, *Consultation on the Regulation of Non-Surgical Procedures in Scotland* (January 2020).
[77] 'Regulation of non-surgical cosmetic procedures: consultation' (January 2020) <https://www.gov.scot/publications/consultation-regulation-independent-healthcare/pages/4/> accessed 1 April 2020.
[78] Healthcare Improvement Scotland, 'Regulation of independent clinics from April 2016 (2020) <http://www.healthcareimprovementscotland.org/our_work/inspecting_and_regulating_care/independent_healthcare/regulation_of_clinics.aspx> accessed 1 April 2020.
[79] *NHS Trust v T* [2004] EWHC 1279.
[80] John Coggon, 'Varied and Principled Understandings of Autonomy in English Law: Justifiable Inconsistency or Blinkered Moralism?' (2007) 15 Health Care Analysis 235.
[81] *Re C (Adult: Refusal of Medical Treatment)* [1994] 1 WLR 290.

assessing this, declaring that capacity is found when patients comprehend and retain information, believe it, and weigh it out against other options.[82] Combined with Lord Donaldson's assertion, as long as patient capacity is present, the motivations behind a patient's decisions are irrelevant.[83] Thus, health-care law's ideal patient is a rational decision-maker with knowledge and understanding, who can have their rights protected through law. In medical law, autonomy is protected through informed consent; this is based on doctors providing thorough information about the risks, benefits, and alternatives of a procedure so the patient can make an informed decision.[84] Because dermal fillers are currently unregulated, patients are often not given adequate information to come to a knowledgeable decision. Moreover, the current law does not reflect the communal harms of the widespread availability of fillers that hamper the exercise of patient autonomy through external social causes. Additionally, the current law regulating fillers does not accommodate the modern patient as defined by Lord Kerr in *Montgomery v Lanarkshire,* as a rights holder, as opposed to a passive recipient of treatment.[85] In modern medical law, patients have the right to be informed of risks even if there is a small chance of their occurrence.[86] Statutory intervention of products, practitioners and premises will harmonise the regulation of fillers with modern medical law by improving informed consent and providing legal redress for prospective patients.

Non-surgical cosmetic interventions can be utilised as tools of empowerment,[87] however the unregulated availability and commodification of dermal fillers is evidenced by the Nuffield Report as contributory to social and communal ills.[88] This report also cites wanting to 'fit in' as a reason prospective users were attracted to cosmetic procedures, with the attractiveness of cosmetic intervention increasing as the procedures became more familiar to patients.[89] This is detrimental to society because the normalisation of collective attitudes towards cosmetic interventions fosters an extreme focus on appearance and discrimination towards those who do not uphold these standards. Additionally, it distorts reality by promoting one standard of beauty, 'contributing to a youth culture that distains aging and the elderly'.[90] This adds to the idea that happiness can only be achieved through cosmetic advancements, [91] by normalizing perfection and pathologizing imperfection.[92] Furthermore, it exploits the inequalities between those who have the economic means to attain an idealised image, while simultaneously putting pressure on socioeconomically disadvantaged sectors of society to achieve those stereotypes. The widespread and unregulated availability of fillers acts as a catalyst to these external pressures, influencing individuals to get dermal fillers without sufficient regard to their risks.

[82] Coggon (n 80).
[83] ibid.
[84] John Coggon and José Miola, 'Autonomy, Liberty, and Medical Decision-Making' (2011) 70 Camb Law J 523, 526.
[85] *Montgomery v Lanarkshire Health Board* [2015] UKSC 11; [2015] 2 WLR 768 para 75.
[86] *Chester v Afshar* [2004] UKHL 41.
[87] Jo Bridgeman and Susan Millns, *Law and Body Politics: Regulating the Female Body* (Dartmouth 1995).
[88] Nuffield Council on Bioethics, *Cosmetic Procedures: ethical issues* (2017) xxii.
[89] ibid.
[90] Danielle Griffins and Alex Mullock, 'Cosmetic Surgery: Regulatory Challenges in Global Beauty Market' (2017) 26 Health Care Analysis 220, 224.
[91] Nuffield Council on Bioethics, *Cosmetic Procedures: ethical issues* (2017) xxii.
[92] Griffins and Mullock (n 90) 220.

Controlling Products

There is consensus among healthcare practitioners that dermal fillers should be administered on a prescription only basis.[93] In the past, Governments have resisted the classification of fillers as POMs due to a lack of data connecting their administration to harms, deeming reports of adverse events anecdotal.[94] That being said, though practitioners are encouraged to collect and show data to the MHRA and the JCCP, unless this is statutorily mandated, there is no way to guarantee long-term data collection which links fillers to the harms they cause. Additionally, this is counterintuitive as it delays aid in patient welfare. It should not take a scandal of the magnitude of PIP to prompt legislative protection, since the government has acknowledged and supported the proposition that fillers should be prescription only, or at the very least have controlled administration.[95] Additionally, limiting dermal fillers to POMs will cultivate social responsibility and accountability among practitioners. Fillers as POMs will enable health-care practitioners to prescribe them according to patients' best interests in contrast to market demands and consumerism.[96] Furthermore, fillers as POMs will ban financial inducements and time-limited deals that encourage vulnerable sectors of society to undergo risky procedures in the name of beauty.[97] As evidenced by the Save Face Audit, 64% of patients chose their practitioners based on price, cheap deals, and offers.[98] This demonstrates the commodification of non-invasive surgery and its detrimental effects on those who are economically vulnerable. Moreover, fillers as POMs will allow practitioners to deny treatment if medically and psychologically necessary, and prevent patients from going to other unscrupulous providers offering cheaper services.

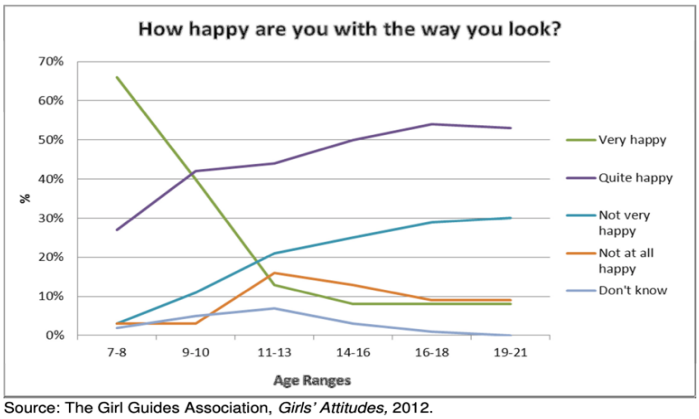
Further, fillers as POMs will improve the consent process and patient autonomy. Patient autonomy is related to conceptions of liberty and freedom to act without the influence of a third party. Dworkin describes autonomy as 'liberty, individuality, absence of external causation, and knowledge of one's own interests'.[99] Thus, rationality, knowledge, and understanding is crucial to autonomy.[100] Fillers as POMs will improve the consent process, by mandating that prescribers take and document the medical history of patients, manage expectations, and communicate realistic outcomes. Additionally, this will have a symbolic effect and reduce the demand of fillers, as a prescription would make patients aware of the risks involved in the procedure prior to their administration.

Additionally, the ASA and CAP, who write and uphold the advertising codes in the UK, prohibit the advertisement of POMs.[101] Consequently, the classification of fillers as POMs

[93] British Association of Dermatologists, 'Response to the Department of Health's Review of the Regulation of Cosmetic Interventions Call for Evidence' (October 2012) <https://www.bad.org.uk/library-media/documents/Response_to_Sir_Bruce_Keogh_review_from_The_British_Association_of_Dermatologists-151012.pdf> accessed 20 April 2020; Nuffield Council on Bioethics, *Cosmetic Procedures: ethical issues* (2017) xxix.
[94] Withey, Mercer and Woollard (n 9) 273.
[95] ibid.
[96] Nuffield Council on Bioethics, *Cosmetic Procedures: ethical issues* (2017) xxvi.
[97] Griffins and Mullock (n 90) 220.
[98] Save Face, *Consumer Complaints Audit Report* (2018) <http://www.saveface.co.uk> accessed 1 April 2020.
[99] Gerald Dworkin, *The Theory and Practice of Autonomy* (Cambridge University Press 1988) 6.
[100] Coggon and Miola (n 84) 526.
[101] ASA, 'Beauty and Cosmetics: Botulinum toxin products' (5 November 2019) <https://www.asa.org.uk/advice-online/beauty-and-cosmetics-botulinum-toxin-products.html> accessed 5 April 2020.

will ban their advertisement through both traditional and social media outlets.[102] The classification of fillers as POMs will prevent endorsed advertisements from health professionals and celebrities, and the use of before and after photographs in marketing.[103] In January 2020, the ASA outlined new guidelines for the advertisement of Botox on social media. This will use monitoring technology to automatically find and remove advertisements of Botox on Instagram, with non-compliance reported to the MHRA or the respective regulatory body.[104] This combats the former shortcomings of the regulatory approach, which was limited in the detection of advertisement breaches on social media.[105]

The prevalence and accessibility of images, advertising, and celebrity endorsements through the internet, and social media in particular, have encouraged changing consumer attitudes towards beauty and led to growth of the industry. As shown below, a study conducted by the Girl Guides Association revealed girls as young as eleven years old becoming unhappy with the way they look because of social media and celebrity culture.[106]



Source: The Girl Guides Association, *Girls' Attitudes*, 2012.

Evidently, there is a need for greater protection of young users' exposure to cosmetic intervention, both invasive and non-invasive. A cultural emphasis on physical perfection renders young users susceptible to media manipulation, and the perception of cosmetic surgery as a commodity.[107] The inclusion of fillers as POMs will ensure advertisement is conducted in a way that is socially responsible as a way to protect vulnerable users and preserve autonomy.[108]

Controlling practitioners and premises

The Nuffield Report suggests 'shared decision making where patients play an active role in decisions about their treatment or care' as an enhanced model to the traditional consent

[102] ibid.
[103] ibid.
[104] ASA, 'Enforcement Notice Advertising Botox and other botulinum toxin injections' (2019) <https://www.asa.org.uk/uploads/assets/a8fa05da-b3ee-4528-82095e7bba2a3e5c/Enforcement-Notice-Advertising-Botox-and-other-botulinum-toxin-injecti.pdf> accessed 5 April 2020.
[105] Department of Health, *Review of Cosmetic Interventions Final Report* (2013) 40.
[106] ibid 9.
[107] ibid 11.
[108] ibid 42.

process between doctors and patients.[109] The effectiveness of the doctor-patient relationship will be strengthened by empowering doctors and patients to use the publicly available register as a resource for 'information, and social authority for positive health outcomes'.[110] Through a statutorily mandated and publicly available register, patients and doctors will be able to engage in shared decision making, strengthening the partnership between them.[111] Moreover, a mandatory register and training to a minimum national standard will eliminate quick training programs fuelled by the widespread demand for cheap fillers, without regard to associated health risks. This will contribute to an empowered public, levelling the power dynamic between doctor and patient.[112] Additionally, a central register will ensure that patients have access to information and support when making the decision to get fillers, aiding their ability to make an informed decision.

A mandatory register of practitioners and premises will contribute to high-quality care by providing a multidisciplinary network of professionals overseen by OffCos and the CQC. This will encourage 'communication, partnership and teamwork',[113] creating a professional network backed by statute which will allow practitioners to recognise the limits of their competence and work together for the well-being of patients. Additionally, the incorporation of a national complaints line will provide accessible resolution and redress, remedying the current gap in law. Finally, it will also improve the safety and quality of procedures, which will promote and protect the patient's health as well as the public at large.[114]

Conclusion

Due to the lack of regulation, non-surgical cosmetic interventions have treated patients like consumers without adequate statutory safeguards to make fully informed decisions. *The Non-Surgical Cosmetic Interventions Act* will improve the current law which regulates dermal fillers, by regulating the products on the market through testing and long-term data collection. Additionally, it will improve the regulation of practitioners by mandating a central regulatory authority, mandatory training to minimum standards, and registration on a publicly available register. Finally, regulation of premises will incorporate the licencing of facilities which administer fillers. This will ensure that patients know that the products used on them have been tested, their chosen clinic is regulated, their practitioner is appropriately trained, and that they have access to redress in case of adverse events.

[109] Nuffield Council on Bioethics, *Cosmetic Procedures: ethical issues* (2017) xxvi.
[110] Felicity Goodyear-Smith and Stephen Buetow, 'Power Issues in the Doctor-Patient Relationship' (2002) 9 Health Care Analysis 9449, 459.
[111] ibid.
[112] Griffins and Mullock (n 90) 220.
[113] ibid.
[114] General Medical Council, *Consent: patients and doctors making decisions together* (2008).

The Regulation of Non-Surgical Cosmetic Procedures

*Sophie Cole**

Abstract

The growth of non-surgical cosmetic procedures has brought with it concerns over the regulation of the industry. Procedures such as dermal fillers and botox injections are becoming increasingly popular. Yet despite the risks involved in these procedures, such as infection and scarring, there is a worrying lack of legislation governing the sector. Dermal fillers, for example, can be administered by anyone, with no training required.

This law reform project therefore proposes the introduction of a comprehensive statute to greater control the products, premises and practitioners involved in the administration of non-surgical cosmetics. The project will assess the current legislation, and the lack of it, before considering a new statute and the positive impact this could have.

Introduction

The purpose of this Law Reform Project is to propose the introduction of greater regulation of non-surgical cosmetic procedures in the UK. The current lack of legislation in this area means that patients are left vulnerable to exploitation. It will therefore be suggested that a statute should be introduced to regulate the products, premises and people who can administer such procedures.

'Non-surgical cosmetic procedures' include a variety of treatments. The most important ones for the purpose of this proposal are botulinum toxin (botox henceforth) and dermal filler injections. Other examples include chemical peels, laser treatment and hair restoration surgery.

The cosmetic industry has continued to grow in recent years. Virtually all cosmetic interventions occur in the private sector. Whilst the whole industry, including surgical and non-surgical options, was estimated to be worth £2.3 billion in 2010,[1] a recent report suggests that non-surgical procedures alone will soon be worth £3 billion.[2] Accounting for 9 out of 10 cosmetic interventions, and approximately 75% of the total market value, non-surgical options are by far the most popular in the market.[3]

The growth of these treatments can be attributed, in part, to the increasing use of social media and how body image is portrayed online. Media coverage of celebrities' procedures and the increasing availability of treatments has created 'a climate in which having a cosmetic procedure is increasingly regarded as normal and the associated risks are often underestimated'.[4]

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[1] 'Cosmetic Surgery Market Intelligence' (Mintel, 2010) <https://reports.mintel.com/display/480789/#> accessed 11 April 2020.

[2] 'Cosmetic Surgery UK Market Review' (LaingBuisson, 2019) <https://www.laingbuisson.com/wp-content/uploads/2019/09/Cosmetic_Surgery_1ed_SALES_FLYER.pdf> accessed 10 April 2020.

[3] *Review of the Regulation of Cosmetic Interventions* (Department of Health 2013) para 3.26 (Keogh Report).

[4] 'Regulation of Cosmetic Interventions: Research among the General public Practitioners' (Creative Research, 28 March 2013)

Non-surgical cosmetic procedures do offer a variety of benefits, providing the recipient the chance to improve their appearance and boost their self-esteem. Autonomous adults should therefore have the choice to opt for these types of interventions. However, the dearth of guidelines and regulation in this area has meant that the consumer is often left without the essential protections that one might expect. This proposal is therefore not seeking to cast judgment over those who choose to engage in these procedures, but to empower patients with the necessary information about what the procedures involve and to enforce high standards across the sector.

Despite risks involved in these procedures, such as infection, burning and scarring, there is a concerning lack of regulation in this area.[5] Dermal fillers, for example, can be administered by anyone; there are no requirements for training or knowledge. Moreover, there is limited regulation concerning the products used, and the premises in which such procedures can be carried out. Whilst the PIP silicone breast implant scandal raised issues regarding the regulation of surgical cosmetic procedures, when it comes to non-surgical interventions, there is seemingly less emphasis on the risks involved.[6] Therefore, it has been argued that the industry has developed into a 'wild west' in regulatory quarters.[7]

These issues have been considered before, but insufficient action has been taken. The Review of the Regulation of Cosmetic Interventions, undertaken in 2013 by Bruce Keogh, highlighted many of the concerns with the lack of regulation and set out a list of recommendations as to how the sector could be improved .[8] Whilst the government paid lip service to many of these recommendations, no significant change occurred, and in some areas, particularly concerning product regulation, responsibility was passed to the EU.[9]

Following this, a bill was proposed to implement some of these suggested changes, however this failed to complete its passage through Parliament and so was not enacted.[10] Another government response followed, which included 40 recommendations, but little action was taken.[11]

The regulations that do exist in this area are predominantly based on EU regulations and so these must be considered, though over the next few years, this will no doubt change owing to Brexit.

<https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/192029/Regulation_of_Cosmetic_Interventions_Research_Report.pdf> accessed 12 April 2020.

[5] Keogh Report (n 3) para 2.4.

[6] Victoria Martindale and Andre Menache, 'The PIP scandal: an analysis of the process of quality control that failed to safeguard women from the health risks' (2013) 106 J R Soc Med 173.

[7] 'UK Non-Surgical Cosmetic Treatments Could Grow to £3BN' (International Medical Travel Journal, 24 December 2018) <https://www.imtj.com/news/uk-non-surgical-cosmetic-treatments-could-grow-3bn/> accessed 12 April 2020.

[8] Keogh Report (n 3).

[9] *Government Response to the Review of the Regulation of Cosmetic Interventions* (Department of Health 2014).

[10] Cosmetic Surgery (Minimum Standards) HC Bill (2012-13) [60].

[11] *Government Response to the Review of the Regulation of Cosmetic Interventions* (Department of Health 2014).

1. The Current Law

The current law governing non-surgical cosmetic procedures is piecemeal and fails to address many of the main issues in the sector. Most of the existing legislation focuses predominantly on surgical interventions.[12] The Care Standards Act, for example, covers invasive surgery and laser treatment.[13] Moreover, the Care Quality Commission (CQC), which has regulated the sector since October 2010, concerns 'cosmetic surgery that involves instruments or equipment being inserted in the body'.[14] The CQC therefore does not regulate the non-surgical procedures with which this reform proposal is concerned. Thus, in his report, Keogh argued that 'a person having a non-surgical cosmetic intervention has no more protection… than someone buying a ballpoint pen'.[15] However, this is not to say that there is no current regulation of the practices in this area, and these will now be explored.

Practitioners

Firstly, there are few statutory limits governing who can lawfully offer such procedures. Under the Medicines Act, prescription medicines such as botox may only be prescribed by dentists, doctors and qualified independent prescribers.[16] Yet there are no controls over the administration of botox, and direct purchase online can circumvent its prescription-only status.[17] Moreover, when it comes to other procedures, such as cosmetic peels and dermal fillers, there are no restrictions as these products do not require a prescription to be obtained. Therefore, these procedures may be carried out by anyone, regardless of qualifications.[18]

Whilst there is a dearth of statutory guidelines concerning the administration of these procedures, professional standards play an important role in regulating the sector. Most UK mainstream healthcare professionals are regulated. The relevant regulatory body sets out standards in their codes of conduct. Doctors, for example, are regulated by the General Medical Council (GMC). All doctors must be registered with the GMC with a licence to practice. The GMC offers guidance for doctors carrying out cosmetic interventions.[19] This includes ensuring that doctors provide patients with all the information they require and that they consider the patients' psychological needs.[20] Advice is also available concerning the prescribing of products, and states that patients must meet with a prescriber face-to-face before botox can be administered. There are even regulations to ensure that professional accountability is retained by prescribers for the product's safe administration.[21]

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[12] Health and Social Care Act 2008, s9.
[13] Care Standards Act 2000.
[14] Care Quality Commission, 'Choosing cosmetic surgery' (November 2019) <https://www.cqc.org.uk/help-advice/help-choosing-care-services/choosing-cosmetic-surgery> accessed 15 April 2020.
[15] Keogh Report (n 3) 5.
[16] Medicines Act 1968, s58.
[17] David Archard and others, 'Cosmetic procedures: ethical issues' (Nuffield Council on Bioethics 2017) para 4.4.
[18] Keogh report (n 3) para 3.31.
[19] 'Guidance for doctors who offer cosmetic interventions' (General Medical Council, 2016) <www.gmcuk.org/Guidance_for_doctors_who_offer_cosmetic_interventions_210316.pdf_65254111.pdf> accessed 15 April 2020.
[20] ibid.
[21] 'Good practice in prescribing and managing medicines and devices' (General Medical Council, 2019) <http://www.gmc-uk.org/guidance/ethical_guidance/14326.asp> accessed 15 April 2020.

Whilst this is helpful in outlining doctors' duties in performing such procedures, none of this guidance is binding on non-medical professionals. Non-surgical procedures such as dermal fillers are often carried out by non-healthcare professionals, such as beauty therapists. The Health and Safety at Work Act does cover these premises, requiring employers to ensure that their employees are not exposed to health and safety risks.[22] However, there are no additional legislative requirements compared to any other professional working in the service sector. Whilst there are various training programmes available for beauty therapists, such as BTECs and NVQs, these qualifications may not include training relevant to these kinds of cosmetic treatments. There are non-compulsory standards bodies to cover these professionals, such as HABIA, but membership is entirely voluntary, and so they do not have a significant regulatory role.[23]

The Keogh Report emphasised this lack of regulation, and suggested that 'all non-surgical procedures must be performed under the responsibility of a clinical professional who has gained the accredited qualification'.[24] It was also recommended that all practitioners should be on a central register, with entry to said register being subject to meeting certain standards.[25] The Cosmetic Surgery (Minimum Standards) Bill included provisions to introduce a central regulatory body, with which all practitioners must be registered, yet the bill was rejected.[26]

The Department of Health did agree that training and standards of non-surgical interventions should be improved and that certain procedures should require clinical supervision, but little action was taken. The Government also chose not to adopt a statutory registration system of the type proposed, claiming that the existing professional registers were sufficient. Support was given, however, to voluntary and independent schemes. The Joint Council for Cosmetic Practitioners, for example, emerged to oversee voluntary regulation and the Cosmetic Standards Practice Authority to set evidence-based standards.[27] Whilst they do provide education for and accreditation of practitioners, the voluntary nature of this register does nothing to prevent unscrupulous individuals from continuing to carry out non-surgical procedures with little or even no training. The Department of Health did promote greater clinical involvement in procedures and stated that legislative options would be 'explored', but again, little action has been taken.[28]

Premises

The regulation of premises shows that insufficient safeguards exist when these procedures are undertaken outside of the medical industry. For example, whilst all health and social care providers must be registered with the CQC if they carry out any 'regulated activities' under

[22] Health and Safety at Work etc. Act 1974, s3(1).
[23] 'The "Standard Setting Body" for the Hair and Beauty Industry' (HABIA, 2019) <https://habia.org/> accessed 16 April 2020.
[24] Keogh Report (n 3), para 3.17.
[25] ibid.
[26] Cosmetic Surgery (Minimum Standards) HC Bill (2012-13) [60].
[27] 'CPSA Supervision Matrix' (CPSA, 2018) <http://www.cosmeticstandards.org.uk/uploads/1/0/6/2/106271141/20180103_cpsa_supervision_matrix_final.pdf> accessed 16 April 2020.
[28] *Government Response to the Review of the Regulation of Cosmetic Interventions* (Department of Health 2014) 9.

the Health and Social Care Act,[29] this does not include premises that carry out solely non-surgical procedures. Therefore, whilst the CQC inspects GPs' and dentists' premises, it does not cover the premises of pharmacies, beauty therapists', or other 'High Street' practices.[30] It has thus been suggested that '70% of clinics in the private sector are effectively unregulated'.[31]

The CQC does, however, offer recommendations for patients seeking non-surgical procedures in any clinic, such as 'asking the right questions' and comparing costs.[32] Yet this is simply general advice and the lack of regulation means that the onus to check the safety and conditions of the premises is once again placed on the patient. Moreover, although Local Authority Environmental Health Officers (EHOs) can inspect such premises to ensure that they comply with general health and safety requirements, they lack the expertise to determine whether the practices being carried out are of an adequate standard. EHOs also lack sanctioning powers. For these reasons, in the Keogh report it was stated that 'Local Authorities [are] not the most appropriate monitor'.[33]

Products

Finally, it is worth considering the regulations that govern the products used. Product regulation has been based on a number of EU Directives. This has recently been amended following Brexit under the UK Cosmetic Regulation,[34] but as this mirrors the areas with which this proposal is concerned, the EU directives will continue to be referred to. The responsibility for regulating medical devices and medicines, and putting these directives into practice, falls on the Medicines and Healthcare Products Regulatory Authority (MHRA).

Cosmetic Products (Safety) Regulations

The Cosmetic Products (Safety) Regulations brought into law the EU Cosmetics Directive.[35] This was recast in 2009 as a European Regulation.[36] The regulations include detailed labelling and record keeping requirements.

EU law defines cosmetic products as substances which are intended to make contact with the external parts of the body, or with teeth, etc. The purpose of the cosmetic product must be to change the appearance, correct body odours, etc. Therefore, these regulations are concerned with make-up, soaps and various hair products.[37] The regulations do not, however, include many of the products used in cosmetic procedures. For example, the Directive specially mentions that peeling products are not classified as cosmetics based on the content

[29] Health and Social Care Act 2008 (Regulated Activities) Regulations 2014.
[30] 'Choosing Cosmetic Surgery' (Care Quality Commission, 14 November 2019) <https://www.cqc.org.uk/help-advice/help-choosing-care-services/choosing-cosmetic-surgery> accessed 16 April 2020.
[31] Cosmetic Surgery (Minimum Standards) Bill Deb 17 July 2012, col 857.
[32] Care Quality Commission (n 30).
[33] Keogh Report (n 3) para 3.28.
[34] The Product Safety and Metrology (EU Exit) Regulations 2019.
[35] The Cosmetic Products (Safety) Regulations 2008.
[36] Council Regulation (EC) 1223/2009 of the European Parliament and of the Council of 30 November 2009 on cosmetic products [2009] OJ L342.
[37] ibid.

of salicylic acid.[38] Schedule 3 also lists those substances which may not be included in cosmetics.[39]

Medicine

Medicines are defined as substances used to diagnose or treat conditions through interaction with the body.[40] Botox, for example, is classed as a prescription-only medicine.[41] EU Directive 2001/83 requires medicines to be granted market authorisation from MHRA before being placed on the market.[42] Companies must test drugs through MHRA approved clinical trials. Once MHRA is satisfied that the medicine works and is safe, wholesalers must prove that the manufacture and distribution meets certain standards.

Medical Devices

Medical devices include a wide range of products.[43] Medicines and medical devices are regulated under separate systems. Medical devices must be approved by 'notified bodies'.[44] These are private sector organisations, whose approval is required before a European Conformity, or 'CE' mark can be placed on the device. The application of a CE mark means that the device is considered safe for use and can be marketed in all EU countries without further controls.[45]

The notified bodies are regulated by a Competent Authority; in the UK this is MHRA. This body can take regulatory action if necessary, such as requiring products to be removed from the market. MHRA is therefore focused on post-market surveillance, and any adverse incidents resulting from the use of these devices must be reported to them.

A key criterion for a product to be classified as a medical device is that the intended use must be for 'diagnostic and/or therapeutic purposes'.[46] Therefore, products whose purpose is entirely cosmetic will not be included. For example, breast implants do qualify as medical devices, presumably because of their role in reconstructive surgery.

However, until very recently, many dermal fillers were not considered 'medical devices'. Unless such fillers were marketed for medical purposes, or mixed with anaesthetic substances, they lacked the therapeutic requirement to be considered a medical device.[47] Therefore, those used for entirely cosmetic purposes were exempt from these regulations.

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[38] ibid Annex 1.
[39] ibid Schedule 3.
[40] The Human Medicines Regulations 2012.
[41] Council Directive (EC) 2001/83/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to medicinal products for human use [2001] OJ L311.
[42] ibid.
[43] Council Directive 90/385/EEC of 20 June 1990 on the approximation of the laws of the Member States relating to active implantable medical devices [1990] OJ L189.
[44] ibid.
[45] 'Medical devices: conformity assessment and the CE-mark' (gov.uk, 27 January 2015) <https://www.gov.uk/guidance/medical-devices-conformity-assessment-and-the-ce-mark> accessed 17 April 2020.
[46] Council Directive 93/42/EEC of 14 June 1993 concerning medical devices [1993] OJ L169.
[47] ibid.

General Products Safety Directive

For those products that do not fall under the definition of medicines, medical devices or cosmetics in the above directives, they may be covered by the General Product Safety Directive,[48] transposed into UK law as The General Product Safety Regulations.[49] The regulations are intended for consumers that are supplied with products for their own use during the provision of a service. They apply to products which lack other applicable provisions in Community Law relating to the product's safety. They are therefore very broad and simply maintain a general responsibility on distributors. In fact, products such as toys and make-up have more stringent requirements than this directive offers. Products covered by this directive include chemical peels sold to the consumer for home use.

This directive was also the main regulator of those dermal fillers not covered by the medical devices regulations owing to their entirely cosmetic status. This directive would cover those placed on the market and sold to the consumer for self-use. Yet those products supplied as part of a professional service, where the product is not being self-administered, were not covered by these regulations, but instead may simply have to comply with the Health and Safety at Work Act.[50] Therefore, in some cases, dermal fillers are exempt from any product safety regulations. This led Keogh to consider that 'most dermal fillers have no more controls than a bottle of floor cleaner', owing to the lack of recognition of their use in medical settings.[51]

Recent Change

However, following pressure from various groups for their inclusion as a device, MHRA has confirmed that from May 2020 all dermal fillers, not just those with a medical purpose, will be regulated as medical devices under Regulation EU 2017/745. This means that fillers must be granted a recognised CE mark from a notified body to confirm their safety. However, MHRA stated that it would not make the fillers prescription only, which was one of the key recommendations put forward by the Keogh report.

2. Reform Proposal

The law reform proposal is that a comprehensive statute should be introduced to regulate all surgical and non-surgical cosmetic procedures. As this proposal is concerned with the latter, only these provisions will be included in the proposal.

The proposal reflects the issues raised in the Keogh Report, and has taken inspiration from recent Scottish proposals,[52] as well as the failed Cosmetic Surgery (Minimum Standards) Bill.[53]

[48] Council Directive 2001/95/EC of the European Parliament and of the Council of 3 December 2001 on general product safety [2001] OJ L11.
[49] The General Product Safety Regulations 2005.
[50] Health and Safety at Work etc. Act 1974.
[51] Keogh report (n 3) 5.
[52] *Consultation on the Regulation of Non-Surgical Cosmetic Procedures in Scotland* (The Scottish Government, Consultation 2020).
[53] Cosmetic Surgery (Minimum Standards) HC Bill (2012-13) [60].

Cosmetic Interventions (Minimum Standards) Bill 2020

Section 1: The Cosmetic Procedures Regulatory Body

(1) There shall be a centralised body established known as the Cosmetic Procedures Regulatory Body (CPRB). CPRB will be the main regulatory body of the sector.
(2) There will be two main subsidiary bodies of CPRB;
    (i) Care Quality Commission (CQC)
    (ii) Non-surgical Interventions Commission (NSIC)
(3) The CQC will be the main body to oversee surgical cosmetic procedures.
(4) The NSIC will be the main body to oversee non-surgical cosmetic procedures.
(5) All practitioners of cosmetic procedures will be required to register with CPRB.
(6) Non-registered practitioners will not be allowed to undertake any of the listed cosmetic procedures.
(7) CPRB will have sanctioning powers as included in CPRB regulations.

Section 2: Section Entry to the CPRB register

(1) Entry to the CPRB register will only be permitted to those practitioners who have;
    (i) obtained the relevant accreditation and qualifications. The qualifications relevant to each procedure are contained in the CPRB's guidelines, and;
    (ii) licenced premises as per section 4.

Section 3: Non-Health Care Professionals

(1) Non-health care professionals may perform the following procedures if they obtain the appropriate qualifications;
    (i) IPL hair removal treatments
    (ii) Weaker chemical peels (subject to CPRB regulations).
(2) Non-health care professionals may only perform the following procedures under the supervision of a clinical professional (relevant procedures) (subject to all professionals having obtained the relevant qualifications);
    (i) Botulinum toxin injections
    (ii) Dermal filler injections
    (iii) Microdermabrasion

Section 4: Premises and Licensing

(1) Any premises carrying out relevant procedures must be licensed.
(2) Licenses for premises carrying out solely surgical activities, or a combination of both surgical and non-surgical activities, will remain the responsibility of the CQC, where surgical activities are those currently regulated under the Health and Social Care Act 2008.
(3) Any premises carrying out solely non-surgical cosmetic procedures must obtain a licence to practice from the NSIC.
(4) The requirements that a premises must meet in order to be awarded a licence are contained in the CPRB guidelines.
(5) CPRB will carry out routine inspections of all licenced premises to ensure standards are maintained.

Section 5: Products

(1) CPRB guidelines contain the list of those products which constitute medicines and those which constitute medical devices.

(2) The following items must be prescribed by a licenced prescriber:

(i) Botulinum Toxin

(ii) Dermal Fillers

4. Justifications

The key reasons behind this proposal are to ensure public safety and provide individuals with a greater understanding of the nature of these procedures. As already stated, there are a variety of risks involved with these non-surgical procedures that may lead to health complications for the individual. There may also be cost implications for the National Health Service if they have to treat patients who have suffered at the hands of cowboy cosmetic practitioners.

The potential psychological impact on patients is another underlying factor. The nature of these cosmetic procedures is that they are undertaken by those who are unhappy with their appearance. Therefore, '[i]f there is a problem and the patient is not emotionally stable… the results can be disastrous'.[54] When these procedures go wrong, they can leave the patient with an appearance even further from their perceived ideal. This impact can be even worse for sufferers of body dysmorphic disorder, a condition which affects around 1% of the population, but is far more prevalent in those seeking cosmetic interventions.[55] Therefore, by increasing regulation, and decreasing the likelihood of substandard procedures, those wanting and needing cosmetic interventions will be more likely to receive a safe and reliable service.

The proposal by no means purports to shut down the industry, but instead aims for non-surgical cosmetics to be viewed as medical procedures that should only be undertaken where the various risks have been sufficiently weighed. The proposal, therefore, seeks to create an empowered public.

The CPRB and the need for a centralised regulating body

The introduction of a centralised body to regulate all cosmetic procedures will provide much needed clarity to the industry. A similar idea was postulated in the Cosmetic Surgery (Minimum Standards) Bill 2013, however there was little explanation as to the body's operation, beyond the fact that it would work with existing organisations, such as the CQC.[56]

Currently, the mix of regulators of some professionals, self-accreditation schemes, and voluntary registers, has made it ever more confusing for the consumer to check whether the service they are receiving is safe and reliable.

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[54] Jenna Goudreau, 'The Hidden Dangers of Cosmetic Surgery' (Forbes, 16 June 2011) <https://www.forbes.com/sites/jennagoudreau/2011/06/16/hidden-dangers-of-cosmetic-surgery/#566fb9917b2b> accessed 18 April 2020.

[55] Dee Anna Glaser and Michael S. Kaminer, 'Body Dysmorphic Disorder and the Liposuction Patient' (2005) 31 Dermatol Surg 559.

[56] Cosmetic Surgery (Minimum Standards) HC Bill (2012-13) [60], s 2(5).

CPRB will act as an umbrella organisation to oversee smaller bodies. The existing CQC will continue to regulate cosmetic treatments that involve surgical procedures. They will also oversee the various professional regulators, such as the GMC, to ensure safe practice across the sector. Their work in this area will be closely monitored by CPRB, which will have ultimate authority.

A new body, the Non-Surgical Interventions Commission, will be created to regulate non-surgical treatments. They will operate in a similar way to the CQC, but will focus on procedures such as botox and dermal fillers, and will again be accountable to CPRB.

This laddering of regulators will ensure greater checks are operating at each level. Moreover, the introduction of CPRB will provide a one-stop shop for a client interested in ascertaining what type of procedure they should undertake, the risks involved, and where such procedures are carried out safely.

The need for a regulatory body has become essential over recent years, as current schemes in place have failed to ensure high standards are met across the sector and existing attempts at self-regulation have been largely unsuccessful. Keogh explained in his report that 'the failure of the sector to self-regulate may also partly reflect public attitudes which assume that there is already legislation'.[57] Surveys have shown that there is a general public perception that if a premises is offering non-surgical treatments, then it must be safe.[58] Thus, the lack of regulation has contributed to a false perception that these treatments are no different to getting your nails painted or having a haircut, when in fact they are medical procedures that carry with them health risks. Therefore, greater regulation would not only increase safety but may also change this misconception and reduce the normalisation of these types of interventions.

Moreover, following the decision to exempt Laser and light treatments from CQC regulation in 2010, the number of practitioners attending training courses has dropped.[59] Whilst bodies such as JCCP[60] and Save Face[61] offer accreditation schemes, their voluntary nature means that they are only regulating those professionals who choose to join the organisations. These professionals are therefore more likely to already abide by the correct codes of conduct, whilst the organisations are not reaching the cowboy practitioners who have no interest in improving their practice.

Similarly, the absence of a compulsory regulatory body of non-surgical cosmetic interventions has meant that the onus to check whether these procedures are being carried out safely is placed on potential customers. This should not be the case, as when someone opts to have such a procedure, they will likely have different priorities to an objective bystander. For example, some customers may prioritise the cost of the service over the experience of the staff. Moreover, external pressures have meant that in some cases, individuals are blinded by their aspiration to look a certain way and will do whatever it takes to reach their idea of 'perfection'.

[57] Keogh Report (n 3) para 3.31.
[58] 'Regulation of Cosmetic Interventions: Research among the General public Practitioners' (Creative Research, 28 March 2013) 38.
[59] Keogh Report (n 3) para 3.31.
[60] Joint Council for Cosmetic Practitioners (2020) <https://www.jccp.org.uk/> accessed 21 April 2020.
[61] Save Face (2019) <https://www.saveface.co.uk/> accessed 21 April 2020.

Therefore, it is insufficient for bodies such as the CQC to offer 'advice' to patients seeking interventions, but instead bodies must act in their best interests to continually hold these professionals and organisations to account.

Finally, CPRB will be empowered to enforce the regulations. Whilst this proposal does not lay out the relevant enforcement powers, going forwards the regulations would contain detailed information concerning the operation of such powers. More information concerning the operation of these sanctioning powers will be contained in the CPRB regulations.

The CPRB Register

Importantly, CPRB will also control the registration, continued professional development, and vetting of current practitioners. A similar idea was proposed in the failed bill.[62] Such a compulsory register was said to be needed to ensure that voluntary codes of practice could not be ignored.

Compulsory registers already exist in other areas of medical practice. The GMC, for example, insists upon the completion of rigorous training programmes before a professional is admitted to the relevant register.[63] However, the absence of any required registration for non-medical professionals has meant that many of these individuals have not been subjected to any regulation.

The proposed CPRB register is similar to those used in other jurisdictions. For example, in 2007 Denmark introduced 'The cosmetics register', which requires 'all those carrying out cosmetic interventions [to be] registered with the Danish Health Board'.[64] This Board also carries out inspections and has been a great success in regulating the industry.

Non-Health Care Professionals

Another important aspect of this Bill concerns who is allowed to carry out certain procedures. Under the proposal, only a very limited number of procedures can be undertaken by non-health care professionals on their own. These professionals could, however, take part in a wider number of procedures, if done so under the supervision of a qualified clinical professional. This would ensure that these professionals still have the opportunity to work in the sector.

Limiting those procedures which can be provided by non-healthcare professionals would increase standards across the sector. It must be remembered that 'non-surgical does not mean

[62] Cosmetic Surgery (Minimum Standards) HC Bill (2012-13) [60].

[63] 'Information on the Specialist Register' (General Medical Council) <http://www.gmc-uk.org/doctors/register/information_on_the_specialist_register.asp> accessed 21 April 2020.

[64] 'Statutory Order regarding cosmetic treatments' (National Board of Health, Denmark) <http://www.sst.dk/publ/Publ2010/TILSYN/Kosmetik/UKversionStatuaryOrderCosmeticTreatment.pdf> accessed 23 April 2020.

non-medical' and therefore the risks involved should not be underestimated.[65] Dermal filler injections, for example, involve needles penetrating the skin, and are not merely superficial skin treatments. Yet the normalisation of these procedures has been facilitated by the fact that they have become more readily available on the high street, with shops including Superdrug now offering botox and fillers.[66] Whilst beauticians can undertake training courses, medical professionals are far better equipped to provide these procedures. They have an in depth knowledge of how to administer needles and cannulas safely and a broader range of expertise to know what to do if a patient has an adverse reaction. After all, 'it is not just about who can wield a syringe but who will have the capabilities to deal with possible complications'.[67]

Premises

The need to regulate the premises in which these treatments are carried out is paramount. A survey undertaken by the Royal College of Nursing found that 36% of nurses performing non-surgical interventions did so either from their homes or their client's homes.[68] There has also been a growth in the performance of these procedures in hairdressing salons, 'pop-up' shops and hotel rooms.[69] The nature of these venues means that local authorities are largely unaware of the procedures going on. Currently, the inspection of premises carrying out non-surgical interventions falls on the Local Authority (LA). Yet, increasing demands on LA resources mean that such inspections will likely be a low priority. Considering the medical implications of these procedures, LAs are not the most appropriate regulator. Therefore it has been proposed that, where non-surgical cosmetic procedures are provided by non-health professionals, licences should be required. These premises would be licenced in a similar way to tattoo parlours. A similar idea is currently under consultation in Scotland, although this proposal includes the local authority as the issuer of the licence, so that LA Environmental Health Officers would be empowered to carry out inspections.[70] Yet under the Cosmetic Interventions (Minimum Standards) Bill, responsibility would fall onto the specially created CPRB body, which would offer universal, specialist expertise in the area. This would also not overburden local authorities.

Products

The biggest change proposed under this section is the inclusion of dermal fillers as prescription only devices. This would limit their sale to licensed prescribers, preventing direct

[65] Sarah Boseley, 'Beauty therapists to be banned from offering fillers unless qualified' *The Guardian* (London, 1 April 2013) <https://www.theguardian.com/money/2013/apr/01/beauty-therapists-banned-from-offering-fillers> accessed 21 April 2020.
[66] 'Skin renew by Superdrug' (Superdrug, 2020) <https://www.superdrug.com/microsite/skin-renew> accessed 21 April 2020.
[67] Sarah Boseley, 'Beauty therapists to be banned from offering fillers unless qualified' *The Guardian* (London, 1 April 2013) <https://www.theguardian.com/money/2013/apr/01/beauty-therapists-banned-from-offering-fillers> accessed 21 April 2020.
[68] 'Survey of nurses who prescribe or administer cosmetic injectables' (Royal College of Nurses, 2012) <www.magonlinelibrary.com> accessed 21 April 2020.
[69] Keogh report (n 3) para 3.27.
[70] *Consultation on the Regulation of Non-Surgical Cosmetic Procedures in Scotland* (The Scottish Government, Consultation 2020).

purchase by general members of the public without being issued a prescription. This is important as it would limit the accessibility of dermal fillers, and would ensure that patients are meeting with a medical professional face-to-face, which may also contribute to changing the public perception towards these treatments.

There would also be greater scrutiny of the sale of these injectables. Even though botox already requires a prescription to be purchased, DIY botox kits are available online to the public. Encouraging home use is dangerous as those who are not properly trained will be unaware of the risks involved. After all, 'it's easy to forget that Botox is actually a poison'.[71] Therefore, as part of their new regulatory platform, CPRB would crack down on sites illegally selling these substances through greater monitoring. Their abovementioned sanctioning powers would extend to companies selling these products to non-licensed individuals.

Another advantage of these products having a prescription only status is that they cannot be advertised, and this is regulated by MHRA. This prevents advertising practices conflicting with patients' health needs. Including dermal fillers in this regulation would also help with to change the public perception towards these medical procedures.

Implementation

To ensure that these changes are effectively implemented, CPRB regulations would require all licenced providers of the procedures to provide their patient with a copy of CPRB's information for the relevant procedure. CPRB's logo must appear in all licenced premises. Existing bodies, such as the CQC, would also be instrumental in advising all interested bodies in the sector of the new guidelines.

Conclusion

In conclusion, clearly there are currently insufficient safeguards to protect those choosing to undertake non-surgical cosmetic procedures. The proposed changes, though not covering every issue in the sector, will begin to remove unscrupulous practitioners from the industry. It is also hoped that by restricting the availability of the procedures that non-health care professionals can offer, procedures performed will be of the highest quality, whilst the public will also begin to understand the medical nature of these procedures and properly weigh the risks.

[71] Huma Qureshi, 'Botox injections for sale on the internet' *The Guardian* (30 April 2009) <https://www.theguardian.com/money/2009/apr/29/botox-for-sale-online> accessed 25 April 2020.

Are the Genetic Resources in Areas Beyond National Jurisdictions Subject to the "Genetic Heritage of Mankind" Principle?

*Eleni Achnioti**

Abstract

It is uncertain whether the genetic resources in areas beyond national jurisdiction are subject to the common heritage of mankind (CHM) or freedom of the high seas principle. This uncertainty is intensified, as the regime governing the Area is itself fragmented, leading to considerable tensions between States as to which regime should govern marine genetic resources (MGR). The aim of this paper is to determine the extent to which MGR in the Area should be the CHM. In doing so, the regime of freedom of the high seas will be analysed to ultimately conclude its inadequacy in governing MGR. In turn, CHM as a regime will be evaluated to determine its adequacy. Ultimately, it will be argued that the most beneficial solution would be for a hybrid of CHM and freedom of the high seas to be created. This would ensure that the majority of State interests are met, thus avoiding tension.

Introduction

In terms of biodiversity, the deep sea is the most species-rich habitat in the world, therefore ensuring the conservation and sustainable management of biodiversity therein could arguably be the most important challenge of the coming decades.[1] With more research being carried out, it has become apparent that marine genetic resources (MGR) found in the deep seabed have significant scientific and economic value.[2] MGR have been observed to survive in extreme environments in the Area, thus making their genetic material a particular interest for science.[3] Article 1 of the 1982 United Nations Convention on the Law of the Sea (UNCLOS) defines the Area as "the seabed and ocean floor and subsoil thereof, beyond the limits of national jurisdiction".[4]

The question of whether MGR are the common heritage of mankind (CHM) shall be dissected in order to analyse the controversy surrounding the regulation of MGR. Firstly, the principle of the common CHM will be explained in order to later determine whether it is reasonable for MGR to fall under it. Secondly, the development of the regime governing the preservation of biodiversity in areas beyond national jurisdiction (ABNJ) will be considered, in order to justify the need for a new legal document and to highlight the weakness of the current regime. It will be argued that the current un-harmonised framework has added to the controversy surrounding MGR and has caused disagreement by States as to whether MGR fall under the principle of CHM or that of freedom of the high seas. Developed States are usually advocates of the view of freedom of the high seas, whereas developing States support the integration of MGR in the CHM. Both of the opposing views will be considered and their persuasiveness will be analysed.

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[1] David Leary, *International Law And The Genetic Resources Of The Deep Sea* (Martinus Nijhoff 2007) 8-9.

[2] Yoshifumi Tanaka, 'Reflections On The Conservation And Sustainable Use Of Genetic Resources In The Deep Seabed Beyond The Limits Of National Jurisdiction' (2008) 39 Ocean Development & International Law 129.

[3] ibid.

[4] United Nations Convention on the Law of the Sea (hereinafter UNCLOS 1982) (adopted 10 December 1982, entered into force UN Treaty Series, vol. 183 p. 3, Article 1(1)(1).

In 2018 an international effort commenced aiming to negotiate a new international, legally-binding instrument to govern the conservation and sustainable use of marine biodiversity in ABNJ, in line with the United Nations General Assembly (UNGA) Resolution 72/249.[5] Topics for negotiation included *inter alia* MGR and the creation of rules for access and benefit-sharing, which were the most contentious topics of the talks. As an aid to the ongoing negotiations, the President issued a paper, which proposed that a hybrid of CHM and freedom of the high seas could be achieved as a means to regulate MGR.[6] This proposal will be considered to determine its viability as a compromise between the conflicting interests of States. Currently, the development of a legally binding treaty has halted due to the Covid-19 outbreak, however, the latest available draft of the new treaty will be considered in the discussion. Consequently, it is important to note that some of the provisions analysed below may be amended or removed entirely from the treaty.

It is recognised that under the principle of CHM a means of equitable sharing of MGR benefits and information should be established under the International Seabed Authority (ISA). However, it is deemed beyond the scope of this essay to analyse exactly how this mechanism would exist and operate.

Common Heritage of Mankind Development

Ambassador Pardo distinguished the current regimes of freedom of the high seas and sovereignty in the territorial sea and argued that if these regimes applied to the Area they would both yield equally undesirable results.[7] He argued that the regime of sovereignty would lead to unreasonable extensions of the limits of national jurisdiction by coastal States.[8] On the other hand, the regime of freedom would likely lead to a scramble by States to exploit minerals on the seabed on a "first-come-first-served" basis.[9] Both of these would eventually lead to political tension, economic injustice and pollution.[10] It is clear that neither of the two regimes would produce satisfactory results in accordance with the mandate of the UN. To avoid the tensions of the aforementioned regimes, CHM was developed as a principle to govern the Area and its resources. It is important to note that the CHM principle does not replace the regimes of sovereignty or freedom, rather it coexists with them while providing an innovative and equitable approach.[11]

[5] Elizabeth M. De Santo and others, 'Stuck In The Middle With You (And Not Much Time Left): The Third Intergovernmental Conference On Biodiversity Beyond National Jurisdiction' (2020) 117 Marine Policy 1, 2.
[6] UNGA President's aid to negotiations (3 December 2018) UN Doc A/CONF.232/2019/1.
[7] Tullio Scovazzi, 'The Rights To Genetic Resources Beyond National Jurisdiction: Challenges For The Ongoing Negotiations At The United Nations' in Catherine Banet (ed) *The Law of the Seabed: Access, Uses, and Protection of Seabed Resources* (Brill 2020) 215.
[8] ibid.
[9] ibid.
[10] Tullio Scovazzi, 'The Concept Of Common Heritage Of Mankind And The Genetic Resources Of The Seabed Beyond The Limits Of National Jurisdiction' (20070 14(25) Agenda Internacional 11, 12.
[11] Scovazzi (n 10) 13.

CHM in UNCLOS 1982

The main features of CHM are reflected in Part XI of UNCLOS. Article 136 succinctly states that 'the Area and its resources are the common heritage of mankind'.[12] Moreover, Article 137 specifies that no State is permitted to exercise sovereign rights nor appropriate any part of the Area, as they will not be recognised.[13] The rights to resources of the Area shall be vested in mankind as a whole, on whose behalf the ISA will act.[14] The Area shall be used exclusively for peaceful purposes, by all States regardless of location (whether coastal or land-locked).[15] Activities in the Area shall be performed on behalf of mankind as a whole, irrespective of geographical location, with special consideration given to the interests of developing States.[16] Finally, the ISA will ensure the equitable sharing of financial benefits emerging from activity in the Area through an appropriate, non-discriminatory mechanism.[17]

Legal Development in Regulating Marine Genetic Resources

One of the reasons for the existing controversy regarding MGR could be the lack of a harmonised instrument regulating them. It is important therefore to examine the relevant legal development that eventually led to an agreement to create a new legally binding treaty for the regulation and conservation of MGR and biodiversity in ABNJ. The proposal by Ambassador Pardo led to Resolution 2749 adopted in 1970, whereby the UNGA declared that the seabed and ocean floor beyond the limits of national jurisdiction, including the resources of the Area, are the CHM.[18] Under the Resolution, it was stated that *all* resources of the seabed in the area fall under the principle.[19]

Although UNCLOS is the main instrument governing the law of the sea, there is little reference to the preservation of biodiversity and no mention of MGR in the treaty. It is important to note, however, that the preamble of UNCLOS mentions that one of the aspirations of the Convention would be for parties to consciously consider problems of ocean space holistically.[20] The preamble of a convention is generally a very integral part of it, which can become relevant when interpreting a treaty.[21] For this reason, it should not be disregarded when considering the rest of the treaty. There are limited relevant provisions found in Part XII; Article 192 places an obligation among States to protect and preserve the marine environment.[22] In addition, per Article 194, States have the duty to prevent, reduce and control pollution by taking appropriate action consistent with UNCLOS.[23] Furthermore, there is also a duty to protect rare and fragile ecosystems as well as habitats of endangered

[12] UNCLOS 1982 (n 4) Article 13.
[13] ibid Article 137(1).
[14] ibid Article 137(2).
[15] ibid Article 141.
[16] ibid Article 140(1).
[17] ibid Article 140(2).
[18] Scovazzi (n 7) 215.
[19] ibid.
[20] UNCLOS 1982 (n 4) preamble.
[21] Vienna Convention on the Law of Treaties (adopted 23 May 1969, entered into force on 27 January 1980) UN Treaty Series vol. 1155 p. 331, Article 31(2).
[22] UNCLOS 1982 (n 4) Article 192.
[23] ibid Article 194(1).

species and other marine life.[24] Arguably, MGR may fall under the category of "marine life" and are thus afforded protection under UNCLOS by virtue of the aforementioned articles. Moreover, Article 197 promotes international cooperation in formulating standards for the protection of the marine environment.[25] It can be argued that the above provisions may find some relevance by analogy in the conservation of MGR and marine biodiversity. However, UNCLOS does not set out a detailed framework specifically for the protection of the marine environment, thus there is a need for another instrument to elaborate on this issue.

In 1992 the Convention on Biological Diversity (CBD) was adopted, with three goals in mind; the conservation of biodiversity, sustainable management of its components, and creation of a fair and equitable sharing mechanism for information of the usage of MGR.[26]

More recently, in 2015 the UNGA adopted Resolution 70/1, which set out 17 sustainable development goals, one of which being the conservation and sustainable use of the oceans and marine resources.[27] In addition, an ad-hoc Informal Working Group was established to assess issues relating to the conservation and use of marine biodiversity.[28] These developments altogether pushed for the implementation of a new, binding instrument specifically addressed to the regulation of marine biodiversity.

Following the adoption of Resolution 72/249 in 2017, negotiations for a new treaty are still ongoing. The third session sat in 2019, whereby a revised draft text of the treaty was agreed upon. According to the draft, the Resolution will be open for all States to sign, regardless of membership to UNCLOS.[29] One of the principles envisaged in Article 9 is that of CHM, in respect of activities involving MGR in ABNJ. The principle itself is not yet defined, rather Article 9 outlines some features of CHM.[30] For example, no State shall be allowed to exercise sovereign rights in respect of MGR found in ABNJ. Part II of the Resolution explicitly addresses MGR and aims to promote the equitable sharing of benefits arising from their use in ABNJ as well as the transfer of marine technology between nations.[31] The draft treaty suggests two possible definitions of MGR in Article 9. The first states *inter alia* that MGR are materials from organisms originating in ABNJ, which contain functional units of heredity with genetic properties of actual or potential value.[32] The second possible definition suggests that MGR are the genetic materials of actual or potential value.[33] Marine genetic material is also defined in Article 1 as any material containing functional units of heredity.[34] It is important

[24] ibid Article 194(5).
[25] ibid Article 197.
[26] Convention on Biological Diversity (adopted 5 June 1992, entered into force on 29 December 1993) UN Treaty Series vol. 1760 p. 79, Article 1.
[27] UNGA Resolution 70/1 (25 September 2015) UN Doc A/RES/70/1, Goal 14.
[28] 'Ad Hoc Open-Ended Informal Working Group To Study Issues Relating To The Conservation And Sustainable Use Of Marine Biological Diversity Beyond Areas Of National Jurisdiction' (United Nations Office of Legal Affairs, 13 March 2015) <https://www.un.org/depts/los/biodiversityworkinggroup/biodiversityworkinggroup.htm> accessed 3 May 2020.
[29] Revised draft text of an agreement under the United Nations Convention on the Law of the Sea on the conservation and sustainable use of marine biological diversity of areas beyond national jurisdiction (hereinafter Draft Treaty)(18 November 2019) UN Doc A/CONF.232/2020/3, Part XII Article 58.
[30] Draft Treaty (n 29) Article 9.
[31] ibid Article 7(a) and (d).
[32] ibid Article 1(9)Alt1.
[33] ibid Alt2.
[34] ibid Article 1(8).

to note that most of Part II of the future treaty remains formatted with square brackets, meaning that the draft is undecided and subject to change, thus potentially indicating the disagreement between States.

Evaluation of Legal Instruments

From a brief explanation of the framework concerning the conservation and use of MGR, it is evident that it is highly fragmented and decentralised. It suffers not only from substantive gaps, but also potential overlaps, as there is no single instrument dealing exclusively with the regulation of the area and its resources.[35] The weakness of the regime itself contributes to the controversy regarding MGR regulation.

It should be noted that Part XI of UNCLOS was highly contended by developed States, leading to many of them abstaining or voting negative when the text of UNCLOS was put to vote.[36] The dissatisfaction was in relation to the monopoly activities of the ISA as well as a sense of discouragement in undertaking mining activities.[37] In 1994 it became clear that UNCLOS would enter into force without the assent of many developed countries.[38] It would thus become impossible to implement the provisions of Part XI without the financial and technological capabilities of those States.[39] Consequently, new negotiations have begun that led to the adoption of the 1994 Implementation Agreement for Part XI of UNCLOS.[40] To satisfy concerns by developed States many provisions were modified, although the principle of CHM was left untouched.

One of the main limitations of the CBD is that it only applies in national waters, not in ABNJ. Another point to note is that the CBD did not incorporate the CHM principle, despite calls from developing countries.[41] Its preamble states that the conservation of biological diversity is the common concern of humankind.[42] Although the wording may be similar, there is confusion regarding the difference between the common concern of humankind and CHM.[43]

Importantly, neither UNCLOS nor CBD provides a satisfactory framework for the regulation of MGR in the Area. While this is a clear gap in the law, there may be a justification for it. It is important to note that, like any legal text, UNCLOS is a product of a different time, specifically 1973 to 1982.[44] It would be naive to think that UNCLOS would be the end of legislation regarding the law of the sea.[45] While it provides a solid framework for the regulations of many aspects of ocean use, it is also the subject of natural evolution and

[35] Erik J Molenaar, 'Managing Biodiversity in Areas beyond National Jurisdiction' (2007) 22 Int'l J Marine & Coastal L 89, 95.
[36] Scovazzi (n 7) 216.
[37] ibid.
[38] ibid.
[39] ibid.
[40] UNGA Resolution 48/263 (17 August 1994) UN Doc A/RES/48/263.
[41] Leary (n 1) 97.
[42] Convention on Biological Diversity (adopted 5 June 1992, entered into force on 29 December 1993) UN Treaty Series vol. 1760 p. 79, preamble.
[43] Leary (n 1) 97.
[44] Scovazzi (n 7) 222.
[45] ibid.

progressive development.[46] At the time of the negotiations, the focus was largely on mineral resources in ABNJ, as little was known about the genetic properties of marine organisms.[47] This is evident as there is no mention in UNCLOS of "genetic resources" and "bioprospecting" in the regime governing the Area. Consequently, it would be absurd to expect the regulation of activities that at the time were not foreseeable.[48] On the other hand, via the 1994 Implementation Agreement, States would have had the chance to alter the definition of "resources", as by that time the knowledge and value of MGR were more widespread.[49] However, the 1994 Agreement maintains that "resources" mean mineral resources. This can be explained as the 1994 Agreement had a specific purpose; to introduce a necessary modification to the mining regime.[50] Consequently, "resources" were not modified, as they were not the objective of the agreement.

Interestingly, it has been argued that bioprospecting already falls within the ambit of UNCLOS, as it is a form of marine scientific research involving MGR.[51] It follows that bioprospecting can be covered by Article 143(1). On the other hand, the lack of a specialised instrument means that MGR in the Area are governed by general rights and principles as laid out in UNCLOS.[52] This has proved dissatisfactory, especially noting the complexity of MGR and the different conflicting State interests surrounding them.

CHM vs Freedom of High Seas

The biggest controversy surrounding MGR is whether they should be governed by the principle of CHM or that of freedom of the high seas. There is a rift between developed States, advocating for freedom of the high seas, and developing States supporting CHM. This disagreement is not novel, as it was very much present during the UNCLOS negotiations, and it is what eventually led to the adoption of the 1994 Implementation Agreement.

In favour of CHM

It is known that the Area is subject to the CHM, however there is no explicit rule of international law that stipulates that the principle would also apply to MGR found in the Area.[53] However, it would be inconsistent to assume that the CHM principle applies to the Area but has no effect on the MGR found therein.[54] Since the MGR found in the Area are inseparable from the unique environment of the Area itself, it can be argued that the legal

[46] ibid.
[47] ibid.
[48] ibid.
[49] Konrad Jan Marciniak, 'Marine Genetic Resources: Do They Form Part of the Common Heritage of Mankind Principle?' in Lawrence Martin, Constantinos Salonidis, Christina G. Hioureas, Ian A. Laird, Borzu Sabahi and Anne Marie Whitesell (eds) *Natural Resources and the Law of the Sea: Exploration, Allocation, Exploitation of Natural Resources in Areas under National Jurisdiction and Beyond* (Juris 2017) 395-396.
[50] ibid 396.
[51] ibid.
[52] Molenaar (n 35) 96.
[53] Tanaka (n 2) 139.
[54] ibid.

effect of the CHM principle should extend to the MGR found in the Area.[55] This argument seems to have the most potential, as it has been echoed by several delegations.[56] Importantly, the effect of this reasoning conforms with the goals of UNCLOS in promoting a 'just and equitable international economic order',[57] taking into account the interests of mankind as a whole as well as those of developing countries.[58] Since Part XI of UNCLOS has already been amended in the 1994 Agreement, there is no reason why a new agreement cannot be reached for the extension of CHM to cover MGR to reflect the concerns of developing States.[59]

Under the current regime of the Area, "activities" refer to the exploration and exploitation of the resources of the Area and "resources" mean all mineral resources *in situ* in the Area.[60] This suggests that under UNCLOS, the principle of CHM does not extend to the non-mineral resources of the Area and thus the rules applicable for the exploration of mineral resources cannot be applied to other resources found in the Area.[61] However, this should not discourage States from proposing the extension of CHM to cover MGR, as such an extension would be regarded as natural evolution within the spirit of UNCLOS.[62] The Convention envisaged a just and equitable economic order.[63] Consequently, the argument for an extension of the CHM principle to cover MGR is not farfetched. More importantly, if the principle of freedom of the seas were to apply to MGR it would naturally lead to a "first-come-first-served" approach, which would have inequitable consequences, as very few states have the means to explore the Area.[64] Such an approach would contradict the principles outlined in UNCLOS and arguably would lead to political as well as economic tensions between States.

From the current draft of the treaty for the regulation of MGR, it is evident that the CHM principle dominates. The draft does not mention that MGR fall under the regime of freedom of the high seas, thus could potentially indicate a regime governed by CHM. However, even if enough States ratify the treaty, if those States lack the financial and technological potential to explore MGR, the problem faced in the implementation of Part XI of UNCLOS would return. Without the means to explore ABNJ and MGR, the agreement would have no meaning. Consequently, in one way or another, developed States need to be satisfied with the agreement to provide the means of implementing it.

In contrast with CHM, other States rely on the principle of freedom of the high seas to demonstrate that MGR should have unrestricted access. Per Scovazzi, that position would be unacceptable, as *mare liberum* was developed by Grotius in the 17th century and was primarily linked to navigation.[65] When the principle was refined there was no way of knowing the extent of activities that would end up taking place in the marine environment nowadays.[66] It would be unreasonable to give a principle of the 17th century the same legal strength as

[55] ibid 140.
[56] Marciniak (n 49) 383.
[57] UNCLOS 1982 (n 4) preamble.
[58] Tanaka (n 2) 141.
[59] Scovazzi (n 10) 23.
[60] Scovazzi (n 7) 222; UNCLOS 1982 (n 4) Article 133(a).
[61] Scovazzi (n 7) 222-223.
[62] ibid 223.
[63] UNCLOS 1982 (n 4) preamble.
[64] Scovazzi (n 7) 224.
[65] Scovazzi (n 10) 21-22.
[66] ibid.

modern-developed principles.[67] This may have been justifiable in circumstances in the past, however, it is no longer possible. It simply does not reflect the reality of many marine activities nowadays. For example, it would not be acceptable for a State to have the right to engage in a marine activity simply by virtue of *mare liberum,* without consideration for other States with similar interests.[68] Scovazzi also argues that the principle of freedom of the seas has 'undergone a process of progressive weakening'.[69] In fact, the dilution of *mare liberum* is the trend under which modern law of the sea evolves.[70] This is evident from UNCLOS, which introduced several revolutionary legal concepts that include *inter alia* the continental shelf, the exclusive economic zone, and now the CHM.[71] The establishment of such concepts is indicative of the inadequacy of a "first-come-first-served" approach based on flag State jurisdiction.[72]

Another way to find support for the CHM principle would be by employing the famous deductive reasoning of Sherlock Holmes, which Lord Millett has previously used in a judgement; 'when you have eliminated all which is impossible, then whatever remains, however improbable, must be the truth'.[73] Although applied in an unrelated case, how Lord Millett comes to his conclusion may have merit in explaining why CHM is the suitable principle in the context of MGR. The reasoning can be applied to the three regimes in UNCLOS; freedom, sovereignty and CHM. By eliminating the sovereignty and freedom regimes, the remaining one must be the appropriate option. The freedom approach would result in a monopoly over MGR by technologically advanced States, contrary to the spirit of UNCLOS.[74] On the other hand, it is doubtful that the regime of sovereignty could provide an adequate framework ensuring the equitable sharing of benefits from the usage of MGR.[75] This leaves CHM as the only logically available option. Coupled with the arguments presented above, there is no reason why CHM should not extend to MGR. However, this reasoning treats the three principles as binary options, without any possibility of combining them. Nevertheless, deductive reasoning could be used as the starting point in finding support for the CHM principle.

In favour of freedom of high seas

According to the United States (US), there is no legal gap regarding MGR in ABNJ, as they fall under the scope of freedom of the high seas in international law as well as UNCLOS.[76] The dominant argument for excluding MGR from the regime of Part XI and subsequently of the CHM principle seems to be derived from Article 133, which defines "resources" as all solid, liquid or gaseous mineral resources *in situ* in the Area.[77] This argument was used by the US in an attempt to show that MGR fall under the freedom of the high seas, as they are not

[67] ibid.
[68] ibid.
[69] ibid.
[70] ibid.
[71] ibid.
[72] ibid.
[73] *Twinsectra v Yardley* [2002] UKHL 12.
[74] Tanaka (n 2) 140.
[75] ibid.
[76] Scovazzi (n 7) 227.
[77] UNCLOS 1982 (n 4) Article 133.

mineral resources. It is mentioned that there is no disagreement in the application of CHM to mineral resources in the Area, however, its scope shall be limited to just that.[78] The US advocate the view that no State can exercise sovereign rights over MGR in ABNJ, thus anyone can freely access MGR so long as they comply with international law.[79] This view was also supported by Russia, suggesting that the new treaty should not include a provision regulating MGR at all.[80] Other States are of the view that MGR exploitation should fall under the provisions of marine scientific research, an explicit freedom of the high seas.[81] It can also be argued that MGR may fall under "living resources", governed by Part VII of UNCLOS.[82] The term is not defined in the Convention, thus if a broad understanding of "living resources" is adopted it can be argued that they encompass MGR.[83] Although, it should be noted that the relevant section begins with the regulation of fishing, albeit making references to the broader category of "living resources".[84]

In assessing a new ocean use that is not specified in Article 87, one should ask whether the use is compatible with the status of the high seas.[85] To satisfy compatibility, the use should have no claim of appropriation of the high seas, no interference with the rights of others in the high seas and not be prohibited or excluded by UNCLOS.[86] If the above are satisfied, then the use should be admitted as a freedom.[87] With this reasoning, it follows that the exploration of MGR may be classed as a freedom of the high seas. In addition, it is also argued that bioprospecting of MGR could fall within the existing freedom to fish, the engagement in marine scientific research, or a hybrid of the two.[88] Moreover, Allen notes that the expansion of the CHM principle to non-mineral resources would be a derogation of the century-old tradition of wide-ranging high seas freedoms.[89]

It is also argued that using the *expressio unius* principle of construction to analyse Article 133, it is evident that resources other than mineral ones are excluded.[90] However, Article 133 does not provide an exhaustive definition of "resources", it merely stipulates one category of resources under Part XI.[91] Had Article 133 stated that it would only apply to mineral resources, the *expressio unius* principle would have been relevant.[92] As mentioned above, the focus on mineral resources can be explained, as at the time they were the only resources thought to be of economic interest.[93]

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[78] Scovazzi (n 7) 227.
[79] ibid.
[80] De Santo and others (n 5) 4.
[81] ibid, 4 and UNCLOS 1982 (n 4) Article 87.
[82] UNCLOS 1982 (n 4) Section 2 Part VII.
[83] Marciniak (n 49) 381.
[84] ibid.
[85] R. R. Churchill and A. V. Lowe, *The Law Of The Sea* (2nd edn, Manchester University Press 1999) 168; Craig Allen, 'Protecting the Oceanic Gardens of Eden: International Law Issues in Deep-Sea Vent Resource Conservation and Management' (2001) 13 Geo. Int'l Envtl. L. Rev. 563, 634-635.
[86] Allen (n 85).
[87] Allen (n 85) 634-635.
[88] ibid 635.
[89] ibid 636.
[90] ibid 630.
[91] Alex G Oude Elferink, 'The Regime of the Area: Delineating the Scope of Application of the Common Heritage Principle and Freedom of the High Seas' (2007) 22 Int'l J Marine & Coastal L 143,152.
[92] ibid.
[93] ibid 153.

The potential hybrid of the two

In 2018 the *President's aid to negotiations* paper was issued, with options of provisions reflecting the positions taken by States.[94] A solution was proposed, under which a hybrid of the high seas' freedom and CHM could be created. It was stated that the freedom of the high seas should regulate the access to MGR in the Area, whereas CHM would govern their exploitation.[95] By introducing a hybrid system there may be hope that States will finally reach an acceptable compromise. This would give developed States the freedom they want, without discouraging investment in marine exploration activities. At the same time, developing States would receive benefits from the exploitation of MGR without free-riding on information stemming from investments of developed States. Both *mare liberum* and CHM have merits as principles, thus by combining them a balance may be reached. The achievement of such a balance is very intricate, however necessary for the operation of the relevant legal instruments. Unless a good balance is struck the new legally binding treaty may face the same problems as Part XI of UNCLOS.

Conclusion

To conclude, throughout this paper it has been made obvious that there are several controversies regarding the regulation of MGR. The most prominent one is whether MGR are the CHM or governed by *mare liberum*. This rift has been evident since the establishment of Part XI of UNCLOS and eventually led to the adoption of the 1994 Implementation Agreement. A compromise must be reached by States in order to avoid another agreement for the implementation of the future treaty. Moreover, this paper has also identified that due to the weakness of the regime of the Area, the complications in regulating MGR has been magnified. It has been shown from the legal developments above that MGR are becoming the focal points of future regulations. However, the current framework of UNCLOS as it stands today is argued to be ineffective and inadequate in dealing with MGR and their preservation. This is understandable, as at the time of the drafting of UNCLOS the spotlight was primarily on mineral resources in the Area. Since the potential of MGR was not discovered by then, it would be absurd to expect UNCLOS to have taken them into account. That is not to say that UNCLOS should be totally discarded, as it still provides general provisions for the protection and conservation of marine life that can be applied to MGR. As mentioned above, there are ongoing negotiations regarding the establishment of a future legally binding treaty that will govern *inter alia* MGR. Although the provisions are not finalised yet, there is no mention of freedom of the high seas as being the governing principle of MGR. Rather, MGR will be the CHM or a balance between the two principles. However, the framework may change, as the negotiations are still ongoing.

A realistic approach to the regulation of MGR would be the extension of CHM to *all* resources of the Area. It has been argued that since resources and the Area are inseparable, the same principle should govern both. Such an approach would be considered a natural evolution within the spirit of UNCLOS, which aims to promote a just and equitable economic order. Additionally, the current negotiations so far stipulate that MGR will be governed under

[94] UNGA President's aid to negotiations (n 6).
[95] ibid (n 6).

CHM. Moreover, it has been argued that *mare liberum* is an outdated principle that inadequately reflects the current reality. The principle itself has been gradually eroded by the introduction of several regimes in UNCLOS, thus it would be absurd to hold present activities to a standard developed in the 17th century. Although it may appear novel, deductive reasoning may aid in determining which principle would be appropriate to govern MGR. It has been shown that neither *mare liberum* nor sovereignty regimes could regulate MGR to an acceptable degree, thus CHM must be the appropriate regime.

The contrasting views suggest that freedom of the high seas should govern MGR. UNCLOS clearly excludes MGR from the definition of "resources" that fall under CHM, thus there is no reason to extend the principle. It has been argued that the exploitation of MGR can be considered to be marine scientific research, which is a freedom granted in the high seas. There is also merit in the argument that MGR may fall under Part VII, as they could be considered within the definition of "living resources". Moreover, as the list of high seas freedoms in Article 87 is not exhaustive, MGR could fall under the existing freedoms or a hybrid of them. This appears to be the least persuasive option and it is unlikely it will prevail.

Lastly, it is argued that in order for States to be satisfied a reasonable compromise must be reached. In the President's aid to negotiations paper, it is suggested that a dual system of CHM and freedom of the high seas could be implemented, with access being regulated by the former and exploitation by the latter. Adopting a hybrid system could incorporate the benefits of each regime, thus satisfying the majority of State interests. It is hoped that a compromise will be reached in the ongoing negotiations for a new treaty.

Insurable Interest Bill 2018: A Critical Analysis

*Sean Burke**

Abstract

In 2016, a consultation exercise was conducted by the Law Commission of England and Wales with the aim of 'improving an antiquated and restrictive insurance law.' Resultantly, in 2018, the Law Commission published a draft Bill, with regards to the reform of insurable interest in life and life-related insurances. The fundamental objective this paper sets out to achieve is to establish whether or not this draft Bill has successfully accomplished its overarching aim of updating the law surrounding life and life-related insurable interest as well as elucidating any discrepancies ingrained within its current existence. This paper will critically analyse this draft Bill with particular attention paid to the pressing problems potentially solved by this legislation as well as the problems potentially caused by it. It will provide a comprehensive analysis into the issues each clause of the Bill will likely cause, doing so in ascending order.

Introduction

Since 2006, the Law Commission of England and Wales (hereinafter 'the Law Commission'), in collaboration with the Scottish Law Commission, have embarked on a radical reform of insurance contract law, with the overarching objective of 'improving an antiquated and restrictive insurance law'.[1] Thus far, the work has led to a usually unresponsive government enacting the recommendations, culminating in Royal Assent being granted and the Consumer Insurance (Disclosure and Representations) Act 2012 (hereinafter CIDRA 2012) as well as the Insurance Act 2015 coming into force. These represent watershed moments in the development of insurance contract law and have, in many ways, fundamentally altered the landscape of such. However, the Law Commissioners identified another area of interest for consultation and possible reform.

In 2016, a short consultation exercise was conducted, and subsequently, a draft Bill was produced with regards to the reform of insurable interest.[2] Overall, it was a popular proposition.[3] However, there was almost unanimous agreement between consultees that, in fact, amendments were required, and details needed reviewing, in particular, there was significant concern over the 'interaction with current market practice'. The most prominent concern, though, regarded non-life insurance. There was an unequivocal consensus that that specific area should be left alone. The comments suggested an 'if it's not broken, don't fix it' type feeling from consultees.[4] Resultantly, two years forward, the Law Commission has published a draft bill, appropriately titled the 'Insurable Interest Bill 2018'[5] (hereinafter the 'Bill'), which is confined to solely life and life-related insurances.

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[1] 'Insurance Contract Law: Insurable Interest' (Law Commission, 2020) <https://www.lawcom.gov.uk/project/insurance-contract-law-insurable-interest/> accessed 17 December 2020.

[2] Law Commission, 'Draft Insurable Interest Bill 2016 For Consultation' (Law Commission, 2016) <https://s3-eu-west-2.amazonaws.com/lawcom-prod-storage 11jsxou24uy7q/uploads/2016/04/draft_Insurable_Interest_Bill_April_2016.pdf> accessed 17 December 2020.

[3] ibid.

[4] ibid.

[5] ibid.

This paper will critically analyse this Bill with particular attention paid to the pressing problems solved by this legislation as well as the problems caused by it. It will provide a comprehensive analysis into the issues each Clause of the Bill is likely to cause, doing so in ascending order. Firstly, the Clause 1 will be analysed. It will analyse what insurable interest is in relation to the Bill. Clause 2 will substantively look at the insurable interest requirement. Clause 3 will analyse the effect of untrue statements. Clause 4 will look at the relationship that the Bill will enjoy with existing law. Clause 5 analyses the exclusion for marine insurance contracts. Clause 6 analyses repeals and any consequential amendments. Clause 7 analyses the short title, commencement, application and extent of the Bill.

The fundamental objective this paper sets out to achieve is whether it has successfully accomplished its overarching aim of updating the law surrounding life and life-related insurable interest as well as elucidating any discrepancies ingrained within its current existence. It will be considered whether or not the inception of the Bill will actually cause additional problems and create more ambiguity. To conclude, the paper will assess the relative success of the Bill in light of the prior discussion. It will declare whether the Bill has resolved the most pressing issues, whether the Bill has created additional discrepancy and whether it has been a success overall. Yet, to commence, the phrase 'insurable interest' needs context and definition.

Clause 1 of the bill - what is insurable interest

Clause 1 of the Bill is somewhat misleadingly titled 'definitions.' One would naturally presume that in a bill concerned solely with insurable interest, the section titled definitions would include a definition of insurable interest. Insurable interest, though, can exist in various contexts and is not an easily definable principle. Its inability to be wholly encapsulated by one single definition was acknowledged by Waller LJ in *Feasy v Sun Life Assurance Co of Canada*,[6] where he noted that 'the words used to define insurable interest in, *exempli gratia*, a property context, should not be slavishly followed in different contexts, and words used in a life insurance context where one identified life is the subject of the insurance may not be totally apposite where the subject is many lives and many events'.[7] I submit that there could have possibly been the inclusion of a definition of insurable interest in relation to life-related policies. This would circumvent the non-conformity issue one rigid definition may have in relation to other types of insurance.

Perhaps the most widely accepted and used definition arises from the judgment of Lord Eldon in the case of *Lucena v Crawford*.[8] Here, insurable interest was described as 'a right in the property, or a right derivable out of some contract about the property, which in either case may be lost upon some contingency affecting the possession or enjoyment of the party'.[9] In *Lucena*, the House of Lords sought the advice of the judges on a few particular questions of law. The most notable of which was whether the Commissioners had a sufficient interest in the ships to be able to insure them. One of the judges, Mr Justice Lawrence, formulated a rather broader test than that adopted by Lord Eldon. As he stated, 'to be interested in the

[6] [2003] EWCA Civ 885, [2003] Lloyd's Rep IR 637.
[7] ibid [71]; see also Waller LJ [80] and Ward LJ [174].
[8] (1806) 2 Bos & PNR 269.
[9] ibid [321].

preservation of a thing is to be so circumstanced with respect to it as to have benefit from its existence, prejudice from its destruction'.[10] Despite the fact that Lord Eldon gave the lead judgment, it is the words of Mr Justice Lawrence that find themselves most frequently cited.[11] The concept of insurable interest, however, spawned many years before the judgment of Mr Justice Lawrence. In fact, its inception into insurance law was due largely to social-historical connotations.

These connotations largely stem from the lack of power of the courts to regulate wagering agreements. From at least the 17th century, such agreements were enforceable before the courts just like any other type of contract as there was simply no scope nor platform by which one could challenge a wager simply disguised as an insurance policy.[12] The old law reports from the times clearly indicate how, albeit with bad grace, the courts would adjudicate on wagering and gambling matters, although there was a consistently cantankerous mood among judges in doing so. This may have extended to an admonishment spoken *obiter dicta* expressing dismay at the 'wasting of precious judicial time,' but the cases were heard, nevertheless. The only discernible exception to this would be when the operation of one of these wagers operated contrary to the principle of public policy.

However, attitudes changed. This happened first in Scotland, with the Scottish courts declaring wagers as *sponsiones ludicrae* from around the mid-18th century; they were thus held to be void.[13] A similar approach was not long after adopted in England. That was the case until the first piece of legislation was implemented by parliament. This occurred in response to two not-before seen phenomena: the exponential growth of the number of maritime insurance policies without interest and its negative effect on British shipping, which, at the time, was the lifeblood of the British Empire, as well as an 18th century fad of insuring the lives of 'famous' individuals. The latter was considered to be contrary to public policy and possibly even, in some circumstances, an inducement to murder.

Clause 2 of the bill - insurable interest requirement

The original consultation, as previously mentioned, found an overwhelming desire to leave non-life and non-life related insurance alone;[14] thus, any problems currently in existence which stem from the operation of the MIA 1745 and subsequent case law are unlikely to be solved with the inception of the Bill.[15] Rather, the problems which the Bill aims to address largely stem from a piece of legislation enacted in response to pernicious practices, regarding life. [16] This piece of legislation is the Life Assurances Act 1774 (hereinafter LAA 1774), s. 1 of which represents the first time in English history that insurable interest became a statutory

[10] ibid [302].
[11] Waller LJ in *Feasy v Sun Life Assurance Co of Canada* [2003] EWCA Civ 885, [2003] Lloyd's Rep IR 637, [70].
[12] See *Whittingham v Thornburgh* (1690) 2 Vern. 206; *Martin v Sitwell* (1691) 1 Show. K. B. 156; *Goddard v Garrett* (1692) 2 Vern. 269; *Le Pypre v Farr* (1716) 2 Vern. 516.
[13] Alistair B Wylie and Sean J Crossan, *Introductory Scots Law* (2nd edn, Hodder Gibson 2010) 165-166.
[14] Law Commission (n 2).
[15] *Da Costa v Jones* (1778) 2 Cowp. 729; *Atherfold v Beard* (1788) 2 Term Rep. 610; *Shirley v Sankey* (1800) 2 Bos. & P. 130.
[16] See Lord Ellenborough CJ in *Gilbert v Sykes* (1812) 16 East 150.

requirement.[17] The Bill repeals s. 1 partially and s. 2 and s. 3 fully (s. 4 not at all), but affirms the insurable interest requirement that was introduced into English law just under 250 years ago. It aims to deal with the incredibly prohibitive and antiquated legislation, which was simply no longer a viable set of rules to deal with modern insurance law, by expanding the scope of people who can now be seen to have an insurable interest and by doing so in various ways.

S. 1 LAA 1774 caused the law to become unduly restrictive.[18] It completely prohibited the making of any insurance 'for the life or lives of any person, or persons, or on any other event or events whatsoever' by people who have no insurable interest – which extends to also include critical illness and personal injury cover. A person may insure his or her own life, or that of a spouse or civil partner (since Marriage (Same Sex Couples) Act 2013),[19] without evidence of loss and for any amount, so long as there is an insurable interest. It is permissible to insure the life of another where the policyholder would suffer financial loss on the other's death. This, however, requires 'a pecuniary interest recognised by law', instead of a reasonable expectation of loss. Moreover, there is a requirement that the loss must be quantified at the time the contract is taken out. This requirement has found itself to have been interpreted strictly, leading to overly harsh results.[20] *Exempli gratia*, the courts have held that a father's expectation that his son would care for him or maintain him was not sufficient to constitute an insurable interest in the son's life.[21]

Moreover, s. 1 is innately ambiguous. It fails to specify precisely when the insurable interest is required by the insured. Upon diligent examination, it becomes clear that s. 1 reads 'no insurance shall be made' without any insurable interest. This suggests that there is the requirement for some *ab initio* interest.[22] On the other hand, the fact that s. 3 mentions that 'no greater sum shall be recovered or received from the insurer or insurers than the amount of value of the interest of the insured in such life or lives' suggests there is the requirement for some interest upon death as well.[23] The case law on this issue has affirmed that, in fact, both requirements seek satisfaction,[24] so there is an interest at the inception of the policy and at the death of the policy. However, the legislation is silent on the matter, and the case law is very old. Thus, these discrepancies represented an opportunity for the Bill to reform another pressing issue of insurable interest but, it has failed to do so. Its omission of an express provision dealing with when an interest is required makes it unclear whether the old case law is still relevant or not. If anything, the Bill will create further problems here, rather than solve them.

A number of the issues created by s. 1 LAA 1774 are resolved in clause 2 of the Bill. It introduces three grounds by which interest can be found. Firstly, there is the proposition of introducing a category of interests based upon specific relationships. If it is proven that a particular relationship subsists, *exempli gratia* a parent and child, then there is the irrebuttable

[17] *Mark Rowlands Ltd v Berni Inns Ltd* [1985] 3 All E.R. 473.
[18] Robert Merkin, *Colinvaux's Law of Insurance* (11th edn, Sweet & Maxwell 2016) para A-0387.
[19] See s. 11, which provides that 'marriage has the same effect in relation to same sex couples as it has on opposite sex couples'.
[20] Malcolm A Clarke, *The Law Of Insurance Contracts* (6th edn, Informa 2009) 65.
[21] *Halford v Kymer* (1830) 10 B&C 724.
[22] Merkin (n 18) para. A-0439.
[23] ibid para. A-0439.
[24] *Godsall v Boldero* (1807) 9 East 72; *Henson v Blackwell* (1845) 4 Hare 434.

presumption that an insurable interest exists. It is sufficiently wide to deal with the more informal familial arrangements which are commonplace nowadays. It provides scope for both adopted children and relationships of guardian to be recognised as capable of producing an insurable interest. There is no need for further proof of any economic dependency or expectation of loss.[25] In an explicit manifestation of the shift in social attitudes than from the times when the LAA 1774 was enacted, cohabitants who are married or are civil partners are included in this list of specific relationships. Likewise, to before, whilst this provision may operate to resolve one of the most pressing issues of insurable interest, namely an omission of recognition of modern social life in that interests can exist beyond the more traditional relationships, it does cause other issues.

It very ambiguously permits an insurable interest when 'the individual who is the subject of the contract'… 'is treated as…the child or grandchild of the insured'. This might quite obviously lead to significant issues. There is not a quantifiable criteria by which one could be accurately measured to be adequately 'treated as' ones' child or grandchild. This will likely be left to the courts to decipher, who in line with their previous policy, will attempt to find an insurable interest, unless starkly contradictory to public policy.[26] The Bill here is likely to cause the finding of many tentative relationships, possibly causing widespread injustice and causing an increase in the number of pay-outs. It solves one pressing issue whilst simultaneously creating another.

Next, the prospect of economic loss as a ground for the finding of an insurable interest is proposed. It allows a policyholder to insure the life of another on the sole grounds that they would suffer a quantifiable economic loss upon the death of that other person, or on the occurrence of another insured event, such as injury. This provision operates similarly to the previous relevant provision in allowing debtors and employers taking key person policy on employees, but also operates to resolve one of the most pressing issues of the incumbent law. It now allows for children and grandchildren to insure their interests, provided the prospect of economic loss can be adequately demonstrated.[27] The previous, rather confining requirement 'pecuniary interest recognised by law' is an example of a pressing problem that is defeated by the Bill. However, while this prominent issue is solved, it yields an unanticipated consequence. It provides some incentive for children and grandchildren to 'knock off' elderly relatives. If there is a mere reasonable expectation of economic loss, then children and grandchildren can safely presume that they have an insurable interest in the life of the elderly relative, and so may be incentivised to 'hurry up' their assured payday.

The last category of permitted insurable interests is that of a group policy, currently prohibited by s. 2 LAA 1774. Alas, this is another example of the law being unduly restrictive and represents another archaic remedy to a no longer relevant issue.[28] It requires the persons interested in the policy, or the persons for whom the policy has been effected, to be expressly

[25] Cristian Luna Chandia, 'Insurable Interest on the Eve of its Legislative Consolidation: it is still not too late to put into reverse gear' (2018) 131 BILAJ 2727.
[26] ibid.
[27] ibid.
[28] Geoffrey Clarke, *Betting On Lives: The Culture Of Life Insurance In England, 1695-1775* (Manchester University Press 1999).

named in the policy document.[29] This was brough in as a response to difficulties in identifying who had an insurable interest in the 1700s.[30] It provided a simple solution to a disruptive issue. Yet, as acknowledged by Birds, Lynch and Milnes,[31] it does not reflect the complexities of modern insurance law. The most prominent issue caused by this restriction is the inability to effectuate a group policy, something particularly frustrating to both stakeholders and employers.[32] S. 2 LAA 1774 is thus repealed by the Bill. At clause 2(3)(b), the Bill acknowledges that group policies would be enormously beneficial, and so, at clause 2(5), allows for automatic inclusion of individuals who fall within a certain class or category of people that the policy covers. This basically removes the requirement for individuals to be named in the policy. The complexities of modern insurance law have finally been somewhat recognised here. These provisions support and affirm the legal legitimacy of group policies, a reward which will be enjoyed and celebrated by numerous different people, including stakeholders and employers.

S. 3 LAA 1774 is also dealt with by the Bill. It currently places express limitation on the amount that can be claimed for. At present, recovery is limited to the interest of the policyholder in the life which has been insured. Whilst this provision does not apply to policies where the basis of insurable interest is based upon natural affection, it is again unduly restrictive and demonstrative of outdated law. The Bill expressly repeals s. 3 LAA 1774. It has seemingly become clear that with the effluxion of over 245 years since Royal Assent was granted, the LAA 1774 has become almost inoperable.[33] It has become over the top, unnecessary and is exactly the sort of antiquated legislation that the Bill has aimed at reforming since the consultation.

Clause 3 of the bill - effect of untrue statements

It is important to note, though, that it is not just the individual pieces of legislation that the Bill has aimed at reforming. The various pieces of legislation together combine to create a tangled myriad of overlapping and muddled rules which can be hard to follow. The Law Commission described these statutes as 'dated, confused and varied'.[34] At present, where an insurance contract fails, then usually the premiums are returned to the insured. This is in pursuance of s. 84 Marine Insurance Act 1906, which also provides an exception when the insured themselves have been a victim of fraud or illegality. However, as has been identified by Merkin, there is no express provision declaring whether or not this applies to insurance contracts other than those of marine insurance.[35] As things are, an insured may be entitled to

[29] Robert Merkin 'Gambling by insurance – a study of the Life Assurance Act 1774' (1980) 9 Anglo-American Law Review 331.
[30] Robert Merkin and Johanna Hjalmarsson, *Compendium Of Insurance Law* (Informa Law 2008) 626-627.
[31] John Birds, Ben Lynch and Simon Milnes, *MacGillivray on Insurance Law* (13th edn, Sweet & Maxwell 2015), para. 1-028 - 1-031.
[32] James Davey, 'Dial M for moral hazard? Incentives to murder and the Life Assurance Act 1774' (2014) 25 Insurance Law Journal 120.
[33] ibid para. 1-028 - 1-037.
[34] Law Commission (n 2).
[35] See Merkin (n 18) para 9-029; *cf.* Birds, Lynch and Milnes (n 31) para 8-030.

recovery of paid premiums, even if such premiums were obtained through fraud, or by deliberately or recklessly misleading the insurer as to the existence of an insurable interest.[36]

The Law Commission has highlighted how the Marine Insurance Act 1906, CIDRA 2012 and the Insurance Act 2015 operate in contradistinction to one another with regards to the principle of the return of premiums. Unlike the above Marine Insurance Act 1906, CIDRA 2012 and the Insurance Act 2015 give the right for the insurer to retain any premiums paid where it is discovered that the policy had been granted unknowingly under the guise of a fraud, whether deliberate or reckless.[37] Clause 3 solves this issue of ambiguity and clarifies firmly the new law. It states that, if an insured makes a misleading or untrue statement about the nature of its insurable interest and also is either in the knowledge that such a statement is untrue or misleading, or conversely simply does not care whether it is either untrue or misleading, then it is within the remit of the insurer to retain the premiums paid, despite the fact that the contract of insurance is void. Here, the Bill is entirely successful in its endeavours to basically tidy up these tangled statutes. It provides a clear, unambiguous set of rules which prudent insurers and those who are insured can comprehend and easily follow.

Clause 4 of the bill - relationship with existing law

Clause 4 of the Bill is also clear, unambiguous and easy to follow. It very succinctly states that any other laws, whether old or new, are repealed by the Bill, insofar that they relate to life insurance. Possibly the most pertinent amendment this provision will make to real-life practice is that the tremendously archaic rule that conferred illegality whence no insurable interest was found is repealed, so that instead, the relevant insurance contract is merely void. This provides the much-needed scope sought after by those who are insured to recover premiums from void policies according to the aforementioned rules on the effects of untrue statements.[38] In particular, the Marine Insurance Act 1788 and the Marine Insurance (Gambling Policies) Act 1909 will be repealed by the Bill. Additionally, s. 1 (to the extent that it relates to life-related insurance), s. 2 and s. 3 of the LAA 1774 will also be repealed.

The express mention of the exact legislation that is to be repealed is helpful on two fronts. Primarily, it provides clarity. It solves the issue of insurable interest for life-related insurance being governed by tangle of 18th, 19th and 20th century statutes,[39] all of which were enacted in response to issues that do not persist in the modern digital world.[40] Furthermore, gambling is now legal and regulated, and the amounts of information needed to actually constitute an effective insurance policy mean that it would be difficult to actually do so without being close to that person.[41] However, another advantage conferred from the Bill is that the provisions

[36] Franziska Arnold-Dwyer, 'Insurance Law Reform By Degrees: Late Payment And Insurable Interest' (2017) 80 Modern Law Review 3.
[37] Sinem Ogis, 'The Influence Of Marine Insurance Law On The Legal Development Of Life And Fire Insurance In England' (2020) 4 Comparative Studies in the History of Insurance Law.
[38] Chandia (n 25).
[39] Eric A. Posner and E. Glen Weyl, 'An FDA For Financial Innovation: Applying The Insurable Interest Doctrine To 21st Century Financial Markets' (2013) 107 Northwestern University Law Review 1307.
[40] Kehinde Anifalage, 'Changing Legal Perspectives Of The Requirement Of Insurable Interest In Insurance Contracts' (2020) 3 Commonwealth Law Bulletin 7.
[41] Mark Templeman Q.C., 'Insurable Interest: A Suitable Case For Treatment?' in Baris Soyer (ed) *Reforming Marine and Commercial Insurance Law* (Informa 2020).

contained within were written with consultation to the market and the people who will be truly using the legislation. The vast majority of legislation does not enjoy the benefit of basically being indirectly written by the people whom it is supposed to govern – something which should lead to the Bill working well in practice. *Prima facie,* Clause 4 does not create any discernible issues.

Clause 5 of the bill - exclusion for marine insurance contracts

On the contrary, Clause 5 does create discernible discrepancies. Most pressingly, it may not even be needed at all. As previously discussed above, there was overwhelming support for the proposals to be limited to life-related insurance only and to leave other insurance alone.[42] The inclusion of this provision is merely the consequences of a hangover from back when the draft Bill was concerned with both life and non-life related insurance.[43] Despite the change in objective, namely converting from reform of both life and non-life to just the reform of life, there has been a consistent request from the consultees of the consultation that the provisions of the Marine Insurance Act 1906 work well and should be kept the same.[44] There was no credible case for reform.[45] This leads to the inevitable question: does the Bill need to include this exception in light of the fact that it now relates solely to life?

Perhaps not. Notwithstanding that fact, it may not hurt to include it anyway. One of the most significant complaints about the old law was that it was unclear. It was a perplexing tangle.[46] At least this provision is clear and sets out definitively exactly what it shall do. The fact that included within the accompanying notes is a question to consultees asking whether Clause 5 should be kept in the Bill is rather telling as to just how unsure the law Commission are here as to whether it will ever be needed. I submit that, whilst I acknowledge that consideration of this matter is complex, the preamble of the Marine Insurance Act 1906 illuminates the uselessness of Clause 5, by stating that it is 'An Act to codify the Law relating to Marine Insurance.' Moreover, this provision is unlikely to create any new problems.

Clause 6 of the bill - repeals and consequential amendments

The same can be said about most of Clause 6, in that it is unlikely to create many new problems, but there is scope for issues and inconsistency. It is basically the effectuation of Clause 4. These two clauses could arguably have been condensed into one clause but, in pursuance of clarity, it is a good idea they were not. Clause 6 expressly repeals or partially repeals three already mentioned pieces of legislation, but, then it also includes the concept of consequential amendments. It does not name specifically what these amendments are. This is where this clause could be improved. There is an accompanying document in which the full list of amendments could be dissimilated, but this opportunity has been missed. There

[42] Law Commission (n 2).
[43] Clarke (n 28).
[44] Law Commission (n 2).
[45] Estian Botes and Henk Cloppers, 'Insurable Interest As A Requirement For Insurance Contracts: A Comparative Analysis' (2021) 26 African Journal of International and Comparative Law 130.
[46] Franziska Arnold-Dwyer, *Insurable Interest And The Law* (Taylor & Francis Group 2020).

are some examples given, like how the Friendly Societies Act 1992, s. 99 is repealed, along with the Civil Partnership Act 2004, s. 253.

Interestingly, public policy would still seem to be the pivotal consideration here rather than just the elucidation of pre-existing legislation. From the accompanying document, it can be seen that one pressing issue is purposely not solved.[47] The Children Act 1989, which operates to exclude a foster parent having an insurable interest in the life of their foster child, is retained. This is noted as being because of 'policy considerations beyond the scope of the project'. This represents one very criticisable feature of the Bill; that there are areas where it could be added to so as to resolve anomalies. The pressing issue surrounding the situation here between foster parents and foster children subsists, and while no new issues have been created, this represents a failure of the Bill.

Clause 7 of the bill - short title, commencement, application and extent

Quite predictably, Clause 7 is the least problematic. In essence, it is an administrative consideration. One notable feature is how Clause 7(3) means that the draft Bill applies solely to contracts which were entered into after it comes into force. Yet, Clause 7(4) provides that insureds who entered into a contract of life-related insurance before that date will be deemed to have an insurable interest if they would have an insurable interest under the provisions of the draft Bill. According to the accompanying document, the Law Commission included it because it was deemed undesirable for the incumbent rules to operate so as to allow insurers or insureds to escape a policy which they entered into and which would otherwise be valid under the provisions of the draft Bill.[48] Another pressing issue is here resolved, without any new issues being created.

Conclusion

In conclusion, it would be fair and just to state that the Law Commission has been relatively successful in their draft Bill, with regards to the overriding objectives. Yet, overall, the title proposition is not correct. Whilst arguably the Bill has resolved the most pressing problems regarding insurable interest, it does not do so without creating new problems. Clause 1 successfully affirms the requirement for insurable interest in life and life-related insurance. However, it misses the opportunity to define insurable interest for life and life-related insurance. Whilst this may not represent a pressing issue, it is still a problem which could have been solved. Clause 2, the key clause which sets out the requirement, is extensively analysed. It is identified how it successfully reforms the very antiquated and restrictive law in relation to the requirement of insurable interest. It untangles the tangle that was this area of law. It repeals unnecessarily restrictive laws. However, it is not perfect. It fails to address the pressing issue of exactly when the interest is required, and also when it must be quantified.

[47] Law Commission of England and Wales, 'Accompanying Notes On Draft Insurable Interest Bill PDF' (2021) <https://s3-eu-west-2.amazonaws.com/lawcom-prod-storage-11jsxou24uy7q/uploads/2015/06/June-2018-Accompanying-notes-on-draft-Insurable-Interest-bill.pdf> accessed 5 January 2021.
[48] ibid.

Clause 3 is the most successful. It creates a clear, unambiguous image of the exact state of the law and comprehensively repeals the pre-existing legislation. It does not create any new issues or discrepancies. Clause 4 is much the same. It provides clarity as to the future of the relationship between the Bill and pre-existing legislation. It is particularly useful for practitioners of insurance law. Clause 5 delineates the exception of marine insurance. This clause is somewhat questionable and could be omitted from the Bill. Nevertheless, it does not cause additional issues. Clause 6 can be similarly analysed. It expressly notes the repeals effectuated by the legislation. Yet again, though, it is not perfect. It is stained by public policy considerations which in turn means foster parents have no insurable interest over foster children. Clause 7, the least problematic, is successful in its administrative duties. Overall, the Bill is a success. It addresses the most pressing problems haunting insurable interest in relation to life, only. So, it is not perfect. There are several amendments which could be made to limit the issues caused by the Bill. Another consultation stage could sort this. Perhaps it is a good thing that it is only a draft, as the real deal could resolve all of these issues in the future.

The Role and Meaning of 'Occupation' in Schedule 3, Paragraph 2 of the Land Registration Act 2002

*Amirah Adam**

Abstract

In *Abbey National Building Society v Cann*, Lord Oliver observed: 'it is, perhaps, dangerous to suggest any test for what is essentially a question of fact, for "occupation" is a concept which may have different connotations according to the nature and purpose of the property which is claimed to be occupied'.[1] This paper focuses on the role and meaning of 'occupation' in Schedule 3, paragraph 2 of the Land Registration Act 2002. It will consider the misconception that the word 'occupation' may be interpreted in ordinary language and argue that rather, the meaning should be deduced from the judgements and regarded in the specific context to which it applies.

Evidently, there is no set definition of 'occupation' in Schedule 3, paragraph 2 of the Land Registration Act (LRA) 2002. As outlined by Mummery LJ in *Link Lending Ltd v Bustard*, 'the trend of the cases shows that the courts are reluctant to lay down, or even suggest, a single test for determining whether a person is in actual occupation'.[2] This illustrates the court's malleable approach in defining 'actual occupation'. Moreover, the meaning of 'actual occupation' within the LRA 2002 is not necessarily the same as the meaning of 'occupation' in other statutes or in ordinary language.

In *Cornerstone Telecommunications Infrastructure Ltd v Compton Beauchamp Estates Ltd*, in considering whether someone counted as 'the occupier' of land in the Communications Act 2003, Lewison LJ emphasized it is common ground that, 'in legal usage, the meaning of the words "occupier" and "occupation" is intensely sensitive to context'.[3] Lewison LJ quoted Lord Walker in *Principal and Fellows of Newnham College, Cambridge University v Commissioners of HMRC*, who held in the House of Lords that the meaning of the word 'occupation' in the statute is 'strongly influenced by the statutory context and purpose'.[4] Lewison LJ then clarified that in some cases, for instance in the context of overriding interests under the Land Registration Acts, the relevant concept is not simply 'occupation' but 'actual occupation'.[5]

Furthermore, he elaborated on the different meanings of 'occupation' in various different statutes such as the Occupiers' Liability Act 1957[6] and Value Added Tax Act 1994,[7] and the marginally different meaning of the phrase 'actual occupation' in the LRA 2002.[8] Therefore, it should be noted that when talking about this statutory concept in Schedule 3, paragraph 2 of the LRA 2002, the phrase 'actual occupation' should be utilized. Furthermore, Lewison

* *LLB (Soton).*

[1] [1991] 1 AC 56 [93] (Lord Oliver).
[2] [2010] EWCA Civ 424 [D36] (Mummery LJ).
[3] [2019] EWCA Civ 1755 [281] (Lewison LJ).
[4] [2008] UKHL 23 [39] (Lord Walker).
[5] *Cornerstone* (n 3) [291] (Lewison LJ).
[6] ibid [43] (Lewison LJ).
[7] ibid [46] (Lewison LJ).
[8] ibid.

LJ refers to the 'Land Registration Acts',[9] as opposed to a single 'Act'. This idea of 'actual occupation' as a particular statutory concept within a scheme of Land Registration was introduced in the LRA 1925, however the LRA 2002 uses the phrase 'actual occupation' to mean the same concept. The importance of this is that the judgements considering the meaning of 'actual occupation' as defined in section 70(1)(g) of the LRA 1925 are still relevant, that is, they can still be used to interpret the meaning of 'actual occupation' in the LRA 2002. This was confirmed by Mummery LJ in *Bustard*.[10] Therefore, though in *Williams & Glyn's Bank Ltd v Boland*, Lord Wilberforce declared that the words 'actual occupation' 'are ordinary words of plain English and should in my opinion be interpreted as such',[11] it can be argued that even in ordinary English, occupation is not a simple and clear-cut concept. As 'occupation' means different things in different statutes including the phrase 'actual occupation' in the Land Registration Statutes, then in that case, relying on one's idea of the meaning of 'occupation' in ordinary English may not be feasible. Thus, the definition of 'actual occupation' must be deduced from the judgements and whether in a specific context, in accordance with the nature and purpose of the property, a specific party was held to be in 'actual occupation'.

In *Cann*, Lord Oliver held that a person claiming to be the holder of an overriding interest for the purposes of s.70(1)(g) must be in 'actual occupation' at the time of completion.[12] However, as explained by Lewison J in obiter dicta in *Thompson v Foy*, 'there must be actual occupation both at the date of the disposition and also at the time of registration'.[13] Nonetheless, the position established in *Cann* has since been confirmed by the wording of Schedule 3, paragraph 2 and the decision in *Cook v The Mortgage Business Plc*.[14] Therefore, if 'actual occupation' arose after completion but before registration then that would be considered an overriding interest for the purpose of Schedule 3, paragraph 2.

Moreover, in *Boland*, Lord Wilberforce claimed that the word 'actual' in 'actual occupation' 'merely emphasises that what is required is physical presence, not some entitlement in law'.[15] This is portrayed in *Kling v Keston Properties Ltd*, wherein Vinelott J proposed that the claimant, though a licensee, was in 'actual occupation' regarding his use of a garage, as there was evidence of Kling's occupancy as well as his intention to sustain its use by parking a car.[16] This was affirmed in *K-Sultana Saeed v Plustrade Ltd*, whereby the Court of Appeal held that 'the right to park'[17] 'under an easement amounted to actual occupation of the burdened land'.[18] However, this may be contrasted with *Epps v Esso Petroleum Co Ltd*,[19] where Templeman J decided that under s.70(1)(g) of the LRA 1925 'the parking of a car on a strip of land did not suffice to establish actual occupation'.[20] Additionally, in *Blacklocks v JB Developments (Godalming) Ltd*, the claimant was deemed by Judge Mervyn Davies to be in

[9] ibid.
[10] *Bustard* (n 2).
[11] [1981] AC 487 [504] (Lord Wilberforce).
[12] *Cann* (n 1) [71] (Lord Oliver).
[13] [2009] EWHC 1076 (Ch) [349] (Lewison J).
[14] [2012] 5 EG 82; Margaret Wilkie, Peter Luxton, Rosalind Malcolm, *Land Law* (10th edn, OUP 2015) [80].
[15] *Boland* (n 11) [505] (Lord Wilberforce).
[16] [1983] 49 P & CR 212 [219] (Vinelott J).
[17] [2001] EWCA Civ 2011 [50] (Sir Christopher Slade).
[18] Martin Dixon, *Modern Land Law* (5th edn, CPL 2005) 53.
[19] [1973] 1 WLR 1071 [1080] (Templeman J).
[20] Wilkie, Luxton and Malcolm (n 14) 83.

'actual occupation' due to constructing a barn on agricultural land.[21] However, in *Bhullar & Anor v McArdle* as per Mummery LJ, 'depositing garden debris and maintaining a compost heap' on the property did not constitute 'actual occupation'.[22]

Consequently, as per Lord Wilberforce's decision in *Boland*,[23] whether an individual 'is "in actual occupation" is a question of fact, not of law'.[24] It may be argued that this key notion underpins Lord Oliver's decision in *Cann*, where he emphasized that 'occupation' suggests 'some degree of permanence and continuity which would rule out mere fleeting presence'.[25] However, there are cases which assess whether an individual is in 'actual occupation' for the purpose of Schedule 3, paragraph 2, wherein there are breaks in one's occupation or an individual's occupation is intermittent. In *Kingsnorth Finance Co Ltd v Tizard*, Judge John Finlay QC held that 'regular and repeated absence' may be in accordance with 'actual occupation'.[26] In addition, in *Chhokar v Chhokar*, Cumming-Bruce LJ upheld that though the claimant was physically absent by virtue of being at the hospital for childbirth, she was in 'actual occupation'.[27] This was evidenced by her belongings still being present at the property. Furthermore, this is confirmed in *Bustard*, as though the claimant was taken into psychiatric care for a year, her possessions were still *in situ*, and she had made weekly visits to the property and collected post.[28] Mummery LJ in the Court of Appeal acknowledged that she had a beneficial interest in the property that was sold. However, she had an overriding interest regardless of her irregular occupation. Therefore, as Clarke and Greer contend, 'temporary absences from a property will not undermine an equitable owner's actual occupation'.[29]

However, Lord Oliver's decision in *Cann*[30] may be distinguished from *Stockholm Finance Ltd v Garden Holdings Inc*,[31] where the Court of Appeal held that the claimant was not in 'actual occupation' due to her intermittent occupation. Although her possessions were in the second home, as she was absent from the property for over a year, Robert Walker J declared that 'there comes a point at which a person's absence from his house is so prolonged that the notion of his continuing to be in actual occupation of it becomes insupportable'.[32] This was upheld in *AIB Group (UK) v Turner & Ors*, where in obiter dicta Anthony Elleray QC stated that as the claimant effectively 'moved to her second home' in Barbados, she was no longer in 'actual occupation', despite her and her son's occasional occupancy.[33] This case reinforces the notion that the 'presence of personal possessions is persuasive, not conclusive'.[34]

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[21] [1982] Ch 183 [193] (Judge Mervyn Davies).
[22] [2001] EWCA Civ 510 [488] (Mummery LJ).
[23] *Boland* (n 11) [505] (Lord Wilberforce).
[24] Mark Davys, *Land Law* (8th edn PM 2013) 263.
[25] *Cann* (n 1).
[26] [1986] 1 WLR 783, ChD [788] (Judge John Finlay QC).
[27] [1984] FLR 313 [329-330] (Cumming-Bruce LJ).
[28] *Bustard* (n 2) [30] (Mummery LJ).
[29] Sandra Clarke and Sarah Greer, *Land Law Directions* (7th edn, OUP 2020) [211].
[30] *Cann* (n 1).
[31] *Stockholm Finance Ltd v Garden Holdings Inc* [1995] NPC 162.
[32] ibid [18] (Robert Walker J).
[33] [2015] EWHC 3994 [88] (Anthony Elleray QC).
[34] 'Mortgages and beneficial occupation' (Walker Morris, April 2016) <https://www.walkermorris.co.uk/publications/mutual-matters/mortgages-beneficial-occupation/> accessed 4 June 2020.

In addition, Lord Denning MR in *Hills (Patents) Ltd. v University College Hospital Board of Governors* confirmed that 'occupation may be shared with others'.[35] Lord Oliver in *Cann* elucidated that 'actual occupation' may not 'involve the personal presence of the person claiming to occupy'.[36] He demonstrated that this may encompass a 'caretaker' or perhaps the 'representative of a company'.[37] Similarly, in *Lloyds Bank plc v Rosset*, Nicholls LJ declared that 'the presence of a builder engaged by a householder' also alludes to 'actual occupation'.[38] Therefore, as Dixon asserted, 'occupation' should not be likened to 'exclusive possession'.[39]

Contrarily, in *Strand Securities v Caswell*, it was held that 'actual occupation' of a licensee in favour of themselves does not render 'actual occupation' for the benefit of the licensor, as delineated by Lord Denning MR.[40] This was affirmed in *Lloyd v Dugdale* by Sir Christopher Slade.[41] In addition, he expressed that though the claimant was physically present, he was not in 'actual occupation… within the meaning of section 70(1)(g) of the 1925 Act' as he was held to be an agent for his company. Therefore, as contended by Harpum, Bridge and Dixon:

> an employee, agent or a contractor (such as a caretaker or a builder) who is specifically employed for a purpose that entails his being in occupation, can occupy on behalf of his employer. However, occupation by a licensee for his own purposes (rather than for the person claiming the right) will not suffice.[42]

Additionally, it is important to note that the concept whereby a wife's 'actual occupation' could be ascribed to her husband's (*Caunce v Caunce*)[43] has been invalidated (*Bird v Syme-Thomson*).[44] Whereas Nourse LJ in *Hypo-Mortgage Services Ltd v Robinson* held that children have no right of 'actual occupation' of their own but 'as shadows of occupation of their parents'.[45]

Further, in *Rosset*, as delineated by Lord Bridge of Harwich, 'actual occupation' may be determined on the basis of the condition of the property.[46] Newey J in *Baker v Craggs* established that, 'even in the case of a house, "occupation" need not involve residence'.[47] This was evident in *Thomas v Clydesdale Bank Plc*, wherein The Honourable Mr. Justice Ramsey held that the 'intentions and wishes' of the claimants to return, as well as their regular presence on the semi-derelict property almost on a 'daily basis' during its renovation, were 'reasonable prospects of establishing' 'actual occupation'.[48]

Also, it should be noted that a claimant's overriding interest may not be discoverable, as their 'actual occupation' of part of a larger plot may not induce 'actual occupation' over the entire

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[35] [1955] 3 All E.R. 365. 97 [99] (Lord Denning MR).
[36] *Cann* (n 1).
[37] ibid.
[38] [1991] 1 AC 107 [378] (Nicholls LJ).
[39] Martin Dixon, *Modern Land Law* (11th edn, Routledge 2018) [6.2.1].
[40] [1965] Ch 958 [980] (Lord Denning MR).
[41] [2001] EWCA Civ 1754 [45] (Sir Christopher Slade).
[42] Charles Harpum, Stuart Bridge and Martin Dixon, *Megarry & Wade: The Law of Real Property* (8th edn, Sweet & Maxwell 2012) [207-208].
[43] [1969] 1 WLR 286, ChD.
[44] [1979] 1 WLR 440.
[45] [1997] 2 FLR 71 [426] (Nourse LJ).
[46] *Rosset* (n 38) [118] (Lord Bridge of Harwich).
[47] [2016] EWHC 3250 (Ch) [12] (Newey J).
[48] [2010] EWHC 2755 (QB) [32], [38] (The Honourable Mr. Justice Ramsey).

property. Robert Walker LJ in *Ferrishurst Ltd v Wallcite Ltd* held that 'the occupier need not, in order to rely on section 70(1)(g), be in actual occupation of the whole of the land comprised in a registered disposition'.[49] However, as Bevan describes, the Law Commission considered this position as culminating in a 'strange result' as it arguably allotted a considerable 'burden on purchasers of registered land to inspect the land than applied if land was unregistered'.[50] Hence, this contravened the aims of the intended 'legislative regime'.[51] Therefore, by virtue of the LRA 2002, the judgement in *Ferrishurst* was overturned. As Schedule 1, paragraph 2 as well as Schedule 3, paragraph 2 outlines, 'interests of persons in actual occupation' extend 'so far as relating to land of which he is in actual occupation'. Accordingly, if an individual 'has a proprietary interest in the whole land but is only in actual occupation of part, this interest will be overriding only in relation to that part of the land touched by occupation'.[52] This was affirmed by Lewison J in *Foy*.[53]

Finally, as illustrated by Lloyd LJ in *Chaudhary v Yavuz*, 'actual occupation' should be discerned from mere 'use'.[54] This must be distinguished from *Keston*, where 'the use of the garage was under a licence, not an easement' and thus, could have constituted 'actual occupation'.[55] In *Chaudhary*, the equitable easement by which tenants utilized a metal staircase in order to access their flats was deemed 'use, not occupation'.[56]

In conclusion, as highlighted in *Hodgson v Marks* as per Russell LJ, the courts have been reluctant to 'lay down a code or catalogue of situations' wherein 'actual occupation' would be presumed.[57] Therefore, whether or not an individual is in 'actual occupation' of property, within the meaning of 'occupation' in Schedule 3, paragraph 2 of the LRA 2002, is a 'question of fact',[58] which would depend on the 'nature and state of the property in question'.[59] Consequently, this may be deemed in accordance with Lord Oliver's observation in *Cann* that 'it is, perhaps, dangerous to suggest any test for what is essentially a question of fact, for "occupation" is a concept which may have different connotations according to the nature and purpose of the property which is claimed to be occupied'.[60]

[49] [1999] Ch 355 [372] (Robert Walker LJ).
[50] Chris Bevan, *Land Law* (1st edn, OUP 2018) [90].
[51] ibid.
[52] ibid.
[53] *Foy* (n 13) [128-129] (Lewison J).
[54] [2011] EWCA Civ 1314 [30] (Lloyd LJ).
[55] *Keston* (n 16) [258] (Vinelott J).
[56] *Chaudhary* (n 54) [32] (Lloyd LJ).
[57] [1971] Ch 892 [932] (Russell LJ).
[58] *Boland* (n 11) [491] (Lord Wilberforce).
[59] *Malory Enterprises Ltd v Cheshire Homes (UK) Ltd* [2002] EWCA Civ 151 [80] (Arden LJ).
[60] *Cann* (n 1).

Dissertations

The following are some of the best LLM and undergraduate dissertations from the 2019-20 academic year.

These dissertations have not been edited.

To what extent can unmanned ships comply with COLREGs 1972 and how will the liability of such vessels be assessed?

*Eleni Achnioti**

Abstract

Unmanned ships are presently able to infiltrate the maritime industry due to the rapid technological advances of this era. Their introduction to the maritime sector could pose novel questions regarding compliance and liability with the established framework. The aim of this research is twofold; firstly to examine the extent to which unmanned ships may comply with COLREGs and secondly how such vessels may be held civilly liable in case of a collision. The types of ships considered will be remote-controlled and autonomous. The underlying theme of the essay will showcase how this binary distinction may have significant consequences regarding compliance. The first part of the study will explore certain COLREGs Rules, namely Rules 2, 3, 5, 6 and 8. It will be concluded that remote-controlled vessels stand a better chance at compliance than autonomous ones. The second part of the research will focus on answering prominent questions regarding liability. It will argue that the fault-based liability can be maintained for remote-controlled ships. Autonomous ships conversely, may benefit from a strict liability model for policy and convenience reasons. The right to limit liability can be invoked by unmanned shipowners and shore-based operators, but not by manufacturers nor software programmers. Ultimately, to ensure the effective integration of such vessels in the industry, it will be argued that either new regulations will need to be drafted or present ones be amended.

Chapter 1: Introduction

Unmanned ships are becoming a real prospect for the coming years and have the potential to revolutionise one of the world's most ancient industries. Consequently, several international conventions may need to be reviewed in order to safely integrate such ships in the lex maritima. The conservative nature of the shipping industry juxtaposes the innovative character of unmanned ships, as traditionally the industry has been resistant to change, evidenced in inter alia the failure of the Rotterdam Rules.[1] This indicates the difficulty in altering the established regulatory landscape and highlights that the current law may struggle to accommodate the new challenges posed by unmanned vessels.[2] Nevertheless, maritime laws and concepts have successfully adapted from the days of sail to the introduction of steam, diesel and nuclear propulsion.[3] There is thus no reason why the law cannot readjust to accommodate unmanned ships.

The benefits of unmanned ships are numerous.[4] They have the potential to cut costs across the board, as by definition, there would no longer be a need for a crew and master onboard the ship. It follows that unmanned ships allow for the possibility of more efficient ship design, since there would be no need for bulky crew accommodation or a bridge. This would increase

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[1] Justyna Nawrot and Zuzanna Pepłowska-Dąbrowska, 'Revolution Or Evolution? Challenges Posed By Autonomous Vessels For National And International Legal Framework' (2019) 25 Comparative Law Review 241.

[2] ibid.

[3] Eric Van Hooydonk, 'The Law Of Unmanned Merchant Shipping: An Exploration' (2014) 20 Journal of International Maritime Law 403.

[4] See: AWAA, Remote and Autonomous Ship – The next steps (2016) <https://www.rolls-royce.com/~/media/Files/R/Rolls-Royce/documents/customers/marine/ship-intel/aawa-whitepaper-210616.pdf> accessed 18 August 2020, 4.

cargo capacity and facilitate an aerodynamic design, boosting the efficiency and performance of vessels.[5] Evidenced from current commercial projects, unmanned vessels are likely to utilise more environmentally friendly propulsion methods than manned vessels.[6] In addition to operational costs, unmanned vessels have the potential to reduce litigation and insurance expenditure. This is partly due to the elimination or reduction of human error, which is estimated to cause approximately 75% to 96% of marine casualties.[7] It is therefore easy to understand the appeal of such vessels, since developments in the maritime industry are primarily fuelled by economic gain. As the shipping industry alone accounts for approximately 90% of all world trade,[8] the ultimate question regarding unmanned ships is the extent to which they can operate as safely as their manned counterparts and whether enforcement of claims can be as effective.[9] It is therefore important to assess firstly, the way in which such vessels will comply with present regulations to ensure that safety at sea is maintained and secondly, how unmanned shipowners can be made liable in case of a casualty.

The International Maritime Organization (IMO) have produced a general term to encompass all types of ships, which can operate without human interaction; MASS, meaning Maritime Autonomous Surface Ships. This term however is somewhat unfortunate, as it could potentially raise definitional uncertainties.[10] For this reason, when referring to both remote-controlled and autonomous ships the umbrella term 'unmanned' will be used. For the purpose of this essay, remote-controlled ships will refer to those classified in degree A2 of the Bureau Veritas Guidelines and autonomous vessels to degree A4.[11] More detail regarding the levels of autonomy will follow.

Unmanned ships came to the attention of the IMO in 2017, who appointed the Maritime Safety Committee (MSC) to carry out a regulatory scoping exercise aimed to be completed in 2020.[12] As part of the exercise, several IMO treaties will be examined including inter alia

[5] Ultimately, an aerodynamic design would result in better fuel consumption, thus meeting the efficiency targets envisaged in EEDI regulations for new ships. See: 'Energy Efficiency Measures' (International Maritime Organization, 2020) <http://www.imo.org/en/OurWork/Environment/PollutionPrevention/AirPollution/Pages/Technical-and-Operational-Measures.aspx> accessed 6 July 2020. Additionally, an aerodynamic and smooth ship design could result in unmanned ships being more pirate-resistant than conventional ships, by making them harder to board. See also Nawrot and Pepłowska-Dąbrowska (n 1) 242.

[6] See below for examples of current projects.

[7] 'Shipping Safety - Human Error Comes In Many Forms' (Allianz Global Corporate & Specialty, 2020) <https://www.agcs.allianz.com/news-and-insights/expert-risk-articles/human-error-shipping-safety.html> accessed 6 July 2020.

[8] 'Shipping And World Trade' (International Chamber of Shipping, 2020) <https://www.ics-shipping.org/shipping-facts/shipping-and-world-trade> accessed 4 July 2020.

[9] Robert Veal and Michael Tsimplis, 'The Integration Of Unmanned Ships Into The Lex Maritima' [2017] Lloyd's Maritime and Commercial Law Quarterly 304.

[10] It is noted that MASS encompasses vessels with automated functions, however in adopting that definition there is potential that remote-controlled ships are excluded from it. This is due to the fact that remote-controlled ships are not, strictly speaking, "autonomous". For more in this issue see: Robert Veal, 'Unmanned Ships On The IMO Work Agenda' (2017) 17 Lloyd's Shipping & Trade Law.

[11] Bureau Veritas Guidelines for Autonomous Shipping, Guidance Note NI641DTR01E (2019) <https://marine-offshore.bureauveritas.com/ni641-guidelines-autonomous-shipping> accessed 28 August 2020.

[12] 'Autonomous Shipping' (International Maritime Organization, 2020) <http://www.imo.org/en/MediaCentre/HotTopics/Pages/Autonomous-shipping.aspx> accessed 6 July 2020.

the COLREGs,[13] SOLAS[14] and STCW.[15] In addition, as of 2019 the MSC has approved Interim Guidelines for MASS trials.[16] MASS have been provisionally defined as 'a ship which to a varying degree can operate independent of human interaction'.[17] The Interim Guidelines are the first instrument the IMO has produced regarding MASS operation and are an important starting point towards the integration of unmanned vessels in the shipping industry. But as the name suggests, these rules are merely provisional and not particularly substantive, thus they could be subject to change in the future.[18] Nevertheless, they provide an important avenue for the commencement of MASS trials and bring the normalisation of such vessels a step closer to reality.[19] Whether the scoping exercise will result in new regulations or amendments is yet to be seen, as development within the IMO has halted due to the Covid-19 outbreak.[20]

This research aims to determine the extent to which remote-controlled and autonomous ships can comply with COLREGs and how collision liability will be assessed between such vessels. It will be shown that the distinction between remote-controlled and autonomous will have different legal implications regarding compliance and liability. It will ultimately be argued that remote-controlled vessels are more likely to effectively comply with COLREGs than autonomous ones. For remote-controlled vessels to be integrated a few amendments and clarifications need to be made to the current regulations. Conversely, for autonomous vessels to be integrated it is most likely that a new instrument or set of rules will need to be established. Upon analysis of the chosen COLREGs, solutions will be contemplated in order to overcome regulatory hurdles. The Collision Convention 1910[21] as well as English law will be considered in order to determine how the liability of unmanned vessels may be assessed. It will be argued that remote-controlled vessels can fit within the current liability framework, whereas autonomous vessels will pose serious problems to the regime and thus it will be proposed that strict liability framework should be established. Regarding limitation of liability, it will be submitted that the right should be afforded to unmanned shipowners and shore-based operators (SBOs), however whether it should extend to manufacturers and software developers is unclear.

1.1 Unmanned vs Autonomous vs Automated

The terminology surrounding unmanned ships is far from being consistent. There are numerous guides defining levels of autonomy, however they are unharmonised and merely

[13] Convention on the International Regulations for Preventing Collisions at Sea 1972.
[14] International Convention for the Safety of Life at Sea 1974.
[15] International Convention on Standards of Training, Certification and Watchkeeping for Seafarers 1978.
[16] IMO 'Interim Guidelines for MASS Trials' (2019) MSC.1/Circ.1604.
[17] 'IMO Takes First Steps To Address Autonomous Ships' (International Maritime Organization, 2018) <http://www.imo.org/en/MediaCentre/PressBriefings/Pages/08-MSC-99-MASS-scoping.aspx> accessed 6 July 2020.
[18] Robert Veal, 'IMO Guidelines On MASS Trials: Interim Observations' [2019] Lloyd's Shipping & Trade Law.
[19] ibid.
[20] The IMO have recently rescheduled all the Committee meetings and the MSC is currently due to have its 102th Session on the 4-11th of November 2020. See: IMO Circular Letter No.4213/Add.6 available from 'Meeting Summaries' (International Maritime Organization, 2020) <http://www.imo.org/en/MediaCentre/MeetingSummaries/Pages/Default.aspx> accessed 4 September 2020.
[21] Convention for the Unification of Certain Rules of Law with respect to Collisions between Vessels 1910.

act as soft law.[22] Nonetheless, it is necessary to acknowledge that the terms unmanned, autonomous and automated are not interchangeable, but can correlate. For this research, the Bureau Veritas Guidelines will be considered when classifying levels of autonomy, as it is the latest instrument of its kind and it approaches the degrees of automation and control logically. The Guidelines consider five levels of autonomy, ranging from human operated to fully autonomous (A0 to A4).[23] The Guidelines also distinguish between degrees of control, which are sub-categorised to reflect the degree of either direct or remote control (DC0 to DC3, RC0 to RC3).[24]

Automation refers to the performance of tasks by machinery rather than humans.[25] Many modern vessels already use certain automation systems, for example Kongsberg's Chief-600, which aids in inter alia monitoring engine performance. Automation can be considered a development regarding manning as well as autonomy levels.[26]

An unmanned ship could be one where there is no crew onboard to operate systems, but is rather remotely controlled or supervised by personnel.[27] Bureau Veritas define degree A2 of autonomy as 'human delegated', meaning that the ship can make decisions and initiate actions contingent upon human confirmation.[28] The human can then reject or accept the decisions.[29] In addition, degree RC3 of control will be considered, meaning that the ship will be remote-controlled and actively monitored at any time by a SBO from a control station outside the ship.[30] Ships classified under the A2 RC3 category will be referred to as remote-controlled ships for the purpose of this research.

An unmanned ship may also be fully autonomous with no human supervision. Degree A4 refers to 'full automation', which involves a self-operating vessel on a pre-determined nautical course that can perform information acquisition and analysis, make decisions and carry out operations without human intervention or approval.[31] For autonomy level A4, degree RC0 will be considered, meaning that there is no available remote control or monitoring outside the ship, nor a possibility to take control in case of emergency.[32] Ships classified under the A4 RC0 category will be referred to as autonomous ships for the purpose of this research.

It should be noted that the degree of autonomy does not necessarily remain static during a voyage, as it depends on the ship's surroundings and circumstances.[33] For example, in a busy traffic lane it may be possible to switch from fully autonomous sailing to remote-controlled.

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[22] See: DNV-GL Class Guideline 'Autonomous and Remotely operated Ships' (2018) <https://rules.dnvgl.com/docs/pdf/DNVGL/CG/2018-09/DNVGL-CG-0264.pdf> accessed 8 September 2020, IMO (n 16) and Lloyd's Register (2017) 'LR Code for Unmanned Marine Systems'. A common element amongst all the guidance rules is the different range of terminology being used.
[23] Bureau Veritas (n 11).
[24] ibid.
[25] Henrik Ringbom, 'Regulating Autonomous Ships—Concepts, Challenges And Precedents' (2019) 50 Ocean Development & International Law 141, 142-143.
[26] ibid 142-143.
[27] Bureau Veritas (n 11) 9.
[28] ibid 10.
[29] ibid.
[30] ibid 11.
[31] ibid.
[32] ibid.
[33] Ringbom (n 25) 143.

Conversely, manning levels are less likely to change during a voyage, presumably for practical reasons.[34] For simplicity, in this research it will be assumed that the ship's level of autonomy will remain fixed throughout a voyage. It will become evident that the binary distinction between remote-controlled and autonomous is most important with respect to regulatory compliance.[35]

1.2 The Technology and Recent Developments

Most unmanned vessels in operation at the moment are predominantly used for scientific research or military purposes.[36] It would appear that unmanned vessels have made progress in several areas, but not yet in the commercial transportation of passengers or cargo.[37] It seems however that the unmanned market is moving towards the realisation of autonomous carriage, with several countries and companies investing and participating in unmanned ship trials. Generally, unmanned ships will use an array of technologies, such as LIDAR,[38] RADAR,[39] GPS[40] as well as satellites and cameras in order to enable them to navigate.[41] Remote-controlled vessels may be controlled from ashore using a joystick and facilitated by radio communications. Autonomous ships would operate based on pre-programmed software and AI[42] systems on board to analyse surroundings, with no human intervention.

The Norwegian vessel Yara Birkeland will be the first zero-emission and autonomous containership, which aimed to begin operations in 2020.[43] However due to Covid-19 her development has stalled. Nevertheless, the project envisaged a gradual progress from Yara being manned to her being remotely operated and eventually becoming fully autonomous by 2022.

Kongsberg and Massterly have joined forces with a Norwegian grocery distributor to employ two autonomous, zero-emission ro-ro[44] vessels to replace at least 800 truck trips.[45] The vessels

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[34] ibid.
[35] CMI International Working Group Position Paper on Unmanned Ships and the International Regulatory Framework (2018).
[36] See: SEA-KIT, 'SEA-KIT USV Successfully Completes 22 Days Of Offshore Operation' (2020) <https://www.sea-kit.com/post/press-release-sea-kit-usv-successfully-completes-22-days-of-offshore-operation> accessed 18 August 2020. See also: 'U.S. Navy Invests $40M In Large Unmanned Vessel Development' (The Maritime Executive, 2020) <https://www.maritime-executive.com/article/u-s-navy-invests-40m-in-large-unmanned-vessel-development> accessed 7 September 2020.
[37] van Hooydonk (n 3) 404.
[38] Light Detecting and Ranging.
[39] Radio Detecting and Ranging.
[40] Global Positioning System.
[41] For a more detailed discussion of unmanned ship technology see: AWAA (n 4) 23-32.
[42] Artificial Intelligence.
[43] *Yara* would be equipped with RADAR, LIDAR, AIS, GPS, sophisticated cameras and sensors as well as satellite communications. 'Autonomous Ship Project, Key Facts About YARA Birkeland' (Kongsberg, 2017) <https://www.kongsberg.com/maritime/support/themes/autonomous-ship-project-key-facts-about-yara-birkeland/> accessed 1 July 2020.
[44] Roll on roll off vessels.
[45] 'Kongsberg Maritime And Massterly To Equip And Operate Two Zero-Emission Autonomous Vessels For ASKO' (Kongsberg, 2020) <https://www.kongsberg.com/newsandmedia/news-archive/20202/zero-emission-autonomous-vessels/> accessed 4 September 2020.

are due to be delivered in 2022 and similar to Yara, it is expected that they will gradually progress towards full autonomy.[46]

More recently, the Mayflower Autonomous Ship (MAS) is set to perform the first fully autonomous transatlantic voyage from the UK to the US in September 2020.[47] Her journey will be a remarkable milestone for the unmanned market and technology. A new AI 'captain' for MAS is currently being trialled in Plymouth UK in order to determine how it will use cameras, AI and other computing systems to navigate safely.[48] Due to the lack of connectivity during her voyage, MAS will use an autonomous computing system to process data locally, enabling her to make quick decisions.[49] MAS's software and short-range radar will enable her to sense her surrounding environment and classify ships, buoys or hazards with enough time to take safe action.[50] It is hoped that the mission will boost the autonomous shipping market with an estimated growth of around $130BN by 2030.[51]

As of May 2020, NYK Group successfully tested remote navigation on a tugboat.[52] The tug was remotely navigated 12 kilometres, while the operator utilised cameras and sensors to determine the vessel's vicinity.[53] NYK are currently pursuing to eliminate ship-to-shore communication issues that were revealed during the trial.[54] Additionally, NYK announced their participation in a project focused on conducting the first successful crew-less MASS demonstration and advancing the practical use of such vessels by 2025.[55]

All the aforementioned developments in the unmanned shipping market will eventually bring those ships closer to reality, offering important insights about these new technologies.[56] A

[46] ibid. Kongsberg have also received approximately €20.1 million as part of the AUTOSHIP project, which aims to boost the realisation of autonomous ships and guide their commercialisation within the EU in the next five years. See: Autonomous Shipping Initiative for European Waters, aims to accelerate the transition towards a next generation of autonomous ships in the EU. For more details see: <https://www.autoship-project.eu>. See also: 'Pioneering Norwegian Autonomous-Ship Project Receives NOK 200 Million In EU Funding' (Kongsberg, 2020) <https://www.kongsberg.com/newsandmedia/news-archive/20202/pioneering-norwegian-autonomous-ship-project-receives-nok-200-million-in-eu-funding/> accessed 1 July 2020.

[47] MAS is a trimaran and will be powered by wind and solar power, with a diesel engine as backup. She measures 15 meters and weighs 5 tons, meaning MAS is considerably smaller than conventional manned merchant ships. See: 'Sea Trials Begin For Mayflower Autonomous Ship's "AI Captain"' (IBM Newsroom, 2020) <https://newsroom.ibm.com/2020-03-05-Sea-Trials-Begin-for-Mayflower-Autonomous-Ships-AI-Captain> accessed 29 June 2020. See also: Jen Copestake, 'Unmanned Ship To Go On 400-Year-Old Journey Across The Atlantic' (BBC News, 2019) <https://www.bbc.co.uk/news/technology-50047449> accessed 1 July 2020.

[48] IBM Newsroom (n 47).

[49] ibid.

[50] ibid.

[51] 'Autonomous Ships Market Statistics & Impacting Factors: Forecast 2030' (Allied Market Research, 2020) <https://www.alliedmarketresearch.com/autonomous-ships-market> accessed 29 June 2020.

[52] 'NYK Successfully Tests Remote Navigation Of Tugboat' (NYK Line, 2020) <https://www.nyk.com/english/news/2020/20200520_01.html> accessed 30 June 2020.

[53] ibid. The operator created an action plan, which was then approved by the master onboard the tug.

[54] ibid.

[55] 'NYK To Participate In Crewless Maritime Autonomous Surface Ship Trial Project' (NYK Line, 2020) <https://www.nyk.com/english/news/2020/20200615_01.html> accessed 30 June 2020.

[56] In addition to technological advancements, some of the world's maritime nations have recently agreed to take part in the MASSPorts initiative, targeted at addressing the challenges of readying ports for autonomous ships. See: 'New Network Supports Port Readiness For Autonomous Shipping' (The Maritime Executive, 2020) <https://www.maritime-executive.com/article/port-network-to-address-challenges-and-support-autonomous-shipping> accessed 18 August 2020.

common element amongst these projects is their territoriality; most operations take place in territorial seas due to the lack of international regulation on the matter.[57] This clearly has an impact on testing unmanned ships that aim to participate in the international carriage of goods or passengers. For instance, the territorial testing environment may not be realistic, as connectivity issues may be exacerbated in the high seas. Additionally, most unmanned vessels at the moment are very modest in size compared to their manned counterparts, especially in the commercial sector.[58] Ultimately, the effective integration of such ships in the maritime sector by means of regulation may aid in incentivising their production. Consequently, it is important to assess whether unmanned ships can comply with the current regulatory framework or whether new regulations need to be developed.

1.3 Scope of Research and Limitations

This research will consider degrees A2 RC3 and A4 RC0 per the Bureau Veritas Guidelines. The remaining autonomy levels outlined in the Guidelines will not be investigated. The assumption of binary operational modes would be the most significant limitation of this research.

The research will be limited to COLREGs provisions that may be problematic when put in the unmanned context. The author has chosen Rules 2, 3, 5, 6 and 8, as they involve the most human cognitive interaction and could potentially cause complications regarding compliance of unmanned ships.

The importance of other IMO Conventions, such as SOLAS and STCW, is recognised, however they are deemed out of scope. The effects on the legal role of the master and crew will not be analysed.

With regard to liability, only civil liability will be considered and not criminal.

It will be assumed that unmanned ships are ships for the purposes of UNCLOS.[59] Considering that there is no universal definition of a 'ship' or 'vessel' it will be assumed to cover unmanned ships. Further, it is argued that the definitional question becomes less relevant as the unmanned ship increases in size and performs operations similar to conventional ships.[60] Lastly, no delegation at MSC has thus far raised concern regarding the consideration of unmanned ships as ships.[61]

[57] This would present a risk to investors and companies, as without hard evidence it is uncertain how the ships will perform in the high seas. However, MAS has endeavoured to sail the high seas, although this has not happened yet.
[58] Of course, unmanned ships are still early in their development stage and the current projects may highlight how the technology works as well as its shortcomings. With more research and development unmanned ships may eventually reach the size of conventional vessels.
[59] United Nations Convention on the Law of the Sea 1982.
[60] Veal and Tsimplis (n 9) 309.
[61] Veal (n 18).

Chapter 2: COLREGs and Unmanned ships

2.1 Overview

The COLREGs introduce several 'rules of the road', such as safe speed and manoeuvring requirements for different vessels in varying conditions of visibility.[62] Rule 1 specifies that the Regulations apply to 'all vessels upon the high seas and in all waters connected therewith navigable by seagoing vessels'.[63] Assuming that unmanned ships fit the definition of 'seagoing vessels', they are legally obliged to follow the COLREGs.[64] Additionally, UNCLOS places a duty on states to ensure compliance with the applicable collision regulations, meaning the COLREGs.[65] Rules that require human sentience and operational decision-making may pose significant challenges for unmanned ships.[66] It will be argued that remote-controlled ships are more likely to comply with COLREGs in their current form, while autonomous ships may fall foul of several of the Rules considered, most notably Rule 2, which is traditionally considered the pillar of the COLREGs.

2.2 Rule 2, Responsibility

2.2.1 Main Features

Rule 2 is the most 'human' of all COLREGs Rules. Arguably, it is also the backbone of COLREGs, as it is almost certain that there will be a violation of Rule 2 in a collision case. Rule 2 lays out the framework under which the other rules of the Convention will be interpreted and introduces the principle of prudent seamanship.[67] Briefly, the first part of the Rule states that nothing in the Rules will exonerate any vessel from the consequences of neglect to comply with the COLREGs or neglect to take any precaution dictated by the ordinary practice of seamen.[68] Secondly, due regard shall be given to in extremis circumstances where departure from the Rules becomes necessary to avoid immediate

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[62] The COLREGs are codified in the UK by Merchant Shipping (Distress Signals and Prevention of Collisions) Regulations 1996. They are constituted by 41 rules and are separated into six sections: Part A - General; Part B - Steering and Sailing; Part C - Lights and Shapes; Part D - Sound and Light signals; Part E - Exemptions; and Part F - Verification of compliance with the provisions of the Convention.

[63] COLREGs 1972 Rule 1.

[64] COLREGs 1972 Rule 3(a) specifies that: 'the word "vessel" includes every description of water craft, including non-displacement craft, WIG craft and seaplanes, used or capable of being used as a means of transportation on water'. As mentioned in Chapter 1, it will be assumed that unmanned ships will fit this definition, especially when their functions are the same or similar to conventional vessels.

[65] UNCLOS1982 Article 94(3)(c), which states that 'every State shall take such measures for ships flying its flag as are necessary to ensure safety at sea with regard, *inter alia*, to the use of signals, the maintenance of communications and the prevention of collisions' and Article 94(4)(c) which states that: 'such measures shall include those necessary to ensure: that the master, officers and, to the extent appropriate, the crew are fully conversant with and required to observe the applicable international regulations concerning the safety of life at sea, the prevention of collisions, the prevention, reduction and control of marine pollution, and the maintenance of communications by radio'.

[66] AWAA (n 4) 45.

[67] Veal and Tsimplis (n 9) 324 and *The Roseline* [1981] 2 Lloyd's Rep 410, 411 (Sheen J).

[68] COLREGs 1972 Rule 2.

danger.[69] Rule 2 places an obligation on captains to deviate from COLREGs in order to prevent a collision, according to the prudent seamanship principle.[70] As a matter of English law, the principle of prudent seamanship provides the basis of the overarching standard of care for negligence claims, which in certain cases, can be discharged by showing compliance with COLREGs.[71] Ordinary practice of seamen is not defined in the COLREGs, rather such practice is acquired through years of navigational experience.

It is evident that the Rule implies human cognitive judgement in determining whether it is necessary to deviate from COLREGs. This is the biggest hurdle that unmanned technology needs to overcome. One of the main questions regarding unmanned shipping is whether and how the duty of prudent seamanship can be discharged in the absence of any seafarers onboard the ship. Another important aspect of the analysis is the extent to which the distinction between remote-controlled and autonomous has an impact regarding compliance with the Rule. For the duty to be successfully discharged, an unmanned ship needs to be capable of stepping outside the letter of the law in certain situations in order to avoid collision, whether that is possible or not is uncertain.

2.2.2 Remote-controlled Ship

One important element of Rule 2 is the requirement of 'contemporaneous human sentience' in deciding whether to deviate from COLREGs.[72] Although the COLREGs require a form of human involvement in the decision-making process, it is not explicitly mentioned that such involvement can only come from onboard the ship.[73] It is argued that if the means of communication used between a remote-controlled ship and a SBO are sufficiently instantaneous, the sentience may be provided from ashore.[74] Arguably however, achieving stable and instantaneous communications may be too ambitious, as in practice it will be difficult to maintain, especially during transoceanic voyages where there is limited connectivity from ship-to-shore. Connectivity issues were also amongst the problems unveiled by NYK's remote tug navigation trials.[75] Nevertheless, the UK's position regarding remote-controlled ships and Rule 2 is that the absence of personnel onboard does not necessarily violate the principle of good seamanship.[76] It is argued that the fulfilment of the duty is ultimately dependent on the safety credentials and sophistication of the remote control system.[77] If it allows the SBO to make informed nautical decisions that are effected by the ship in due time, then there is no reason why the principle cannot be satisfied.[78]

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[69] For more in-depth description of COLREGs see: AN Cockcroft and JNF Lameijer, *A Guide to the Collision Avoidance Rules* (7th edn, Butterworth-Heinemann 2012).
[70] *The Tasmania* (1890) 15 App.Cas. 223, 226 (Lord Herschell). It was held that mariners were not only justified in departing from Rule 2, but were bound to do so and to exercise their best judgement to avoid danger.
[71] Veal and Tsimplis (n 9) 325.
[72] ibid 325.
[73] CMI Position Paper (n 35) 20-21.
[74] Veal and Tsimplis (n 9) 325.
[75] NYK (n 52).
[76] British Maritime Law Association 'CMI Questionnaire: UNMANNED SHIPS' (2017) <https://www.bmla.org.uk/documents/2018/BMLA-Response-to-CMI-Questionnaire-on-Unmanned-Ships.pdf> accessed 28 August 2020, 4.1.
[77] ibid.
[78] ibid.

While the UK's position is agreeable, it should be noted that the discharge of the duty is contingent on the SBO having appropriate training to enable them to do so.[79] This is a corollary issue of the shift to remote-control navigation, as it is questionable whether years of navigational experience can be compressed into a manual.[80] Moreover, the SBO lacks the physical experience of being on the bridge, thus arguably they may lack the intuitive feel for a situation.[81] This could affect the action taken by the SBO, as it may seem reasonable to them, however in the eyes of seafarers it may seem inappropriate and in contradiction to prudent seamanship. It is therefore important for SBOs to be trained accordingly in order to enable them to make diligent navigational decisions and thereby discharge their duty of care. Conversely, the case law relating to the prudent seamanship requirement holds that officers must be situated on deck, thus presenting difficulty for a remote-controlled ship to comply without an onboard crew.[82] However, by its nature, common law changes and adapts to new technologies. Due to the contemporary nature of the technology there is no case law on the matter, however it would be unconvincing to suggest that due to an old precedent remote-controlled ships may be unable to comply with Rule 2. Consequently, there is a strong possibility that the precedents will be overruled and adapted.

Assuming the technology permits for instantaneous ship-to-shore communication, it is argued that remote-controlled vessels are likely to comply with Rule 2 of COLREGs in its current form.

2.2.3 Autonomous Ship

To establish compliance with Rule 2 in a fully autonomous context, the picture is very different, as there is no human to provide the required contemporaneous sentience. This raises the fundamental question of whether it is possible for a fully autonomous ship, without human supervision or interaction, to comply with the duty of seamanship.[83] The answer is probably no. Deciding when to deviate from COLREGs involves a highly sophisticated cognitive process based on nautical experience and insight.[84] This adds a major obstacle to the equation, as the fact that there is no quantifiable hint within Rule 2 as to when deviation from COLREGs is required, makes the production of such an algorithm unworkable.[85] This is due to the fact that deviation from COLREGs and appropriate action cannot be specified before the event that requires such action to be taken.[86] Not only that, there is not one correct action to be taken when deviating from COLREGs, the possibilities are endless.

[79] ibid.
[80] While this argument can be rebutted by saying that SBOs should be experienced seafarers, there may be a possibility in the future, when all ships become autonomous, that those operating the ship will not have had any real maritime experience and hence would have to learn good seamanship principles from ashore.
[81] van Hooydonk (n 3) 406.
[82] Veal and Tsimplis (n 9) 325 See also: *The Arthur Gordon, The Independence* (1861) Lush 270, *The Voorwarts and Khedive* (1880) App Cas 876 (HL).
[83] Veal and Tsimplis (n 9) 325.
[84] ibid.
[85] Thomas Porathe, 'Maritime Autonomous Surface Ships (MASS) And The COLREGS: Do We Need Quantified Rules Or Is "The Ordinary Practice Of Seamen" Specific Enough?' (2019) 13 TransNav: The International Journal on Marine Navigation and Safety of Sea Transportation 511.
[86] Veal and Tsimplis (n 9) 325.

Consequently, if there is no software in production to satisfy the practical requirements of the Rule, it is likely that autonomous ships will not be able to comply.

Another question to consider would be whether prudent seamanship prohibits the operation of an autonomous collision avoidance system.[87] The answer is potentially different from above. Firstly, it is argued that by the time the prudent seamanship standard becomes relevant, the risk of collision is already high.[88] Consequently, it appears that COLREGs do not explicitly exclude the possibility of autonomous systems being used in order to prevent ships from ever coming in close quarters situations.[89] Presently, the trials of autonomous ships aim to use algorithmic collision avoidance technology, which would allow the ship to visually and aurally sense the surrounding environment, while classifying nearby objects.[90] If those systems can eradicate the creation of close quarters situations and meet a number of safety parameters, there is no reason why they should not be allowed to operate. However, so long as autonomous ships co-exist with manned ships the possibility of error from the part of the latter is almost certain.

Although a collision avoidance system may be able to categorise between different targets, it is questionable whether it can distinguish between passenger ships, laden tankers and ships in ballast.[91] This is important, as prudent seamanship is embodied by an inherent ability to morally evaluate actions. It is uncertain how an AI system will react to being in a situation where a collision becomes unavoidable.[92] One such scenario could involve a tanker laden with oil and a passenger ferry both approaching the autonomous ship and creating an unavoidable collision. Would she collide with the tanker and risk an oil spill or hit the ferry and injure the passengers? Whether prudent behaviour in that scenario can be programmed is uncertain.

Additionally, a prudent seaman would have to follow instructions from the coastguard or port authority. It is uncertain how such instructions will be communicated and understood by an autonomous ship, thus complicating the future code even further.

Many English cases hold that over reliance on technology over keeping a proper lookout is contrary to good seamanship.[93] Consequently, full reliance on an autonomous system may be analogous and thus contradict with the standard. This is clear from the wording of the Rule itself, which requires a value judgement in deciding whether to follow COLREGs or deviate by taking an unspecified action according to seamanship principles.[94] The UK's position regarding autonomous ships states that unless AI used in navigation reaches the level of knowledge of a trained seafarer, Rule 2 cannot be complied with.[95] This is due to the lack of

[87] Ringbom (n 25) (emphasis added) 155.
[88] ibid.
[89] ibid.
[90] See: Veal and Tsimplis (n 9) 325, Kongsberg (n 43) and MAS (n 47).
[91] Veal and Tsimplis (n 9) 326.
[92] The ethical dilemmas of machine ethics have been studied in relation to autonomous cars as well see: 'Moral Machine' (2020) <https://www.moralmachine.net> accessed 8 September 2020. This is a platform to gather human perspective in different ethical dilemma scenarios. See also: J. J. Thomson, 'The Trolley Problem' (1984–85) 94 Yale L J 1395.
[93] The Fogo [1967] 2 Lloyd's Rep. 208, The Anneliese [1970] 1 Lloyd's Rep. 400. There is also further discussion of related case law in Section 2.3 below.
[94] CMI Questionnaire (n 76) 4.2.
[95] ibid.

sophistication of the current collision avoidance algorithms. For the aforementioned reasons, autonomous ships that assume no remote control would be unable to comply with Rule 2 in its present form.[96]

2.3 Rule 5, Lookout

2.3.1 Main Features

Rule 5 states that 'every vessel shall at all times maintain a proper lookout by sight and hearing as well as by all available means appropriate' in order to comprehensively assess a situation and the risk of collision.[97] It is evident that the Rule requires human visual and aural observations by those stationed onboard a ship, consistent with the prudent seamanship requirement. Evidently, a failure to comply with Rule 5 would affect compliance with Rule 2 as well. A critical element of the Rule is also the exercise of human perception, which may prove a hindrance for unmanned ships.[98] The main question is whether the duty to maintain a proper lookout can be satisfied by camera and aural sensing equipment, or if it is an action only able to be performed by persons on board.

2.3.2 Remote-controlled Ship

Rule 5 requires human perception in maintaining a lookout, however it does not stipulate that this can only be provided by persons on board the ship.[99] Using the purposive approach to statutory interpretation, it is clear that the underlying purpose of the Rule is to ensure an adequate lookout is maintained throughout a voyage in order to assess potential risks of collision. The requirements of Rule 5 may be satisfied thusly if the technology could enable SBOs to appraise a situation and make informed decisions to the same proficient level as an officer of the watch (OOW) on board the ship.[100]

The question still remains whether the lookout may only be performed by persons on board, as it is not expressly mentioned in Rule 5. Due to the cutting-edge technology, no case has been brought in front of the courts.[101] However, parallels can be drawn from current case law, which can help decipher the court's potential position. In The Nordic Ferry it was held that due to heavy fog, it would have been acceptable to discharge the lookout obligation with the help of harbour-based support.[102] This is also evident in practice during single-handed yacht races, where shore-based personnel maintain lookout in order for competitors to take some sleep.[103] Furthermore, the use of technology in maintaining a lookout is implied by Rule 7, which stipulates that vessels are obliged to use all available means in assessing the risk of collision.[104] It is evident therefore, that the use of technological means is not only encouraged,

[96] CMI Position Paper (n 35) 14.
[97] COLREGs 1972 Rule 5.
[98] Veal and Tsimplis (n 9) 326.
[99] CMI Questionnaire (n 76) 4.3.
[100] ibid 4.3.
[101] Veal and Tsimplis (n 9) 327.
[102] *The Nordic Ferry* [1991] 2 Lloyd's Rep 591, 596.
[103] Veal and Tsimplis (n 9) 328.
[104] COLREGs 1972 Rule 7(a) (emphasis added).

but required in maintaining a proper lookout. This duty was also echoed in The Anneliese, where it was held inter alia that a vessel was at fault for failing to keep proper radar lookout.[105] However, it was emphasised that it would be contrary to the principle of prudent seamanship to rely only on radar observation without any visual lookout.[106] Additionally, the terms "appropriate" and "proper" have an inherent vagueness as to how lookout should be achieved, thus leaving room for an electronic lookout to be acceptable.[107]

Conversely, there have been occasions where over-reliance on technology has produced, instead of avoided casualties. Most famously, the collision between MS Stockholm and SS Andrea Doria, which was due to excessive speeds and poor use of radar. In The Fogo it was held that 'it is on men that safety at sea depends and they cannot make a greater mistake than to suppose that machines can do all their work for them'.[108] This view was also echoed in the later case of The Maloja II, where it was held that radar was not an acceptable substitute for visual lookout.[109] Moreover, Rule 7 states that no assumptions shall be made on the basis of scanty radar information, thus conveying that over-reliance on radar would be contrary to COLREGs.[110] By analogy therefore, complete reliance on technology may not discharge the duty of lookout. Nevertheless, due to the fluid nature of the common law, there is scope to argue that the above position may change in light of technological advances. Ultimately, the aim of COLREGs is to promote safe navigation, and if remote-controlled ships are found to be at least as safe, or safer than manned vessels, it is strongly arguable that the law will follow suit and adapt.

Importantly, the lookout requirement imposed by Rule 5 must also be "proper". This would depend on inter alia the quality of the recordings of the system, its reliability and instantaneousness.[111] It should be noted that the SBO will be lacking the feel of being on the bridge.[112] This may be a double-edged sword. On the one hand, being on the bridge is a very stressful task, but arguably it would allow for a better apprehension of events both on board and around the ship. On the other hand, the information transmitted through advanced sensors will be much more reliable than the human eye, and the fact that the SBO is distanced from the stresses of watchkeeping on the bridge, may allow for a more rational apprehension of events. Whether the SBO can properly appraise a situation from ashore is uncertain, but not impossible. An interesting argument likens the role of the SBO to that of an OOW navigating in restricted visibility, who is ever more reliant on radar observations.[113] There is little difference between a manned vessel navigating in restricted visibility with the OOW on the bridge absorbed in deciphering radar readings and a SBO with the same radar picture in a remote control centre.[114] To further the example, in a situation of extremely restricted

[105] *The Anneliese* [1970] 1 Lloyd's Rep 355, See also *The Bovenkerk* [1973] 1 Lloyd's Rep 70-71, *The Maritime Harmony* [1982] 2 Lloyd's Rep. 400.
[106] *The Anneliese* [1970] 1 Lloyd's Rep 355, 359.
[107] AWAA (n 4) 46.
[108] *The Fogo* [1967] 2 Lloyd's Rep 208, 221 (Mr Justice Cairns).
[109] *The Maloja II* [1993] Lloyd's Rep 48.
[110] COLREGs 1972 Rule 7(c): 'Assumptions shall not be made on the basis of scanty information, especially scanty radar information'.
[111] Veal and Tsimplis (n 9) 328, and CMI Questionnaire (n 76) 4.3.
[112] van Hooydonk (n 3) 406.
[113] Robert McLaughlin 'Unmanned naval vehicles at sea: USVs, UUVs, and the adequacy of the law' [2011] Journal of Law, Information and Science 100, 111.
[114] ibid.

visibility and with a faulty radar, the OOW only has his eyes and ears to conduct collision avoidance. There is thus no reason why a SBO who can receive the same, if not better, sensor information cannot navigate as safely and accurately.[115]

Ultimately, it is uncertain whether reliance on visual and aural technology will satisfy the requirements set out by Rule 5. However, it can be argued that it is likely that remote-controlled vessels may be able to comply with the Rule to the extent that the SBO is able to make informed decisions in good time, with the same proficiency as an OOW on the bridge. For this reason, the use of electronic aids does not necessarily take the operation of remote-controlled ships outside the spirit of Rule 5.[116] After all, the law has developed to accommodate new technologies, thus it is argued that Rule 5, and COLREGs in general, should keep on par with technological developments and adapt to accommodate them. From plain visual lookout and the use of sextants to the use of radar, remote-controlled navigation is the next step in the natural evolution of the law.

2.3.3 Autonomous Ship

From the above analysis, it is clear that Rule 5 requires human input in assessing the situation, at least at some stage.[117] While a collision avoidance algorithm may allow an autonomous ship to gain spatial awareness, it is doubtful whether that amounts to lookout by "sight" and "hearing" for the purposes of COLREGs.[118] It is submitted therefore, that an autonomous ship cannot satisfy the requirement of appraisal by sight and hearing, as there is no human input. One can imagine a future of autonomous ships dominating the seas, all fitted with collision avoidance systems that prevent close quarters situations by maintaining constant communication with each other.[119] If such system of ships ever exists, arguably the Rule 5 requirement becomes obsolete, as in theory, all autonomous ships will avoid close quarters situations. However, that is far from realistic at the moment, especially as manned ships will have to co-exist with unmanned ships.

One does ponder whether it would ever be possible for an autonomous ship to visually observe and hear something, or whether such functions are only inherent to humans. It is generally understood that sight and hearing involve the human senses and whether autonomous ships can appraise a situation by sight and hearing raises important questions with regard to COLREGs. For instance, are other ships never in sight of autonomous ships, or are they constantly in sight of autonomous ships? It is evident that this has far-reaching consequences, notably with regard to which steering and sailing rules apply.[120]

Autonomous ships are perhaps a few steps ahead in the evolutionary ladder, thus it would be unrealistic to expect the current rules to cater for autonomous ships before they can definitively cater for remote-controlled ones. It is ultimately argued that autonomous vessels will not satisfy the Rule 5 requirement of appraisal by sight and hearing, as there is no human in the loop.

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[115] ibid.
[116] CMI Position Paper (n 35) 14 and AWAA (n 4) 46. Also note the flexible wording of the rule.
[117] Veal and Tsimplis (n 9) 326.
[118] ibid.
[119] See: CMI Position Paper (n 35) 14. It is argued that in that scenario a breach would only be technical.
[120] This issue will be further explored in the next Section.

2.4 Rule 3(k)

2.4.1 Main Features

Rule 3(k) specifies that vessels shall be deemed in sight of one another only when one can be observed visually from the other.[121] This is a significant rule, as it dictates which steering and sailing rules will apply and determines obligations between vessels in different conditions of visibility.[122] The question regarding unmanned ships is whether it is possible to visually observe another vessel. The Cambridge Dictionary defines visual as 'relating to seeing';[123] whether seeing is restricted to human vision is a matter of interpretation, as it could extend to cover the electronic eyes of cameras.

2.4.2 Remote-controlled Ship

Since remote-controlled ships are under the control of a SBO, arguably there should be no issue regarding the fulfilment of Rule 3(k). Nevertheless, the relevant question is whether the use of camera equipment affects the moment vessels come in sight of one another. Remote-controlled ships equipped with advanced cameras may detect another vessel much faster than the human eye. Since the SBO will have a live feed of those cameras, they will be able to visually observe another vessel earlier than that vessel. Arguably therefore, remote-controlled vessels should be held to a higher standard.

2.4.3 Autonomous Ship

The question for autonomous ships is how they can visually observe another vessel if the lookout obligation is not fulfilled. Whether electronic aids can substitute the human eye in keeping a lookout is a matter of interpretation, as it can be argued both ways. Under a wide interpretation of "visually" it can be argued that an autonomous ship equipped with cameras and other aids may be able to fulfil the lookout obligation and thus visually observe other ships. A strict interpretation of "visually" would prevent autonomous ships from complying, mutatis mutandis.

Assuming a broad interpretation of visually is adopted, the question becomes whether manned ships are constantly in sight of autonomous ships, especially if they are equipped with infra-red and night vision cameras. This raises an even more complex question of whether the rules of restricted visibility will ultimately become obsolete regarding autonomous ships.[124] It

[121] COREGS 1972 Rule 3(k).

[122] Either Section 2, applicable to vessels in sight of one another, or Section 3 will apply to vessels not in sight of one another in or near an area of restricted visibility.

[123] 'Visual Meaning In The Cambridge English Dictionary' (Cambridge Dictionary, 2020) <https://dictionary.cambridge.org/dictionary/english/visual> accessed 28 August 2020.

[124] The spectrometers onboard an autonomous ship may not interpret "restricted visibility" the same way as the human eye would. See: Porathe (n 85) 516. This would complicate things when an autonomous ship meets a conventional manned ship in conditions where the manned ship would be unable to visually observe the autonomous one, but the autonomous one would have already detected the manned ship. Assuming a collision of such kind occurs it will be uncertain whether the rules of restricted visibility will apply or not. Especially since ships are deemed in sight of one another only when one can be visually observed from the other. See COLREGs

is uncertain whether autonomous ships should be held to a higher responsibility standard than manned ships, as they are able to detect manned ships much faster. These are all questions that require international cooperation and agreement.

2.5 Rules 6 and 8, Safe Speed and Early Action

2.5.1 Main Features

Rule 6 states that vessels shall always proceed at a safe speed in order to take effective action to avoid collision.[125] In determining safe speed several factors must be taken into account including, inter alia the visibility and traffic density.[126] It is evident from the Rule that the safe speed requirement applies to all vessels, including unmanned ships. Safe speed is a matter of prudent seamanship and is thus understood in a relative sense, as it depends on existing circumstances and varies from ship to ship.[127] To maintain a safe speed at all times, it is necessary to maintain a continuous appraisal of circumstantial and environmental changes, followed by any necessary speed adjustments.[128]

Rule 8 outlines actions to be taken when avoiding a collision and specifies that any action should be taken in accordance with COLREGs, be positive, made in ample time and with due regard to the observance of good seamanship.[129]

2.5.2 Remote-controlled Ship

In order to discharge their duty, SBOs need to be able to assess the vicinity of the vessel and take appropriate actions. This links back to the problem outlined in the Rule 5 analysis; the lack of "feel" for a situation due to not being onboard the vessel. There is a lack of the sensation of speed that could hamper the judgment of safe speed.[130] Nevertheless, nothing in the Rules suggests the need for personnel onboard, thus there is real potential that the requirements for safe speed and collision avoidance may be conducted from ashore.

Any delay in communications would need to be factored in the safe speed calculation, as it could have detrimental effects. It has been argued that the risk of communication delay is so certain that it is questionable whether close quarters situations should be handled remotely at

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1972 Rule 3(k): 'Vessels shall be deemed to be in sight of one another only when one can be observed visually from the other'.

[125] In full, Rule 6 states that: 'every vessel shall at all times proceed at a safe speed so that she can take proper and effective action to avoid collision and be stopped within a distance appropriate to the prevailing circumstances and conditions'.

[126] COLREGS 1972 Rule 6(a).

[127] Cockcroft and Lameijer (n 69) 18 and Aleka Mandaraka-Sheppard, *Modern Maritime Law Volume 2: Managing Risks And Liabilities* (3rd edn, Informa Law 2014), 1.6.2.2. See also *The Roseline* [1981] 2 Lloyd's Rep 410.

[128] ibid.

[129] COLREGs 1972 Rule 8(a). The Rule 8 requirements are also interlinked with Rules 16 and 17, as they both echo the need to take early and substantial action to avoid collision. For example, Rule 16 states: 'every vessel which is directed to keep out of the way of another vessel shall so far as possible, take early and substantial action to keep well clear'.

[130] This is similar to flight and motor racing simulators.

all.[131] Additionally, any communication delays could significantly affect the early collision avoidance manoeuvres as prescribed by Rule 8. Many collisions occur because avoiding action is taken too late, consequently it is crucial that the SBO is in constant connection with the ship, in order to ensure action is taken promptly.[132] On the other hand, there is scope to argue that loss of connection in the open seas may not be so detrimental. However, in busy traffic lanes it would be crucial to be in constant connection with the ship.[133] From a reading of the CMI Position Paper, it is implied that a delay in communications does not necessarily suggest that a remote-controlled ship would fall foul of Rules 6 and 8.[134] Nevertheless, it is argued that unless the SBO is constantly connected with the ship, it is likely that Rules 6 and 8 cannot be complied with.

2.5.3 Autonomous Ship

Rules 6 and 8 are clearly linked with Rule 2 and the seamanship requirement, which autonomous ships are likely to conflict with. There have been previous attempts within the IMO to quantify safe speed in relation to different factors, however they have not yielded an acceptable method of calculation of the safe speed for different conditions.[135] Consequently, Rules 6 and 8 would present difficulty in programming an algorithm, as there are infinite potential factors in calculating safe speed and ample time. To mention a few examples; "ample time", "large enough to be readily apparent", "sufficient sea room" are qualitatively phrased, meaning that there is not one correct value, as they all depend on the circumstances the vessel finds herself in.[136] The software programmer will thus find difficulty in programming when to execute an early and substantial action and determine what action that should be.[137] Arguably, a lot depends on the location of the potential incident. For example, if two ships meet in the high seas, programming such action may be relatively straightforward. Conversely, if there is an incident in a highly trafficked area the task of programming the software evolves to a different dimension. There is now a large amount of ships congregated in a limited space, which affects the variables of "ample" and "sufficient" actions, notwithstanding the fact that an evasive manoeuvre for one ship may lead to a close quarters situation with another.[138]

Another hurdle for autonomous ships would be the fact that certain areas have developed different customs, which may contravene with COLREGs.[139] For example the high-speed ferry Stena Carisma enters the Gothenburg-Fredrikshavn line in 30+ knots, as she keeps out of the way of everything due to her high manoeuvrability.[140] This may firstly be 'confusing' to

[131] Ringbom (n 25) 156.
[132] See *The Topaz and Irapua* [2003] 2 Lloyd's Rep 19, 20 (Gross J).
[133] This is less ambitious than maintaining constant connection with the ship, as usually traffic lanes are near the coast, where signal for communications can be easily maintained.
[134] CMI Position Paper (n 35) 14-15.
[135] Cockcroft and Lameijer (n 69) 20.
[136] See Porathe (n 85) 513 — the author talks about Rules 15-17, but the wording is similar to Rules 6 and 8, so the argument can apply by analogy.
[137] ibid 514.
[138] ibid 514.
[139] ibid.
[140] ibid.

an autonomous ship, but also difficult to program due to the existence of different customs globally.

Ultimately, it is argued that autonomous ships may not be able to comply with Rules 6 and 8 for two reasons. Firstly, there is difficulty in complying with the good seamanship principle, which is required by the Rules. Secondly, the qualitative wording of the Rules render it unworkable to attempt to program a suitable algorithm. Although safe speed can be determined as a matter of fact after the relevant collision, it is fundamental to be able to calculate safe speed before the collision occurs. If safe speed is not adequately programmed, probabilistically there will be a time where the algorithm will get the speed wrong and cause a collision.

2.6 Solutions

The regulatory future of remote-controlled ships is arguably much brighter than for autonomous ships. For remote-controlled ships to be integrated in the framework, only modest amendments or clarifications are needed to the COLREGs.[141] In contrast, it is likely that for autonomous ships either a new set of rules be drawn up or a comprehensive addendum be added in COLREGs. Moreover, new regulations would need to be drawn up to clarify inter alia the technological requirements to maintain an electronic lookout, the certification methods for SBOs and the construction of unmanned ships.[142] Even though unmanned ships may be unable to comply with some of the key provisions of COLREGs, it is argued that the solutions may not be as onerous as they seem.

It is important to keep in mind that the COLREGs were adopted in the 1970s, where the prospect of unmanned shipping was non-existent. It is therefore argued that drawing far-reaching conclusions, merely due to the fact that no provision precludes the operation of unmanned ships, may contradict the rules of treaty interpretation.[143] An affirmation by IMO States, in the form of a non-binding recommendation could aid in making the legal position of unmanned ships clearer.[144] Such recommendations could be construed as agreement between parties and could thus impact the interpretation of IMO Conventions.[145]

A provision-by-provision approach to amend current regulations should be advised against, as it would be too inefficient. Ideally, new, goal-based regulations should be introduced within the IMO to govern unmanned operations.[146] If such regulations are in place, there is no need

[141] CMI Position Paper (n 35) 21.
[142] Danish Maritime Authority, 'Analysis Of Regulatory Barriers To The Use Of Autonomous Ships' (2017) 53.
[143] Ringbom (n 25) 160. See also Article 31(1) Vienna Convention: 'a treaty shall be interpreted in good faith in accordance with the ordinary meaning to be given to the terms of the treaty in their context and in the light of its object and purpose'.
[144] ibid. Such recommendation could clarify for example which crew functions can be performed away from the ship, or confirm that complete reliance on technology by an unmanned ship does not violate years of established case law.
[145] ibid.
[146] Goal-based regulations place the focus on achieving a goal, rather than the precise way in which the goal is achieved. Goal-based regulations and annexes may be seen in SOLAS 1974 Annex 12 (adopted in May 2010), which adopts goal-based ship construction standards for bulk carriers and oil tankers. Goal-based regulations are also seen in the International Code for Ships Operating in Polar Waters (Polar Code) 2014 and 2015. The

to constantly update each provision in light of new technologies, thus preserving the letter of the law for a longer period of time against new technologies. DNV-GL suggest that the goal of the regulations should centre around making unmanned ships as safe as conventional ships of the same type.[147] In light of aiding regulation, parallels can be drawn from the aviation as well as automotive industries, as both have seen developments in automation. For the meantime however, the relevant industry codes and standards remain significant and could aid in formulating regulations.

One of the difficulties posed by unmanned ships in general, is when manned ships come into sight with unmanned ships. As outlined above, it is uncertain when ships will be deemed in sight of one another. The most logical solution would be to place a higher duty on unmanned ships to act once they have visually observed another vessel. Especially due to the fact that, for the time being at least, unmanned ships will be navigating alongside manned ones.

2.6.1 Remote-controlled Ship

The most prominent barrier to the operation of remote-controlled ships would be the risk of loss of communications. One way to overcome this issue would be for such ships to be equipped with autonomous collision avoidance systems, which will be activated once communications are lost.[148] Alternatively, it may be possible to program the onboard system to raise signals and lights to indicate that the vessel is "not under command".[149] However, it is argued that this would be impractical, as the loss of communications is almost certain to happen. This would mean the vessel oscillating between being in command and not under command, notwithstanding the fact that this may cause confusion for other vessels in the remote-controlled ship's vicinity. It is argued that the most viable option would be to have an autonomous navigation system as a failsafe when communications with the remote-controlled ship are lost.[150]

With regard to Rule 5, it would be possible to avoid any amendments to COLREGs provided that a sufficiently large consensus of IMO States agree that the human perception requirement can be met using cameras, to the extent that the vessel is remotely controlled by a SBO.[151] However, it is likely that an amendment to Rule 5 or a new case precedent will be needed in order to allow the SBO to be completely reliant on technology without contradicting the good seamanship requirement. Alternatively, goal-based regulations may be adopted on an international level, coupled with regulations establishing the appropriate training and certification standards for SBOs.

Polar Code is a particularly interesting example, as it amended several key conventions, notwithstanding the fact that it adopted a dual system of goal-based and prescriptive regulations.

[147] DNV-GL 'Remote-controlled and Autonomous Ships in the Maritime Industry Position Paper' (2018) 12. Then the relevant classification societies can focus on developing specific assurance procedures in compliance with the new regulations, which will co-exist with the relevant industry codes and standards. See: Maritime Autonomous Surface Ships UK Code of Practice, A Voluntary Code Version 2 November 2018.

[148] Veal and Tsimplis (n 9) 329 and DNV-GL (n 147) 12.

[149] Veal and Tsimplis (n 9) 329.

[150] This is also the position reflected by DNV-GL (n 147) as well as Ringbom (n 25), who argues that it is likely to have a sliding scale of operations on one ship.

[151] Danish Maritime Authority (n 142) 47.

2.6.2 Autonomous Ship

It is evident that autonomous ships cannot meet the requirement of prudent seamanship as outlined in Rule 2. For this reason, it is proposed that instead of attempting to code algorithms according to COLREGs, a new set of rules be established to govern autonomous shipping, which will be added as an annex to COLREGs.[152] Although such a process will be time-consuming, it is argued that it would ultimately ensure the safe integration of autonomous ships. As highlighted by the analysis of COLREGs Rules, it is evident that some of the Rules rely on interpretation. There is not only difficulty in programming such an algorithm, but also risk of algorithms interpreting the COLREGs differently, thus potentially causing an accident.[153] For this reason, DNV-GL suggest that effort be committed to creating quantitative COLREGs with clear parameters that do not leave room for conflicting interpretations.[154] Such rules have been developed by the aviation industry, where quantified sets of rules exist and are homogenised for all planes.[155] Alternatively, goal-based regulations could provide the most practicable solution.

As discussed above, "sight" and "hearing" do not have to be limited to human functions, as there is scope to interpret Rule 5 more widely in order to include cameras and sensors. However, it is argued that a limit equivalent to eyesight should be set. For example, radar alone should not constitute seeing, as it would go against years of established case law and has been proven, at times, to generate an unreliable picture.[156]

As a solution to the non-compliance of autonomous ships, it has been argued that they should be considered to be "not under command" or "restricted in her ability to manoeuvre", and thus obliging other vessels to keep out of the way.[157] However, it would be absurd for a vessel perfectly capable of navigating to be considered "not under command". Additionally, that status is only reserved for ships that have come to difficulty.[158] Moreover, if autonomous ships are considered vessels "not under command" there is risk that they will be unseaworthy and uninsurable.[159]

[152] ibid 48. See also L Carey, 'All Hands Off Deck? The Legal Barriers to Autonomous Ships' (2017) 23 JINL 3, 15.
[153] DNV-GL (n 147) 11 — this is what happened to Bashkirian Airlines Flight 2937 and DHL Flight 611, where the main cause of the collision was the conflicting orders received by pilots from the Air Traffic Control and the onboard aircraft collision avoidance system.
[154] ibid.
[155] ibid.
[156] For example, sometimes radar signals may not pick up smaller vessels or may confuse them with waves. This is one of the reasons why smaller craft, and yachts in particular, have to be equipped with radar reflectors.
[157] Danish Maritime Authority (n 142) 48.
[158] COLREGs 1972 Rule 3(f), states that a vessel 'not under command' is one 'which through some exceptional circumstance is unable to manoeuvre as required by the Rules and is therefore unable to keep out of the way of another vessel'. See also: *The Navios Enterprise and The Puritan* [1998] 2 Lloyd's Rep 16. Unmanned ships in general may be considered not under command after they have come into difficulty, provided they can raise the appropriate light, sound and shape signals. However, considering them 'not under command' simply due to their unmanned orientation would undermine the purposes of 'not under command' status.
[159] Veal and Tsimplis (n 9) 329.

2.6.3 Future Expectations

In order to ensure that unmanned vessels are as safe as their manned counterparts, it is argued that the functions of autonomous and remote-controlled ships will need to be amalgamated into one ship. For example, an autonomous ship should have a remote-controlled option as a fallback in case of technical failure, and a remote-controlled ship should have an autonomous mode in case communications are lost.[160] It is argued that this is the most realistic way unmanned ships can be integrated in the regulatory landscape in its current form, as the human sentience requirement may be fulfilled. In addition, the ship will get the best of both worlds, while minimising the limitations of each mode of operation.

Lastly, laws developed to bind humans, not machines, thus it is questionable whether unmanned ships will ever be able to comply with rules aimed to be understood by humans. For example, many rules make reference to qualitative wording, which can be understood and processed by humans. However, when it comes to programming such words it becomes impossible. For this reason, the suggestion of a new goal-based annex to the COLREGs, or a set of goal-based regulations specifically for unmanned ships seems necessary.

2.7 Concluding Thoughts

Remote-controlled ships should be able to observe the requirements of Rules 2 and 5, however there may be a significant issue when it comes to Rules 6 and 8. The loss of connectivity seems to be the most substantial problem, as it is very likely to occur during a voyage and could significantly affect the requirements for safe speed and early action. For this reason it has been argued that it is likely remote-controlled ships will fall foul of the aforementioned rules. Similarly, autonomous ships would be unable to comply with Rules 6 and 8, as it would be impossible to program an algorithm with the wording of the rules, notwithstanding the fact that compliance with Rules 2 and 5 cannot be achieved. This is due to the lack of human sentience in autonomous operations. Most of the literature reviewed suggests that unless there is a possibility of assuming remote-control of the autonomous ship, she is unlikely to comply with Rules 2 and 5.[161] Compliance with the rest of the COLREGs should be possible, provided that the unmanned ship has the situational awareness required by Rules 2 and 5, as well as the capability to understand and raise relevant signals, sounds and shapes.[162]

Ultimately, to ensure the safe integration of unmanned ships in the industry, it is most likely that they will consist of at least two, or more, modes of operation. This would resolve the connectivity issues of remote-controlled ships and satisfy the human sentience requirement that autonomous ships cannot. It is finally argued, that the most viable solution to the aforementioned problems would be the introduction of goal-based regulations for unmanned ships.

[160] DNV-GL (n 147) 12.
[161] CMI Position Paper (n 35) 14 and Veal and Tsimplis (n 9) 325.
[162] CMI Position Paper (n 35) 15.

Chapter 3: Collision Liability and Unmanned Ships

3.1 Overview

Much of the academic literature surrounding unmanned ships focuses on aspects of the regulatory framework and leaves liability out of the question. However, liability is equally as important. Determining who will be liable within the current liability framework will be difficult, as unmanned ships pose complex questions and introduce new liability players. While traditionally navigation is left to the hands of an experienced master, in an unmanned setting it will either be the task of the SBO or software developers and programmers.[163] It is foreseeable that there will be an impact on the nature of responsibilities between the relevant parties.[164] The traditional culpa-based liability regime will need to adapt in order to effectively deal with unmanned ships. Moreover, as more ships will become reliant on advanced equipment it could be possible to see an increase in product liability claims. Some of the most prominent questions regarding liability will be considered below. It will ultimately be argued that new regulations may be needed in order to rectify any complexities arising out of the current framework. Before the unmanned context is considered however, it is important to understand how collision liability is imposed presently.

3.2 Collision Liability, Traditionally

As a matter of English law, there is no longer a presumption of fault by a mere breach of COLREGs.[165] Instead, the principles of the law of negligence will apply and the claimant would need to show that there was a duty of care, which was breached by the defendant, caused the collision and the damage claimed.[166] No liability will be imposed, even if negligence is shown, unless the claimant can prove that the negligence was causative of the collision.[167] A breach of COLREGs would be a factor to be taken into account when determining fault. Specifically for collisions at sea, the Collision Convention 1910[168] prescribes fault-based liability, which is apportioned according to the degree of fault of each vessel.[169] If it is impossible to determine the degree of the fault, or if the parties are equally at fault, then liability shall be apportioned equally.[170] Usually collisions occur due to faults by the crew, for which the shipowner will be held vicariously liable.

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[163] ibid 17.
[164] ibid 19.
[165] The presumption of fault was abolished by Article 4(1) the Maritime Conventions Act 1911, however in *The Aeneas* [1935] P128 it was evident a shadow of the principle was present. That was until *The Heranger* [1939] AC 94, which abolished the doctrine once and for all.
[166] Mandaraka-Sheppard (n 127) 3.1. The burden of proof lies with the claimant to discharge the elements of the claim in negligence. See *The Heranger* [1939] AC 94, which affirmed the common law rule regarding the burden of proof in the Admiralty context.
[167] See: *The Calliope* [1970] 1 Lloyd's Rep. 84.
[168] Convention for the Unification of Certain Rules of Law with respect to Collisions between Vessels 1910, enacted in English law under Section 187 of the Merchant Shipping Act 1995.
[169] Collision Convention 1910 Article 4.
[170] Collision Convention 1910 Article 4, Merchant Shipping Act 1995 Article 187(2), for example see: *The Pearl and The Jahre Venture* [2003] 2 Lloyd's Rep 188, 199-200 (Gross J).

Conversely, for certain offences a mere breach suffices to attract liability. Such strict liability regimes are commonly prescribed in relation to oil pollution and wreck removal.[171] Strict liability is imposed on a party without the need to prove fault, it suffices that the claimant shows that the tort occurred and that the defendant was responsible. Such liability generally attaches to activities that are inherently dangerous, for example the carriage of oil.

As the final step in proceedings, shipowners are afforded the right to limit their liability under certain conventions, such as the LLMC 1996.[172] A claim that attracts such a right could be one arising out of a collision.[173] The term shipowner is construed broadly so as to include the owner, charterer, manager or operator of a seagoing ship.[174]

3.3 Fault-based or Strict Liability?

It is important to assess whether the 1910 Collision Convention may find application in the unmanned context. Apportioning liability according to fault adopts a commonsensical approach to liability, thus it is argued that the same regime should be applied in unmanned casualties. However, in practice this may be difficult to establish, therefore whether imposing strict liability would resolve any uncertainties will be considered. Ultimately, this Section will argue that the current fault-based regime can be preserved for casualties involving remote-controlled ships, however in the case of autonomous vessels a strict liability framework would be more functional.

Article 4 of the 1910 Convention specifies that in a collision where multiple vessels are at fault, the liability of each vessel shall be in proportion to the degree of fault committed.[175] For the purposes of the Convention, fault may be determined from an array of factors, such as adherence to COLREGs and the prudent seamanship requirement. Importantly however, part of Article 4 regarding third party liabilities is omitted from Section 187 of the MSA 1995,[176] thus the common law position will apply. Liability to third party claimants would be joint and several, per The Devonshire.[177] Articles 3 and 4 provide for liability to be apportioned according to fault, however Article 2 mentions non-liability scenarios, so the question for English law is whether a strict liability can be introduced within the meaning of Article 2. In accordance with English law and the interpretation of the 1910 Convention, there is no room to introduce a strict liability regime under Article 2 of the Convention.[178]

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[171] See: International Convention on Civil Liability for Oil Pollution Damage 1992 Article III, which states that the owner of a ship 'shall be liable for any pollution damage caused by oil which has escaped or been discharged from the ship as a result of the incident'.
Also, Nairobi International Convention on the Removal of Wrecks Article 10, which provides that 'the registered owner shall be liable for the costs of locating, marking and removing the wreck'.

[172] Convention on Limitation of Liability for Maritime Claims 1976, as amended by the 1996 Protocol. Codified in English law via the Merchant Shipping Act 1996 ss.185-186. Note however, that some countries are still party to the International Convention Relating to the Limitation of the Liability of Owners of Seagoing Ships 1957, under which different rules apply, but this is not the case with the UK.

[173] LLMC 1996 Article 1(1) and 2(1)(a).

[174] ibid Article 1(2).

[175] LLMC 1996, Article 4.

[176] Merchant Shipping Act 1995.

[177] *The Devonshire* [1912] AC 634.

[178] CMI Questionnaire (n 73) 6.2.

Consequently, if such regime is to be introduced it must be done as an annex to the 1910 Convention or a separate internationally-agreed document.

3.3.1 Remote-controlled Ship

So long that a remote-controlled ship is under the control of a human, the fault-based liability framework can continue to apply, since the line of control and responsibility is clear.[179] It would be illogical to make the shipowner strictly liable to third parties, since a human will be in control of the ship's operation. This is similar to the way liability is assessed for self-driving cars, whereby the insurer is liable if the car is insured and causes damage to a third party while driving itself.[180] If the vehicle is not insured at the time of the accident then the owner will be liable for the damage.[181] Although collisions at sea may not be as straightforward as road collisions, important parallels can be drawn for remote-controlled ships. Namely, as long as a SBO is in control of the ship, they will be held liable and the shipowner will bear the losses for the collision via vicarious liability. It is evident therefore that there is little to consider in terms of changing the current liability model to a strict one for remote-controlled ships.

3.3.2 Autonomous Ship

In order to preserve the fault-based regime, the liability for an autonomous ship casualty would have to be proportionately split between several parties, such as the shipowner, software manufacturer and programmer.[182] Evidently, this will be a complicated process, as each of the parties could be separate or conjoined corporate entities.[183] Nevertheless, until the liability norm is internationally or nationally amended, autonomous shipowners will face the current fault-based regime, under which several factors could be considered in order to assess fault. Factors could include the appropriate maintenance and upkeep of the autonomous system and compliance with the relevant guidelines for the design of autonomous ships.[184] Additionally, since the software programmer or manufacturer could be targets to liability, due diligence needs to be proven on their end. A relevant factor could be the extent of adherence to established programming and manufacturing guidelines.

It is evident however that such an apportionment of fault would produce an expensive and time-consuming judicial process, which could hinder a third party claim. Conversely, if a strict liability framework is established, third parties may be able to recover their loss from the shipowner without undue delay.[185] The shipowner will still have the option of a recourse action against the manufacturer or developer, during which fault would have to be

[179] Baris Soyer and Andrew Tettenborn, *New Technologies, Artificial Intelligence And Shipping Law In The 21St Century* (Informa Law Routledge 2019) 2.2.1. See also: McLaughlin (n 113) 103-104 — although the author was writing about unmanned military vehicles, the principle remains the same and can be applied by parallel to commercial unmanned vessels.
[180] Automated and Electric Vehicles Act 2018, Section 2(1).
[181] ibid Section 2(2).
[182] CMI Position Paper (n 35) 19.
[183] ibid.
[184] Danish Maritime Authority (n 142) 85.
[185] Soyer and Tettenborn (n 179) 2.1.

apportioned between the different parties, however at that point the third party claimants would be out of the question and not affected by lengthy litigation.[186]

An interesting viewpoint states that the ethical values of the software developer will be reflected in the behaviour of autonomous vessels.[187] As mentioned in the previous chapter, there are many situations at sea where an autonomous vessel would need to make an ethical decision.[188] It is evident that ultimately the autonomous system will do what its developer thinks is ethical. If the programmer choses a morally ambiguous option, such as intentionally colliding with another vessel to avoid running aground and risking environmental catastrophe, it could create challenging questions for the court to resolve if a fault-based liability system is in operation.[189] At this point it may be relevant to consider how ordinary mariners are judged when using the defence of necessity in court. In The Hessa it was held that a mariner faced with the choice of two potentially perilous situations is expected to exercise discretion as a prudent seaman and subsequently, a degree of leeway is afforded.[190] Whether such leeway can be afforded to autonomous ships is uncertain, especially since it is unlikely that they can obey the prudent seamanship requirement of COLREGs. Furthermore, an autonomous ship system is likely to process the relevant information much quicker than a human would, therefore it is questionable whether such ships should be afforded a leeway.

Another point to consider is the possibility of AI systems becoming superintelligent and acting beyond the parameters of the programmer's intentions. This could mean that an autonomous ship with an AI 'captain' may start behaving in an unpredictable way, especially in the eyes of seafarers, and could thus pose a potential risk to manned vessels.[191] It follows that attempting to allocate fault in cases where an autonomous ship has learned to act in defiance of the COLREGs and rules given to it by its programmer would be a task beyond possibility.[192] It is logical therefore, to suggest the imposition of a strict liability regime, especially in cases where traditional tort law cannot address such technologically advanced questions of liability. Conversely, as explored in Chapter 2, it is realistic that unmanned vessels will use several modes of operations, including remote-controlled.[193] For this reason, adopting a strict liability for autonomous ships may be unreasonable, as there is potential that the damage could be caused by a SBO. Perhaps a fault-based liability model can be maintained for vessels utilising more than one operational modes. However, the difficulties when apportioning fault where the damage has occurred when the vessel is in autonomous mode will remain unresolved. Consequently, a strict liability framework seems more suitable for autonomous ships.

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[186] ibid.
[187] ibid.
[188] ibid. The ethical scenarios at sea have similarities to the dilemmas present in the autonomous car industry, see n 92.
[189] ibid.
[190] *The Hessa* (1921) 9 Lloyd's Law Rep 271. See also: *The Koursk* (1920) 2 Lloyd's Law Rep 244 (HL). However, a defendant cannot rely on this defence if the necessity was a cause of its own negligence, per *Southport Corp v Esso Petroleum Ltd* [1954] 2 QB 182.
[191] Porathe (n 85) 517. Automation surprise is commonly present in the aviation industry, see: Frederic Dehais and others, '"Automation Surprise" In Aviation' [2015] Proceedings of the 33rd Annual ACM Conference on Human Factors in Computing Systems - CHI '15, 2525–2534 — their solution involves a series of notices from the system to inform the pilot of its actions, the same could apply to autonomous ships, if via their AIS system they transmit information to other vessels.
[192] Soyer and Tettenborn (n 179) 2.1.
[193] Unmanned operations in general should not be understood as binary options, as it is most likely that they will exist in a variable scale of operations, see: Ringbom (n 25) 143.

If one considers a scenario where an autonomous ship has been compromised by hackers who have obtained control of the ship and caused damage to third parties, should the shipowner remain strictly liable? Several strict liability regimes establish specific exceptions, for example under the CLC 1992[194] a shipowner will not be liable if the damage was resulted from an act of war or force majeure.[195] Consequently, it is argued that a similar framework, which is tailored to the specific acts that the shipowner may have no control over, should be established for autonomous ships. However, by constituting an exception to the strict liability, third parties are left vulnerable, especially if they are not insured against such risks.[196] Additionally, it is the shipowner who ultimately decides to operate an autonomous ship, knowingly of the risks of such an operation, therefore it should be the one bearing the liability.[197] However it is argued that this would place an immense amount of responsibility for the shipowner to bear and also insure. Evidently, a balance is needed and it is argued that such balance can be struck by establishing certain exceptions to the shipowner's strict liability, similar to the CLC 1992 and other strict liability conventions.[198]

Lastly, it would make no sense to talk about fault-based liability, to the extent that all navigational decisions are taken by an autonomous system without human involvement.[199] Conversely, it is argued that even if the general principle cannot identify those liable for an act, it does not automatically mean that there is no one to be held responsible, especially considering that an autonomous ship may be remote-controlled by a SBO at some stage in her voyage.[200] Nevertheless, it is submitted that the main reason to justify the shift to strict liability for autonomous ships would be a policy one. It is simply more practical for the shipowner to be strictly liable, rather than enduring costly and time-consuming litigation in order to determine the correct apportionment of fault between different parties. Moreover, a strict liability regime would aid in re-assuring the public that the relevant technology is safe, by ensuring that compensation is awarded swiftly on the rare occasion that the technology malfunctions.[201] It is therefore argued that the fault-based liability will eventually shift to strict liability for the autonomous shipowner. However, a lot remains to be seen on the effect of a sliding scale of operational modes on the liability norm.

3.4 Channelling Liability

One of the most prominent issues to resolve would be to determine to whom the liability attaches. Consequently, it is necessary to assess whether the new parties will affect the traditional overarching liability position assumed by the shipowner on behalf of its servants. Liability between the shipowner and manufacturer will most likely be agreed on contractual terms, however when it comes to third parties the position is less clear. Importantly, whether

[194] International Convention on Civil Liability for Oil Pollution Damage 1992, Article III(2).
[195] ibid, Article III(2)(a).
[196] Soyer and Tettenborn (n 179) 2.2.1.
[197] ibid.
[198] See for example: Nairobi International Convention on the Removal of Wrecks 2007, Article 10(1)(a) stipulates that the shipowner remains liable unless it can prove that the maritime casualty that caused the wreck resulted from 'an act of war, hostilities, civil war, insurrection, or a natural phenomenon of an exceptional, inevitable and irresistible character'.
[199] Danish Maritime Authority (n 142) 85.
[200] McLaughlin (n 113) 104.
[201] Soyer and Tettenborn (n 179) 2.1.

the shipowner or manufacturer will attract liability, and under what circumstances, should be discussed.

3.4.1 Remote-controlled Ship

3.4.1.1 Shipowner Liability

Regarding remote-controlled ships, it is important to clarify the extent to which the SBO will assume the role of the master and hence its responsibilities and duties. English legislation defines the master as 'every person (except a pilot) having command or charge of a ship'.[202] Such a broad definition does not place significance on onboard presence, rather it makes reference to the person occupying the highest hierarchical position aboard a ship.[203] It is therefore argued that there is scope to include a SBO, tasked with full responsibility to navigate the vessel.[204] Moreover, the SBO is likely to assume even more duties, as they will be responsible for the whole voyage and thus potentially assume some functions of the crew.

The master is usually considered a servant of the shipowner, meaning that the latter will be vicariously liable for any negligence of the former. Unless it can be shown that the master was acting beyond the scope of its employment.[205] It follows that if the SBO assumes duties equivalent to those of the master, the shipowner will be vicariously liable for its actions. There have also been instances where the master has been held to be personally liable.[206] This highlights the need for clarity regarding the SBO and the role of the master, as there is a chance that the SBO can be held personally liable.

3.4.1.2 Manufacturer Liability

Remote-controlled ships will be equipped with an array of technological components, thus leaving room to consider how manufacturer liability may come into play. If one imagines a collision where the sole cause was a malfunction of the remote-control systems, for example the GPS fitted not showing the vessel's actual position, it is important to assess whether the manufacturer should be liable, in place of or jointly with the shipowner. The divisive line between shipowner and manufacturer liability is blurry and can depend on several factors, such as the latency of the default.[207] It could thus be possible, in theory, that the manufacturer can be made liable for a defective product.[208] This would depend on the claimant being able to prove that the fault was causative of the loss.[209] Difficult questions will arise regarding the nature of the manufacturer's right and the extent to which its right will span.[210] More importantly, how will this right interact with the shipowner's duty to maintain and inspect the

[202] Merchant Shipping Act 1995, s.313.
[203] Veal and Tsimplis (n 9) 317.
[204] ibid 317-318, van Hooydonk (n 3) 413 and CMI Position Paper (n 35) 19.
[205] See: *The Druid* (1842) 1 W Rob 391. However, proving that a master was constituting 'a frolic of their own' is extremely difficult and rare. Whether this decision can be regarded as good law however is questionable. See for example: *Navarro v Moregrand Ltd* [1951] 2 TLR 674.
[206] See *Adler v Dickson* [1955] 1 QB 158.
[207] CMI Position Paper (n 35) 18.
[208] ibid.
[209] ibid.
[210] ibid.

ship?[211] It will be a complex process to determine with certainty when negligence on the part of the manufacturer can be deemed to be causative of a collision.[212]

At this point it may be relevant to consider a case from the aviation industry, in an attempt to clarify the above issue. The case concerned a plane crash due to a faulty 'artificial horizon' equipment.[213] The High Court did not find negligence on the part of the manufacturer, since the equipment had been certified by the relevant regulatory authorities and was classified as an 'on condition' item.[214] The fact that the equipment met regulatory requirements was held to carry considerable weight, especially when an activity is highly regulated.[215] A parallel can be drawn here from the aviation to the shipping industry. Although the case may only be persuasive, it offers insight into what the court is likely to consider when determining liability for faulty products. Additionally, it highlights the need for regulatory requirements and certifications for new technologies in order to protect the manufacturer from liability claims. Once the product in question is approved by the relevant regulatory agency it is questionable whether the manufacturer can be held to have been negligent.

Alternatively, a claimant may sue under the European Product Liability Directive.[216] If a product falls below a level of reasonably expected safety, the manufacturer may face strict liability for harm caused by their product.[217] Per Article 2, products are all "movables", including electricity.[218] Therefore, it is clear that remote-control equipment will fall within the scope of the Article.[219] Moreover, a product is deemed to be defective when it fails to provide the safety a person is entitled to expect.[220] What is uncertain is the extent to which ordinary product liability will apply in the unmanned context or whether special rules will need to be developed.[221] After all, the shipowner is reasonably expected to inspect its products to a higher standard than the average consumer.[222]

Furthermore, it would appear that the Directive excludes damage to commercial property from claims which it applies to, as it specifies that damage covers items intended for private use.[223] That could include pleasure craft, however it is clear that vessels used for commercial purposes are not within the scope of the Directive. Nevertheless, for the purposes of Article

[211] ibid.
[212] ibid.
[213] *Lambson Aviation v Embraer Empresa Brasiliera de Aeronautica SA* [2001] All ER (D) 152.
[214] *Lambson Aviation v Embraer Empresa Brasiliera de Aeronautica SA* [2001] All ER (D) 152, para 17 (Mr Justice Tomlinson).
[215] ibid.
[216] Directive 85/374/EEC 25 July 1985 in the approximation of laws, regulations and administrative provisions of the Member States concerning liability for defective products, which is transposed in English law by Consumer Protection Act 1987.
[217] CMI Position Paper (n 35) 18.
[218] Directive 85/374/EEC, Article 2.
[219] For more detailed analysis of product liability in the maritime sector see: Felix Colin, 'Maritime Product Liability At The Dawn Of Unmanned Ships – The Finnish Perspective' (UTULAW Research Paper Series 2/2018).
[220] Directive 85/374/EEC, Article 4.
[221] CMI Position Paper (n 35) 19.
[222] ibid.
[223] Directive 85/374/EEC Article 9(b)(i) states that for the purposes of Article 1, damage means damage to, or destruction of property, given that the item of property 'is of a type ordinarily intended for private use or consumption'.

1, damage can include death or personal injury at sea.[224] It is important to clarify whether unmanned shipping products would fall within the scope of the Directive, or whether changes are needed to encompass commercial products within the Directive.

Ultimately, it is argued that in the case of remote-controlled ships the traditional way of channelling liability to the shipowner can be maintained, due to the fact that the SBO may be considered to be a servant of the shipowner. Whether manufacturer or product liability will gain more relevance in this context is uncertain. If it will, then there are necessary amendments and clarifications to be made with respect to the manufacturer's right span and the scope of the EU Directive.

3.4.2 Autonomous Ship

3.4.2.1 Shipowner Liability

While it may be possible for a SBO to assume the role of the master, a programmer of an autonomous ship will probably not. Firstly, the role of the master cannot be deferred to AI or an automated system, due to the definitional requirement of contemporaneous influence.[225] Secondly, it is unlikely that the programmer that presses the button will be considered to be in command of the autonomous ship and would thus fail to meet the hierarchical requirement of the master. It is therefore unknown what the exact role of the programmer will be, as no parallel can be drawn to current roles in the maritime domain.[226] It is more likely that the programmer's role can be likened to that of an engineer, however the programmer's conduct before the autonomous ship's voyage may have a more significant effect on the ship's navigational safety.[227] Nevertheless, it can be said conclusively that the programmer will not be assuming the role of the master. For the shipowner to be held liable there needs to be a person for whom it can vicariously assume liability. Consequently, it is important to consider whether software developers and programmers may be considered to be the shipowner's servants for the purposes of vicarious liability. If such parties are akin to engineers, then they could be considered servants of the shipowner, per The Lady M.[228] The difference however, is that a software developer may not be employed by the shipowner in the same way as an onboard engineer.[229] Therefore, there is scope to argue that the programmers may be considered to be independent contractors, thus complicating the picture even further.[230] If this is the case, the shipowner would be liable only if it did not take reasonable care in hiring the independent contractor. It is important therefore to clarify the precise legal position of programmers, as potentially the shipowner may not be able to assume vicarious liability for their actions.

Vicarious liability has been developed to facilitate compensation and ensure that the defendant can afford to pay the affected third parties. It is evident therefore, that the liability

[224] Directive 85/374/EEC Article 9(a): 'damage caused by death or by personal injuries' is wide enough to encompass death and personal injuries at sea.
[225] Veal and Tsimplis (n 9) 318.
[226] CMI Position Paper (n 35) 19.
[227] ibid.
[228] *The Lady M* [2017] EWHC 3348 (Comm).
[229] For example, the developer or programmer may instead be contracted for through a separate entity.
[230] *Mersey Docks and Harbour Board Ltd v Coggins & Griffiths (Liverpool) Ltd and MacFarlane* [1946] 2 All ER 345.

framework as it stands is inadequate to cover an autonomous ship casualty, insofar that the process under which the shipowner is made liable is unworkable for autonomous ships. This point further highlights the need for a strict liability framework, which would automatically channel the liability to the shipowner.

3.4.2.2 Manufacturer Liability

Since the shipowner may be unable to assume vicarious liability for harm caused by an autonomous ship, whether the manufacturer can be held liable shall be considered. It is argued that if the liability for autonomous ships remains fault-based, there is potential for the manufacturer to be held liable. Conversely, if the liability becomes strict, it would be strict for the shipowner and not the manufacturer.[231]

Holding the manufacturer liable for a defective product has an instinctive appeal, however upon examination of the issues that could arise, it is argued that this should not be the case. Firstly, the advanced nature of the technology is likely to involve several parties in the construction and assembly of an autonomous ship. Consequently, it may be impossible to determine with clarity which party to hold liable. This would force manufacturers to purchase acceptable liability insurance, which could end up being costly, considering the fact that the current limitation of liability regime does not cover manufacturers.[232] Furthermore, after the autonomous vessel is delivered, it is expected that the shipowner will be diligent in the maintenance and inspection of the vessel's systems.[233] For this reason, it is submitted that after the delivery of the vessel the shipowner shall be the party responsible for the ship.

As explored above, a third party may bring a claim under the EU Directive against the manufacturer. Whether an autonomous ship or its software will fall under the definition of a product is uncertain, but possible. The Directive covers "all movables", which could include the ship's hardware as well as sensors. However, there is uncertainty surrounding more intangible things, such as the ship's software or algorithms. Recently, concern has been has voiced internally within the EU regarding the Directive.[234] Some of the suggestions for change included inter alia, considering the need to update the Directive's definitions in light of AI and software development.[235] Whether such changes will be effected remains to be seen, however it is evident that they would have a profound effect in the present context. Ultimately however, the claim would fall short of the Directive's ambit, as autonomous ships for the purposes of this research are intended to have a commercial purpose. However, there is always scope for change, especially in light of new technologies. In the maritime context however, even if negligence on the manufacturer is proven, it may avoid liability if the shipowner has failed to exercise due diligence in the maintenance and inspection of the ship.[236] Ultimately, the effect of the interaction between the shipowner's duty of inspection and the

[231] Although, the shipowner would still have the option to initiate a recourse action against the manufacturer of a defective product.
[232] Soyer and Tettenborn (n 179) 2.2.2.
[233] ibid 2.2.2.
[234] Specifically, the Committee on the Internal Market and Consumer Protection has called on the Committee on Legal Affairs to consider updating the Directive, see: 'Draft Opinion Of The Committee On The Internal Market And Consumer Protection For The Committee On Legal Affairs On Civil Liability Regime For Artificial Intelligence' (European Parliament, 2020) <https://www.europarl.europa.eu/doceo/document/IMCO-PA-648381_EN.pdf> accessed 19 August 2020.
[235] ibid.
[236] Soyer and Tettenborn (n 179) 2.2.3.

manufacturer's duty of due diligence is uncertain and should be clarified on an international level.

3.4.3 Conclusion

Although the liability norm may change over time, especially for autonomous ships, there is merit to presume that the person to whom the liability attaches will remain the shipowner, in its capacity as the largest stakeholder in the operation of a ship. There are several policy issues underlying such a decision. Namely, the shipowner is the party that assumes the risk of the operation and is financially able to insure against it.[237] Although there is potential to hold the manufacturer liable, it is argued that it should not be the case for reasons of convenience and policy.

3.5 Limitation of Liability

The shipowner traditionally bore the weight of considerable responsibility, thus to strike a reasonable balance, it was entitled to limit its liability to a predetermined amount based on the tonnage of the ship in question, regardless of the actual damages.[238] From as early as 1733 the reason behind limitation of liability was clear: to help increase the number of British merchant vessels and thereby promote commercial trade.[239] More recently, allowing the shipowner to cap its liability was targeted to encourage the purchase of liability insurance.[240] Limitation of liability in the UK is presently governed by the LLMC 1976[241] and the 1996 Protocol.[242] As explored above, unmanned shipping has the potential to introduce new liability parties. It is important thusly, to determine the extent to which the new parties, as well as the unmanned shipowner, may be afforded the right to limit their liability.

Under the LLMC 1996, a shipowner may limit its liability with respect to seagoing ships.[243] Of course, what constitutes seagoing ships is not defined in the Convention, however MSA 1995 clarifies that ships are vessels used in navigation.[244] Evidently, since unmanned ships concerned with in this research will assume commercial usage, it is argued that they do indeed fall within the meaning of seagoing ships, and can thus be subject to limitation of liability. The main issue concerning the unmanned ships currently under development is their modest size, as the LLMC 1996 traditionally covers vessels over 300 grt. Nevertheless, discretion is

[237] Regarding insurability, the shipowner will most likely have the support of P&I Clubs, whereas the manufacturer does not. Hence, why the shipowner should bear the responsibility for an autonomous ship.
[238] David Steel, Ships are Different: The Case for Limitation of Liability [1995] LMCLQ 77, 78-79.
[239] ibid 79.
[240] *The Garden City* [1982] 2 Lloyd's Rep 382.
[241] Convention on Limitation of Liability for Maritime Claims 1976.
[242] Protocol of 1996 amending the Convention on Limitation of Liability for Maritime Claims. Both limitation of liability conventions are transposed into English law via the Merchant Shipping Act 1995, ss. 185-186.
[243] Article 1(2) states: 'The term "shipowner" shall mean the owner, charterer, manager or operator of a seagoing ship'.
[244] Merchant Shipping Act 1995, s. 313. See also *R v Goodwin* [2005] EWCA Crim 3184 and *Michael v Musgrove t/a YNYS Ribs (The Sea Eagle)* [2012] 2 Lloyd's Rep 37, it was held that the absence of a cabin onboard was not decisive in determining whether a ship is a seagoing one. Using this precedent unmanned ships, which are likely not to have cabins, may be considered seagoing ships. Fundamentally, the Merchant Shipping Act 1995 governs non-seagoing ships as well in Schedule 7, Part II, Paragraph 2.

given upon countries to prescribe rules for vessels under 300 grt.[245] Under English law, vessels of less than 300 grt are entitled to limit their liability in accordance with certain parameters, consequently smaller unmanned vessels may also do so.[246]

3.5.1 Shipowner

Considering that the right to limit one's liability was developed to promote commercial shipping, one could argue that so long as the purposes of unmanned shipping remain the same, there is no reason why the right cannot cover unmanned shipowners. In addition, the right to limit one's liability is virtually unbreakable, thus there is no reason why it would not extend to unmanned shipowners.[247] After all, unmanned ships will face the same perils of the sea as manned ships.

3.5.2 SBO

It is fairly clear that the shipowner will not lose its entitlement to limit liability in relation to unmanned shipping. The more important question is whether the SBO will be afforded a similar right. Traditionally, the master and crew would be entitled to limit their liability under Article 1(4) of the 1996 LLMC. If the submission that SBOs will take the role of the master is widely approved, then it is likely that they will be entitled to limit their liability.[248] The purpose of this provision was to prevent parties suing seafarers and masters personally in order to circumvent the effects of limitation of liability.[249] For this reason, it is argued that SBOs should be entitled to limit their liability to avoid reintroducing the aforementioned loophole. If the right does not extend to SBOs and they become the subject of a lawsuit, it is likely that their assets will not be enough to cover the full extent of the claim, thus rendering such a claim pointless.[250] Importantly however, even if SBOs are not considered of equal stature as the master, they will still be an employee of the shipowner and thus be able to limit their liability. The ability to limit one's liability has never been contingent on being employed onboard the ship, thus there is no reason for it not to extend to cover SBOs.

If the SBO is employed by the shipowner the situation is clear, however difficulties can arise if the operator has not been hired by the shipowner and it is rather an independent company providing SBO services to shipowners.[251] One could argue that this is a very likely possibility and thus international agreement is needed to clarify this very issue.

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[245] LLMC 1996 Article 15(2).
[246] Merchant Shipping Act 1995, Schedule 7, Part II, Paragraph 5.
[247] The right to limitation of liability was considered unbreakable after the 1976/1996 LLMC. The Conventions imposed higher limits of liability *quid pro quo* establishing a more stringent test for losing the right to limit, as outlined in Article 4.
[248] They would do so under LLMC 1996 Article 1(4), which states 'If any claims set out in Article 2 are made against any person for whose act, neglect or default the shipowner or salvor is responsible, such person shall be entitled to avail himself of the limitation of liability provided for in this Convention'.
[249] Patrick Griggs, Richard Williams and Jeremy Farr, *Limitation Of Liability For Maritime Claims* (4th edn, LLP 2005), Chapter 1(a), also see *The Himalaya* [1954] 2 Lloyd's Rep. 267.
[250] After all, it is a well-established principle of law that it is more beneficial to sue a financially able party rather than an insolvent one.
[251] Danish Maritime Authority (n 142) 32.

SBOs may also be able to limit their liability under Article 1(2), as managers and operators are deemed to be within the definition of a shipowner.[252] Recently, in The Stema Barge II, the Court of Appeal was called to clarify for the first time exactly what persons are to be considered managers or operators of a ship.[253] A manager was held to be a person whom the owner has entrusted sufficient of the tasks involved in inter alia the safe operation and maintenance of the ship.[254] However, a person with one limited task would not be considered a manager.[255] Consequently, it is crucial to precisely define the scope of the SBO's rights and obligations regarding a remote-controlled ship, in order to determine whether they can be considered to be a manager. Furthermore, an operator for the purposes of Article 1(2) may not be the master or crew, thus if the SBO assumes an equivalent role, they may not be considered to be the operator of a vessel. This is due to the fact that 'operator' refers to a certain level of abstraction, as one which has control over the management and operation of the ship.[256] Depending on the rights of the SBO, there is a possibility of including them within Article 1(2), as managers or operators, thus permitting the right to limitation of liability.

3.5.3 Software Programmer & Manufacturer

It is also important to determine whether the right to limit liability can be extended to a software programmer or manufacturer. Under the 1996 LLMC, manufacturers, software programmers et al. will not be able to limit their liability. A reading of Article 1 using the principle of expressio unius est exclusio alterius, suggests that manufacturers are not within the persons entitled to limit their liability. Whether such a right should be extended will be a policy decision.[257] Regardless of whether a strict or fault-based liability regime is established, it may become necessary to allow manufacturers to limit their liability. Otherwise, a claimant could sue the manufacturer in order to benefit from a claim with no liability cap.[258] Alternatively, the ability of third parties to sue the manufacturer could be barred, in order to prevent such parties from exploiting the above loophole. Whether the manufacturer will be able to limit its liability in a recourse action against the shipowner is also unclear.

Conversely, if one considers the manufacturer's job is akin to that of a shipbuilder, then it is clear that neither persons are servants of the shipowner, as they are both contracted for. The extent to which manufacturers can be regarded as independent contractors and be entitled to limit their liability is questionable. Traditionally, independent contractors are not persons for whom the shipowner will be responsible, as they are not its servants or employees. However, there is potential that manufacturers will become appealing targets to lawsuits if claims against them are not barred or afforded limitation rights.

Furthermore, the 1996 LLMC does not permit for a claim to be brought with respect to defective products. The Convention provides an exhaustive list of claims that attract

[252] LLMC 1996 Article 1(2).
[253] *The Stema Barge II* [2020] EHWC 1294.
[254] ibid 64 (Mr Justice Teare).
[255] ibid.
[256] *The Stema Barge II* [2020] EHWC 1294, 79.
[257] Soyer and Tettenborn (n 179) 2.2.5.
[258] This would re-introduce the loophole mentioned in Section 3.4.2, but instead of suing the master or SBO, a claimant would sue the manufacturer.

limitation and it is doubtful whether a claim for a defective product can fit within the list.[259] Unless defective equipment can be deemed to be in direct connection with the operation of the ship, there is nowhere else within the options listed that such a claim can be brought.

Ultimately however, with the introduction of new technologies responsibilities between parties may change as the law evolves. For this reason, the traditional view may alter and amendments to current conventions may be made to reflect these changes. One such change could involve the manufacturers to be introduced within the persons entitled to limit liability.

3.6 Concluding Thoughts

Ultimately, there is a need for balance between exposing manufacturers to excessive risk and burdening the shipowner with overwhelming liability. This can be achieved by maintaining the fault-based liability regime for remote-controlled operations, thus not imposing inequitable liability on the shoulders of the shipowner. As for autonomous ships, a strict liability framework can be established, to ensure prompt compensation to affected third parties. Within such a framework certain exceptions, akin to other civil liability conventions, should be established to ensure the shipowner is not held liable for occurrences beyond its control. It is thus concluded that the shipowner should remain the main party liable vis-à-vis third parties. It is the most financially able party, both in terms of assets and insurance.

The trend explored in the previous Chapter is evident with regard to liability; remote-controlled ships are more likely to comply with the current framework, whereas autonomous ships may struggle. Ultimately, it is likely that remote-controlled ships can be integrated within the current fault-based liability regime, as there is an easily identifiable person for whom the shipowner will be vicariously liable. It is argued that autonomous ships, mutatis mutandis, may function more effectively under a strict liability regime, since there is no human directly controlling the ship's navigation. With regards to limitation of liability, it is submitted that the position of the shipowner should remain unchanged. It is only logical that the right should extend to SBOs, as they have a position akin to the master and can be considered to be servants of the shipowner. The position regarding manufacturers is overall less clear and whether they should be afforded the right to limit their liability is up for debate. If it is deemed necessary for manufacturers to limit liability, then amendments to the current framework are needed.

What has been made clear from this Chapter is the need to clarify the precise rights of the SBO and manufacturer, in order to make the liability picture clearer. This highlights the need to develop new regulations and practices to cover unmanned ship operations, which could take the form of due diligence standards for the shipowner, certification requirements for the manufacturers and new training standards for programmers and SBOs.[260]

[259] LLMC 1996, Article 2.
[260] CMI Position Paper (n 35) 20. The relevant classification societies will also need to gain expertise in the new era of operations, in order to discharge their own regulatory duties.

Chapter 4: Conclusions

The aim of this research was twofold; firstly to determine the extent to which unmanned vessels may comply with COLREGs and secondly, how such vessels and their respective owners may be made liable under the current liability framework. The running trend in each Chapter was that the distinction between remote-controlled and autonomous would have a profound effect on the ship's ability to comply with the framework. In the context of COLREGs, this was due to the ability of remote-controlled ships to satisfy the human sentience so required by several rules and most notably Rule 2. Mentions across the rules of the human senses may also pose difficulties for unmanned ships, especially with respect to Rule 5. Nonetheless, with international agreement the picture should crystallise. Another important aspect of the analysis of COLREGs was the possibility of unmanned ships to be held to a higher responsibility standard when it comes to taking avoiding action, as their equipped aids would enable them to observe other ships much earlier.

Most issues of compliance can be resolved if a hybrid of a remote-controlled and autonomous ship is constructed. This way, the relevant ship can minimise non-compliance while enjoying the benefits of both modes of operation. This is the most realistic type of ship with the relevant modes of operation placed on a sliding scale and not seen as binary options. However, as evidenced in Chapter 3, this may have consequences with regards to the allocation of liability. Nevertheless, it is submitted that the liability for autonomous ships should become strict, justified mainly as a policy decision. Conversely, the clear-cut line of responsibility in remote-controlled ship operations is predominantly the reason for maintaining the culpa-based liability framework for such ships. This dual mode of liability would ensure the shipowner remains the main party liable for casualties and protects the manufacturer and SBO from inequitable exposure to risk.

Regarding limitation of liability, it was clear-cut that there was no reason why the right should not extend to unmanned shipowners, especially considering that the risks involved in unmanned shipping will be the same as manned shipping. It is ultimately argued that the right of limitation should extend to SBOs, in order to avoid claimants suing the SBO personally to avoid the limitation caps. Whether such right would extend to manufacturers will be a policy decision and would best be clarified on an international level.

The swiftest way to normalise unmanned ships in the maritime sector would be to integrate them in the current framework, which would require amendments or clarifications.[261] Alternatively, new goal-based regulations could be established, either in an instrument governing solely unmanned operations or as an addendum to COLREGs. It is submitted that adopting goal-based regulations is more preferable, due to their suitability in dealing with technologically advanced activities. Such regulations introduce a much-needed flexibility in achieving a goal, rather than being overly prescriptive and may preserve the letter of the law for longer against new technologies.[262] If no regulation is effected on an international level, then it could be left to national jurisdictions to make the necessary amendments, each to their respective frameworks. However, such means of regulation would inevitably produce

[261] For instance, Rule 5 of COLREGs would benefit from an amendment or clarification in order for unmanned ships to be able to fulfil the lookout requirement whilst being reliant on technology. See Chapter 2.6.
[262] This way several modes of automation can be dealt with effectively in one instrument. See also: Chapter 2.6.

unharmonised rules and create uncertainty. It is ultimately argued that goal-based regulations may be the most advantageous method of incorporating unmanned ships in the maritime domain.

Looking at the greater picture, it is evident that there are several areas that may present difficulties for unmanned ships, which this research has been unable to consider. Firstly, the extent to which unmanned ships are safe in terms of piracy and cyber risks.[263] Especially when millions of pounds of cargo and technology are at stake, cyber security is of utmost importance.

Secondly, the area of salvage poses significant difficulty for unmanned ships. During the operation of a manned vessel the crew are able to intervene and resolve minor risks, such as small fires, from escalating into major incidents.[264] Moreover, in cases where a major incident does happen, the crew act to mitigate the losses and the master may provide invaluable information regarding the status of the incident to salvors.[265] The extent to which a SBO may act in the same capacity is questionable and is essential to be clarified. Otherwise, there is serious risk that unmanned vessels may be lost due to a minor event.[266]

Thirdly, the shift to unmanned shipping may disturb the traditional duties of the relevant parties involved in the carriage of goods.[267] For instance, it is uncertain who will issue bills of lading in the absence of a master.[268] Additionally, the scope of several traditional obligations of the shipowner may change; with regards to seaworthiness, it should be expected that the duty will broaden to include diligent inspection and update of the relevant software onboard a ship.

Fourthly, it is undetermined how the duty to render assistance will evolve regarding unmanned ships.[269] Considering that it would take some time for all ships to become unmanned this is important. Also noting that pleasure craft and cruise ships will carry persons at sea, the duty will certainly not lose its relevance. However, precisely how unmanned ships may render assistance is uncertain. Moreover, the extent to which the SBO will assume the role of the master should be clarified, as it could affect several areas of maritime law; not only for rendering assistance, but also for issuing bills of lading, being in charge of the ship etc.

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[263] This is one of the most pertinent issues in the autonomous car industry, with much research highlighting the ease with which one can infiltrate and gain access to the car's controls. See: Sasan Jafarnejad and others, 'A Car Hacking Experiment: When Connectivity Meets Vulnerability' [2015] 2015 IEEE Globecom Workshops (GC Wkshps).

[264] Veal and Tsimplis (n 9) 334.

[265] ibid.

[266] ibid.

[267] See: Hague-Visby Rules 1968 Article III(1)(b), whereby the carrier is bound to ensure the ship is properly manned. It is uncertain how a carrier may show that an unmanned ship is properly manned. Also Article III(3), which states that a master must issue a bill of lading after receiving the goods. See also: van Hooydonk (n 3) and Carey (n 152) 4-10.

[268] Additionally, will electronic bills of lading ever be accepted by the industry? See for example: *MSC Mediterranean Shipping Company SA v Glencore International AG* [2017] EWCA Civ 365.

[269] The duty to render assistance is imposed on masters via several conventions. See for example: UNCLOS 1982 Article 98, SOLAS 1974 Chapter V Regulation 10.

In addition to legal difficulties, the usage of unmanned ships also poses serious socio-economic considerations. Namely, with regard to job losses and demands.[270] Moreover, it is expected that unmanned ships will face resistance from sceptics of technology about their viability, especially during an era where misinformation about new technologies travels faster than ever. Furthermore, the shift to unmanned shipping may not be as cost-effective yet, as the construction of such ships is more expensive than manned ships.[271] However, considering the effect of economies of scale, it is likely that the more unmanned ships are built, the cost of their production will eventually decrease. Consequently, it is important to incentivise their production by means of regulation.

At the moment, during Covid-19 a lot seems to have changed. The pandemic could potentially act as a catalyst to give a strong push to the industry towards the development of unmanned technology.[272] Especially as the industry is striving towards decarbonisation.[273] Combining automation with sustainable ways of propulsion, like many of the current unmanned ship projects, the industry will see a rise in efficiency of operations. In addition, with little or no crew onboard, life at sea can become easier and safer.[274] Provided that safety parameters are met by unmanned ships, it should be plain sailing with regards to their integration in the industry. Although fully autonomous ships may be too far ahead in the game, currently remote-controlled or partly autonomous ships place real pressure on the relevant authorities to clarify the regulatory framework, in order for the industry to capitalise from these technological developments. Two barriers to unmanned shipping soon have the possibility of being lifted. Firstly, the ongoing IMO scoping exercise results should hopefully bring clarity to the regulatory framework and secondly, as unmanned ship trials will ramp up solutions to technological problems, such as connectivity issues, may be implemented. Changes across the whole discipline of maritime law should be expected in order to keep at pace with the rapidly developing technology and integrate unmanned ships in the industry.

[270] Considering that most crews are comprised of nationals from developing countries, there may be a shift in demand for 'crews' (ie. SBOs) from developed countries that possess the resources and technology to train them. This in turn may be faced by resistance from seafarer's unions. See: Veal and Tsimplis (n 9) 334.

[271] Of course, the first unmanned operations are the least cost-effective, not least because of efficiency of design and functionality but also due to lack of relevant knowledge. As more and more trials are carried out, more information regarding unmanned ships will eventually emerge.

[272] 'Maritime's Opportunity To Advance Automation, AI And Autonomy' (Lloyd's Register, 2020) <https://www.lr.org/en/insights/articles/maritime-opportunity-to-advance-automation-ai-and-autonomy/> accessed 18 August 2020.

[273] ibid. See also: 'Energy Efficiency And The Reduction Of GHG Emissions From Ships' (International Maritime Organization, 2020) <http://www.imo.org/en/MediaCentre/HotTopics/GHG/Pages/default.aspx> accessed 30 August 2020.

[274] Lloyd's Register (n 272). Especially considering the effect of the pandemic regarding crewing changes. A lot of the hardship faced by crewmembers could be avoided with the operation of unmanned ships.

Should the courts be moral censors of biotechnological innovation? An analysis of the morality provisions of patent law with specific reference to Rule 28(1)(c) of the Implementing Regulations to the EPC concerning embryonic stem cell patents

*Louise Clarke**

Abstract

This dissertation considers the legal treatment of the morality provisions in patent law, exclusively in the context of biotechnological inventions. Specifically, the dissertation will focus on Article 53(a) EPC and Rule 28(1)(c) of the Implementing Regulations, the equivalents of Articles 6(1) and 6(2)(c) of the Biotechnology Directive, respectively. First, I examine the jurisprudence of the European Patent Office and conclude that while the morality provisions were conventionally interpreted narrowly, this has now changed to a liberal approach via specific case law surrounding Rule 28(1)(c) (prohibition of inventions that use human embryos). These decisions are then subjected to critical analysis, leading to the conclusion that the judgements, in particular *Brüstle v Greenpeace*, lacked merit in broadening the morality exclusions to patentability. Finally, I discuss the potential consequences of these decisions in both a commercial and legal setting. Overall, I suggest that an alternative, narrower approach to morality is warranted, so as to prevent the courts becoming moral censors of biotechnological innovation.

Introduction

The need for intellectual property protection in today's competitive global market is increasingly apparent; however, the desire for inventors or researchers to obtain patents for their inventions in a biotechnological context is ever more controversial. Economic arguments are (correctly) always at the fore when justifying the patent system as a core aspect of commercial development.[1] Against this view are the moral concerns of society, which believes that granting monopoly rights over inventions that deal with living matter is inappropriate and unethical.[2] In other words, intellectual property rights cannot and must not be placed above the right of all human beings to live a full and productive life.[3] This conflict is accentuated in the case of patents for human embryonic stem cell (hESC) technology. As hESCs are pluripotent, meaning they can develop into any cell of the adult body,[4] technologies based on hESCs are unique in that they possess remarkable diagnostic and therapeutic potential.[5] For instance, these cells can be used to support basic research on the differentiation and function of human tissues and to provide material for testing that may improve the safety and efficacy of human drugs.[6] Additionally, hESCs carry the potential to provide an endless amount of tissue for transplantation therapies that could treat a wide range of degenerative diseases including heart disease, leukaemia, and diabetes.[7]

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[1] Oliver Mills, *Biotechnology Inventions: Moral Restraints and Patent Law* (Revised edn, Ashgate 2010).

[2] ibid.

[3] ibid.

[4] 'Pluripotency' (Nature Research) <https://www.nature.com/subjects/pluripotency> accessed 10 March 2020.

[5] A Leventhal and others, 'The benefits and risks of stem cell technology' (2012)18(3) Oral Diseases 217.

[6] J Yu and J.A. Thomson, 'Embryonic Stem Cells' (National Institutes of Health) <https://stemcells.nih.gov/info/Regenerative_Medicine/2006Chapter1.htm> accessed 18 March 2020.

[7] ibid.

After a brief discussion of the moral debate, upon which a favourable stance to the economic justification of patents is adopted, this dissertation analyses the relationship in practice between ethics and patent law by examining how the morality exclusion to patentability, namely Article 53(a) European Patent Convention (EPC) (the equivalent of Article 6(1) of the Biotechnology Directive), is interpreted. Subsequently, I conduct an observation of case law specifically in relation to Rule 28(1)(c) EPC (the equivalent of Article 6(2)(c) of the Directive) concerning the use of the human embryo as it pertains to patent law. The decisions are then subject to critical analysis, which ultimately answers the question of whether the courts have gone too far in broadening their interpretation of morality. Lastly, the consequences of the courts' new broad approach to ethical considerations are investigated in both a legal and commercial context.

Chapter 1: An Overview of the Patent System and the Biotechnology Directive

1.1 Introduction

The biotechnology industry develops and capitalises on the commercial applications of biological manipulation;[8] it is one of the most research-intensive and innovative industries in its field.[9] In Europe specifically, the sector substantially contributes to fundamental EU policy objectives such as job creation, economic growth, and public health.[10]

This chapter provides context by outlining the legal framework of the EU in the application of patent law to biotechnological products. It gives the background of the enactment of what became known as the Biotech Directive, followed by a statement of the Directive provisions which are relevant for the forthcoming discussion.

1.2 The European Patent Organisation

> [The] European Patent Organisation is an international, intergovernmental organisation, which the sovereign contracting states have entrusted with some of their national powers in the field of patents.[11]

The Organisation was established on 7 October 1977 on the basis of the European Patent Convention, signed in Munich in 1973. The EPC provides a legal framework for the granting of European patents[12] via the European Patent Office (EPO). Alongside the convention's articles are the 'Implementing Regulations,' the function of which is to detail how the articles

[8] 'Biotechnology in the UK – Market Research Report' (IBIS World, July 2019) <https://www.ibisworld.com/united-kingdom/market-research-reports/biotechnology-industry/> accessed 5 February 2020.
[9] Mills (n 1).
[10] 'Biotechnology Industry in the European Union' (Invest in EU) <http://www.investineu.com/content/biotechnology-industry-european-union> accessed 5 February 2020.
[11] *President's Reference/Programs for Computers* G3/08 [2011] [OJ EPO Published 12 May 2011].
[12] Article 2(1) EPC.

should be applied.[13] For our purposes the relevant provision of the EPC is Article 53(a) which states that 'patents shall not be granted for inventions the commercial exploitation of which would be contrary to *"ordre public"* or morality.'

1.3 The Biotechnology Directive

In 1988, the importance of patent protection for biotech inventions became apparent along with the attendant need for its formalisation, such protection being governed at the time by a range of national laws and international conventions.[14] With this in mind, the European Commission issued its Proposal for a Council Directive on the Legal Protection of Biotechnological Inventions.[15] The Commission declared that:

> [w]hereas the two leading nations in biotechnology, the US and Japan, have been able continuously to adapt their patent protection according to the latest needs of the industry, science and consumers, the Member States, representing comparable potential of intellectual manpower and capital, are immobilised, by a not yet completed and…in part outdated legal framework.[16]

The intention was to stimulate the European biotechnology industry via a harmonised patent system,[17] aimed at removing deterrents to the exchange of research among Member States,[18] while furthering trade otherwise impeded by the fact that 'the export of biotechnological products into areas with uncertain or weak protection is less than attractive.'[19]

After ten years of debate following its initial proposal, the Directive on the Legal Protection of Biotechnological Inventions[20] (hereafter the Biotech Directive or the Directive) was formally adopted in the EU in 1998. The central reason for the delay was due to opposition led by Parliament's Green Party,[21] whose concerns were grounded in morality and ethics.

The provisions of the Biotech Directive that are relevant for our forthcoming discourse include Articles 6(1) (the equivalent of Article 53(a) EPC) and 6(2)(c) which are as follows:

> 6(1) Inventions shall be considered unpatentable where their commercial exploitation would be contrary to *ordre public* or morality[22]

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[13] Legal Research Service for the Boards of Appeal, European Patent Office, Case Law of the Boards of Appeal of the EPO (8th edition, July 2016), III.H.6 : "Implementing Regulations."
[14] Donna M. Gitter, 'Led Astray by the Moral Compass: Incorporating Morality into European Union Biotechnology Patent Law' (2001) 19 Berkeley J. Int'l Law 1.
[15] Proposal for a Council Directive on the legal protection of biotechnological inventions. COM (88) 496 final, 17 October 1988.
[16] ibid (n 15).
[17] Gitter (n 14).
[18] Proposal for a Council Directive (n 15).
[19] ibid.
[20] EC Directive 98/44/EC of 6 July 1998 on the Legal Protection of Biotechnological Inventions [1998] OJ L 213/13 (The 'Biotech Directive').
[21] Gitter (n 14).
[22] The Biotech Directive (n 20) Article 6(1).

(2) On the basis of paragraph 1, the following, in particular, shall be considered unpatentable:
(c) uses of human embryos for industrial or commercial purposes[23]

The question of what a national court would do if the EPC and the Directive were at odds[24] was resolved when the Directive was incorporated into the Implementing Regulations of the EPC,[25] harmonising the two bodies of legislation.[26] Accordingly, Rule 28(1)(c) of the Implementing Regulations is derived from Article 6(2)(c). The Council also provided that the Directive should be used as a supplementary means of interpreting the EPC;[27] as a result, the Recitals to the Directive can be considered where relevant.[28]

1.4 Summary

In summary, the relevant European framework consists of the EPC and the Biotech Directive, which was enacted in response to concerns regarding the need for the formalisation of intellectual property protection for biotech products. The procedure of passing the Directive was made difficult by moral concerns which are still widespread today. The next chapter outlines in more depth the moral debate that continues to confront patent law in this area, with specific reference to embryonic stem cell technology.

[23] The Biotech Directive (n 20) Article 6(2)(c).
[24] Lionel Bently and others, *Intellectual Property Law* (5th edn, OUP 2018).
[25] Administrative Council of the EPO 16 June 1999 amending the Implementing Regulations of the EPC [1999] OJ EPO 437, 573 (in force from 1 September 1999).
[26] Gitter (n 14).
[27] ibid.
[28] British Group of AIPPI, 'Report Q150: Patentability Requirements and Scope of Protection of Expressed Sequence Tags (ESTs): Single Nucleotide Polymorphisms (SNPs) and Entire Genomes' [2000] EIPR 39, 40.

Chapter 2: The Moral Debate on Embryonic Stem Cell Patents

2.1 Introduction

As noted, the Biotech Directive developed through ten years of governmental debate within the EU and is arguably one of the most important legislative enactments considered by the European Parliament.[29] Opposition was raised in particular by Parliament's Green Party, who believed that the provisions of the Directive did not sufficiently safeguard moral standards. On the other hand, supporters of the biotech industry accepted the Directive as a necessary political compromise, while at the same time lamenting what they felt to be its shortcomings, and ultimately opposed the use of patent law to protect morality.[30] As it stands, the Directive does incorporate these concerns and the debate on this issue remains prevalent today. This chapter sets out the positions of the two sides: those for the inclusion of morality in patent law and those against it. This dissertation, while conceding that morality is a necessary consideration in this area, intends to advocate a pro-patent stance overall for reasons that will become evident.

2.2 For

Those in support of the morality exclusion in European patent law believe that it is required in order to protect society against monopoly control over controversial innovation.[31] One of the most contentious focal points of the discourse is issuing patents for parts of the human genome, commonly referred to as 'life patents'.[32] The concerns are primarily of a deontological nature, surrounding basic notions of human rights and dignity in relation to what the layperson may view as the proprietorship of human beings.[33] Jasanoff notes that patents 'have the effect of removing the thing being patented from a category of nature to the category of artifice'.[34] When a human embryo is involved in the process, this shift evokes emotive social reactions due to its relation to a fundamental symbol of life.[35]

From an economic perspective, patents are seen as facilitating an individual's role in a free market system and recognising the importance of maximising benefits of one's available resources.[36] Opponents of this view argue that knowledge is a communal good; accordingly, extensive private property in the form of patents could lead to what has been termed 'the

[29] Dr. Nick Scott Ram, 'Biotechnology Patenting in Europe: The Directive on the Legal Protection of Biotechnological Inventions: Is This the Beginning or the End?' (1998) 2 Bio-science L. Rev. 43, 43.
[30] Gitter (n 14).
[31] T. Gummer, Rethinking morality: human embryonic stem cell innovation, to patent or not to patent? (Part 2)' [2012] SJOL <www.sjol.co.uk>.
[32] Ellen-Marie Forsberg and others, 'Patent Ethics: The Misalignment of Views Between the Patent System and the Wider Society' (2018) 24 Science Engineering Ethics 1551–1576.
[33] Ned Hettinger, 'Patenting life: Biotechnology, intellectual property, and environmental ethics' (1995) 22(2) Boston College Environmental Affairs Law Review 267–305.
[34] Sheila Jasanoff, *Designs on nature: Science and democracy in Europe and the United States* (Princeton University Pres 2005).
[35] Brian Salter and Charlotte Salter, 'Bioethical ambition, political opportunity and the European governance of patenting: The case of human embryonic stem cell science' (1982) 98 Social Science & Medicine 286.
[36] Richard Posner, *Economic analysis of law* (6th edn, Aspen 2003) 3-4.

tragedy of the anti-commons'.[37] This describes a situation in which too many private owners exclude others from using goods, which unduly limits access to necessary products such as healthcare.[38] Ultimately the argument is that the commercial market use of patents is secondary in importance to its deployment in achieving certain rights such as human health, dignity, and cultural identity.[39] This countervailing view is reinforced when one recalls the need for underdeveloped nations to secure their right of access to medicine by contesting the rise in drug prices that accompanied the implementation of the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) in light of the HIV pandemic.[40]

2.3 Against

First of all, it is important to consider the extent to which the patent system is the proper forum to deliberate issues of morality.[41] Difficulties arise when patent law is applied to new, fast-moving technologies,[42] as opposed to those of a more classical mechanical nature; thus, it is not the most suitable place to regulate biotechnology. Arguably, any attempt to do so by disallowing patents on moral grounds is misplaced, as such a solution does not match the nature of the problem.[43] Furthermore, it can be stated that patent judges are unsuitable and lack the necessary qualities and resources to decide multifaceted issues surrounding ethics and religion.[44] In addition and more generally, it is questionable whether the patent system should purport to perform a regulatory function concerning science. That is arguably the legitimate role of the state government and it may be a role that is usurped by an unelected administrative body able to pass judgement on the morality of new technologies.[45] This is problematic considering the example of the UK, which invests millions of pounds each year in support of stem cell research. How is it acceptable that these efforts might be impeded by the EPO?[46]

In reference to stem cell technologies specifically, it is appropriate to consider the claim above: that patents involving the human embryo cause considerable emotional reactions. In response to this, one could note the concept of birth control; this is a strong example of interference in the process of nature, yet where is the moral protest here?[47] On this basis, the mere fact that patenting allows control of life is thus not a sustainable moral objection. Unless and until human control over nature exerted via genetic engineering can be differentiated from control which humans routinely exercise over nature in other ways, genetic engineering must remain

[37] Michael A. Heller, 'The Tragedy of the Anticommons: Property in the Transition from Marx to Markets' (1998) 111 Harvard Law Review 621.
[38] Michael A. Heller and Rebecca S. Eisenberg, 'Can patents deter innovation? The anticommons in biomedical research' (1998) 280 *Science* 698.
[39] Salter and Salter (n 35).
[40] Phillippe Cullet, 'Patents and medicines: the relationship between TRIPS and the human right to health' (2003) 79 International Affairs 139..
[41] Elizabeth Siew-Kuan 'Immoral Inventions – Interaction between Ethics and Biotechnology Patent Law' (2010) 22 SAcLJ 931.
[42] Brad Sherman, 'Patent Law in a Time of Change: Non-obviousness and Biotechnology' (1990) 10 Oxford Journal of Legal Studies 278.
[43] Mills (n 1).
[44] Siew-Kuan (n 41).
[45] Abbe E.L. Brown and others, *Contemporary Intellectual Property Law and Policy* (5th edn, OUP 2019).
[46] ibid.
[47] Mills (n 1).

on a moral par with any other human-made intrusion.[48] Furthermore, moral concerns which focus on the concept of human dignity must be considered in light of the right to health, which is specifically recalled by Article 35 of the Charter of Fundamental Rights of the EU.[49] For example, Member State legislation on hESC research often justifies the grant of patents for stem cell inventions with reference to their prospective health benefits,[50] in that they ultimately outweigh any moral concerns regarding the development process of cellular therapy products.

Ultimately then, it is economic arguments that always come to the fore when justifying the patent system.[51] Indeed this is supported by Demsetz, who argues the imperative that innovation necessitates ownership. For instance, if we had shared rights to new ideas, incentives to advance such ideas would be absent; whereas if we extend some private rights to the inventors, these ideas will come forward at a more favourable pace.[52] Consequently, it can be argued that the purpose of intellectual property rights is to produce the optimal production levels of intangible goods. Lehman reinforces this in saying that intellectual property rights can be viewed as a restriction on competition at the level of production, in favour of competition at the level of innovation.[53] These economic rationales that underpin the patent system should not be forgotten, despite the fact we live in an age of moral pluralism. In the bio-economy specifically, patents represent units of 'bio-value' that ease market operation through their commodification of the incorporeal capital of knowledge and their resulting potential to be traded in various ways.[54] A 2005 report from the EPO[55] recognised the economic importance of patents via the finding that intellectual assets now account for a substantial proportion of a firm's market value. Additionally, it is well-recognised that upon the decision to invest in a company, a primary consideration is now the existence of patents held by that company.[56] This correlation between patents and financial markets is evident when one considers the prompt response of stock prices to the issue of new patents.[57]

It should finally be noted that the grant of a patent does not mean a right to commercialisation. So while it is clearly necessary to contemplate and address ethical issues

[48] ibid.
[49] Charter of Fundamental Rights of the European Union [2012] OJ 326/02 (EU Charter).
[50] Rosario M. Isasi and Bartha M. Knoppers, 'Towards Commonality? Policy Approaches to Human Embryonic Stem Cell Research in Europe' in Aurora Plomer and Paul Torremans (eds), *Embryonic Stem Cell Patents: European Law and Ethics* (OUP 2009) 34.
[51] Mills (n 1).
[52] Horacio M. Spector 'An outline of a theory justifying intellectual and industrial property rights' (1989) 11(8) E.I.P.R. 270.
[53] ibid.
[54]Henry Etzkowitz and Andrew Webster, 'Science as intellectual property' in Sheila Jasanoff, Gerald Markle, James Petersen and Trevor Pinch (eds), *Handbook of Science and Technology Studies* (Revised edn, SAGE 1995) 480-505.
[55] 2005 report from the EPO and the organisation for economic cooperation and development: 'intellectual property as an economic asset: key areas in valuation and exploitation'.
[56] Richard Florida and Mark Samber, 'Capital and creative destruction: venture capital, technological change, and economic development' (1994) <https://kilthub.cmu.edu/articles/Capital_and_Creative_Destruction_Venture_Capital_Technological_Change_and_Economic_Development/6471089/1> accessed 26 January 2020.
[57] Martin Haemmig, *The globalisation of venture capital: A management study of international venture capital firms* (Haupt 2003).

in patent law, this cannot be done in isolation.[58] Remember that a patent is a negative monopoly; it is used only to stop others from developing and marketing the same idea and, in any event, does not mean that the patent holder can commercialise their product.[59]

2.4 Summary

It is clear from this discussion that the patentability of biotechnological inventions is subject to much ethical scrutiny and debate. I should clarify that I do not assert that patent law should have no inclusion of moral constraints. Rather, the importance of accommodating such concerns is recognised in the pursuance of compromise in Europe's democratic society. However, I contend that moral exclusions should be approached with caution. Ultimately, patent law is not the proper forum to deliberate morality, particularly in a complex area such as biotechnology. Furthermore, regardless of legal suitability, I argue that the correct justification for the patent system is and always has been economics-based. It suffices to say that the ability of the biotech industry to develop, along with its attendant advances in healthcare, should not be excessively constrained by ethical reservations.

[58] James Field, 'The Patentability of Human Embryonic Stem Cell-Based Inventions in the European Union' (2015) 6 Aberdeen Student L. Rev. 1.
[59] Field (n 58).

Chapter 3: How Have the Morality Provisions in Patent Law Been Interpreted?

3.1 Introduction

So far, I have discussed the general concept of morality, concluding that the role of ethics, while necessary, should have limited scope in the realm of patent law. It is now relevant to consider how the morality exceptions to patentability have been interpreted in practice. This chapter examines the two different approaches. First, the traditional narrow approach is described and justified, followed by an account of the more recent expansive interpretation, as shown by cases that focus on hESC patents specifically. The purpose of this chapter is to compare the two approaches and demonstrate the change that has occurred, while maintaining the favourability of the narrow approach. The broad approach that is described here is then subject to critical analysis in chapter 4.

3.2 The traditional narrow interpretation

Perhaps the most unostentatious statement of the narrow approach comes from *XY/Selected sperm*,[60] in which the Technical Board of Appeal (TBA) held that 'any exception to patentability must be construed narrowly'.[61] I will now describe the prior decisions of the EPO to ascertain the basis for this contention.

In *LUBRIZOL/Hybrid plants*,[62] it was asserted that Article 53(b) EPC must be narrowly construed, akin to 'any exception to a general rule of this kind'.[63] Reference to this notion was made in *HARVARD/Onco-Mouse*,[64] with an extended explanation being made via the positive wording of Article 52(1)[65]; i.e. where the legal criteria for patentability are met, a patent shall be granted.[66]

This proposition was reinforced in *PLANT GENETIC SYSTEMS/plant cells*[67] by reference to the *travaux préparatoires* of the EPC,[68] which declare that the 'concept of patentability in European law must be as wide as possible'.[69] Logically, the conclusion is then that exceptions to patentability must be narrowly construed.[70]

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[60] *XY/Selected sperm* (T1199/08) [03 May 2012].
[61] ibid, Reasons for Decision [29].
[62] *LUBRIZOL/Hybrid plants* (T0320/87) [OJ EPO Published 10 November 1988].
[63] ibid [6].
[64] *HARVARD/Onco-Mouse* (T0019/90) [OJ EPO Published 03 October 1990].
[65] ibid, Reasons for the Decision [4.5].
[66] Article 52(1) EPC – European patents shall be granted for any inventions, in all fields of technology, provided that they are new, involve and inventive step and are susceptible of industrial application.
[67] *PLANT GENETIC SYSTEMS N.V./Plant cells* (T0356/93) [OJ EPO Published 21 February 1995].
[68] ibid, Reasons for the Decision [8].
[69] Document IV/2071/61-E 5, page 5, point 2, paragraph 1.
[70] *PLANT GENETIC SYSTEMS* (n 67).

It is recognised that in *CYGNUS/Diagnostic methods*,[71] the notion of 'an a priori principle' of narrow interpretation was held not to apply without exception.[72] Nevertheless, the decision remained to be concluded on such a narrow approach, based on the wording and purpose of the relevant exclusion clause.[73]

In *MEDI-PHYSICS/treatment by surgery*,[74] the Board acknowledged that the principles of interpretation from Articles 31 and 32 of the Vienna Convention apply when interpreting the EPC[75] (as established from J10/98[76] and T1173/97[77]) and that, following from this, no general principle of a narrow construction of exclusions can be derived from the Convention.[78] Thus, they disagreed with the Court of Justice of the European Union (CJEU) in *Reyners v Belgium*,[79] where it was asserted that there should generally be a narrow interpretation of derogations from fundamental EC treaty principles.[80] Nevertheless, the Board conceded that the exclusionary character of such provisions does bear weight on the deduction of the correct interpretation to be so applied.[81] Therefore, it is plausible that a narrow interpretation could likely result when general interpretive principles are applied.[82]

Finally, it is useful to note *MICHIGAN STATE UNIVERSITY/Euthanasia Compositions*,[83] whereby reference to the preamble of the EPC, paragraph 2 was made.[84] Paragraph 2 refers to obtainable protection via a single procedure for the grant of patents and the establishment of certain standard rules for governing granted patents.[85] The Board asserted that, based on the preamble, a narrow interpretation of Article 53(a) is required given the EPC's fundamental objective of inaugurating comprehensive patent protection between contracting states.[86] The Board opined that such a limiting approach is not only correct, but also justified on the basis of three observations. First of all, it was held that the words 'contrary to *ordre public* or morality' apply to the objective facts of publication/exploitation,[87] leaving no question of whether the invention as such,[88] or the inventor's undertakings in product development, could be regarded as a breach of morality.[89] Secondly, the relevant exploitation

[71] *CYGNUS/Diagnostic methods* (G0001/04) [OJ EPO Published 16 December 2005].
[72] ibid, Reasons for the Opinion [6].
[73] ibid [6.1].
[74] *MEDI-PHYSICS/Treatment by surgery* (G0001/07) [OJ EPO Published 15 February 2010].
[75] Case Law of the Boards of Appeal – Principles of interpretation of the Vienna Convention (European Patent Office, July 2016) < https://www.epo.org/law-practice/legal-texts/html/caselaw/2016/e/clr_iii_h_1_1.htm > accessed 9 March 2020.
[76] *ASTRAZENECA/Priority from India* (J0010/98) [OJ EPO Published 02 December 2002].
[77] *IBM/Computer program product* (T1173/97) [OJ EPO Published 01 July 1998].
[78] *MEDI-PHYSICS* (n 74) Reasons for the Decision [3.1].
[79] C-2/74 *Reyners v Belgium* [1974] E.C.J. 631.
[80] ibid.
[81] *MEDI-PHYSICS* (n 74).
[82] Ella O'Sullivan, 'Is Article 53(a) EPC still of narrow interpretation?' (2013) 7(9) Journal of Intellectual Property Law & Practice 680-690.
[83] *MICHIGAN STATE UNIVERSITY/Euthanasia Compositions* (T0866/01) (Unpublished) [11 May 2005].
[84] ibid, Reasons for Decision [5.2].
[85] Preamble of the EPC, paragraph 2 <https://www.epo.org/law-practice/legal-texts/html/epc/1973/e/apre.html> accessed 2 January 2020.
[86] *MICHIGAN STATE UNIVERSITY* (n 83), Reasons for Decision [5.2].
[87] ibid [5.6].
[88] ibid [5.6(a)].
[89] ibid [5.6(c)].

is the normal avowed use indicated in the application,[90] as stated in *NOVARTIS II/Transgenic Plant*,[91] where it was considered that while potential further embodiments of a product could be considered contrary to *ordre public* and morality, it does not follow that the product as claimed in the application would be excluded from patentability.[92] The Board also referred to decision T361/87,[93] whereby it was decided that although specific embodiments covered by the claim could not actually be carried out, the claim was still allowable; this approach has been endorsed in *GENETECH I/Polypeptide expression*.[94] Lastly, the Board observed that, under Article 53(a) EPC, a patent should be disavowed only if the intended exploitation as stated in the claim would infringe *ordre public* or morality.[95] Taking all the preceding considerations together emphatically supports the view that a narrow interpretation of Article 53(a) is indeed warranted.

This consensus of the EPO is not exclusively within the juridical context, but rather has been supported academically by commentators such as Warren Jones, who supposes that 'since the patent system is designed to encourage innovation, provisions limiting it should be construed narrowly'.[96]

Accompanying this argument, Armitage and Davis describe the European framework as 'universal in principle',[97] noting that any exemption from universality should be narrowly understood.[98] It is notable that both academics were present at the commencement of Article 2(a) of the Strasbourg Convention,[99] which influenced the conception of Article 53(a) EPC;[100] this could therefore be evidence of the legislature's intention.[101]

3.3 The broad approach

The first time a decision was seen to deviate from the traditional narrow approach was regarding the *Edinburgh* patent,[102] initially granted by the EPO, which concerned the 'isolation, selection and propagation of animal transgenic cells'.[103] The grant was for a method involving genetic engineering to isolate, inter alia, human embryonic stem cells. The Opposition Division (OD) heard proceedings based on the notion that 'human' is within the nomenclature of the term 'animal,' and that therefore, the patent extended to human embryos, which are expressly excluded from patentability under Rule 28(1)(c) EPC (formerly Rule 23d(c)). The OD responded by amending the patent to exclude the mention of 'human'

[90] ibid [5.7].
[91] *NOVARTIS II/Transgenic plant* (G0001/98) [OJ EPO Published 20 December 1999].
[92] ibid.
[93] Not published in OJ EPO.
[94] *GENETECH I/Polypeptide expression* (T292/85) [OJ EPO Published 27 January 1988].
[95] *MICHIGAN STATE UNIVERSITY* (n 83) [5.8].
[96] Amanda Warren-Jones 'Vital Parameters for Patent Morality: A Question of Form' (2007) 2 JIPLP 832, 843.
[97] E Armitage and I Davis, *Patents and Morality in Perspective* (Intellectual Property Institute 1994) 26.
[98] ibid.
[99] Convention on the Unification of Certain Points of Substantive Law on Patents for Invention 1963.
[100] O'Sullivan (n 82).
[101] Armitage and Davis (n 97) 24.
[102] European patent No. EP0695351.
[103] ibid.

and 'animal'.[104] In its justification, the division referred to Rule 29(1) EPC, the equivalent of Article 5(1) of the Directive, which prohibits the patentability of 'the human body at the various stages of its formation and development'.[105] Based on this, it was reasoned that the legislators could not have intended Rule 23d(c) to be interpreted narrowly, as doing so would render the provision redundant over the provision in Rule 29(1) EPC.

After *Edinburgh*, the Wisconsin Alumni Research Foundation (*WARF*) filed a patent application[106] for the preparation of human embryonic stem cells from primate blastocysts (structures from which the embryo forms).[107] It is notable that the only applicable method to produce the stem cell cultures required the use and destruction of embryos. The Examining Division denied the grant based on a broad interpretation of Rule 23d(c), similar to the decision in *Edinburgh*; however, the grounds for such an approach were different. In *WARF* it was claimed that:

> The use of a human embryo as starting material for the generation of a product of industrial application meant a use thereof for industrial purposes and was thus prohibited under Rule 23d(c) in conjunction with Article 53(a).[108]

The matter was referred to the Enlarged Board of Appeal (EBA) for clarification on the extent of Rule 23d(c). The EBA concluded that it is prohibited to grant a patent to claims directed to products which, at the filing date, could be prepared exclusively by a method which necessitated the destruction of the human embryo from which the said products are derived, even if the method is not part of the claim.[109]

Part of the Board's reasoning for their more liberal approach, particularly in relation to the term 'human embryo', is based on the absence of a general consensus on the definition of the phrase. It was observed that neither the EU nor the EPC legislature chose to define the term 'embryo' in the Directive or the EPC.[110] The Board compared this with national laws of Member States such as the UK, where an embryo consists of a two-cell zygote and an egg during fertilisation,[111] or Germany, where the definition is as simple as including a fertilised egg.[112] In light of this and the presumption that the legislators would be aware of these national provisions, it was concluded that it was in fact a conscious decision to leave the term without a definition.[113] Therefore, to give 'embryo' a narrow meaning would frustrate the intention of the legislators; so it was decided that ultimately the definition is a question of fact for any particular patent application.[114]

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[104] Decision of the Opposition Division of 21 July 2003 on European patent No. EP0695351 (*University of Edinburgh*).
[105] Rule 29(1) EPC.
[106] European patent No. 96903521.1 (Primate embryonic stem cells).
[107] W.C. Shiel Jr 'Medical Definition of Blastocyst' (MedicineNet, 2018) <https://www.medicinenet.com/script/main/art.asp?articlekey=18258> accessed 3 March 2020.
[108] European patent No. 96903521.1 (Primate embryonic stem cells).
[109] *WARF/Use of embryos* (G0002/06) [OJ EPO Published 25 November 2008].
[110] *WARF* (n 109) [20].
[111] Human Fertilisation and Embryology Act 1990, Section 1(1).
[112] Gesetz zum Schutz von Embryonen of 13 December 1990 §8 (Embryo Protection Act of 13 December 1990 Section 8).
[113] *WARF* (n 109) [20].
[114] ibid.

The most central case for this discourse, to which I now turn, is *Brüstle v Greenpeace*.[115] The German patent in question concerned isolated and purified neural precursor cells derived from hESCs. The application also covered the said method of production for the precursor cells, as well as their use for the treatment of neural defects. Greenpeace applied to revoke the patent based on the fact that the claims were dependent on cells from human embryos.

The German Supreme Court requested a clarification from the European Court of Justice (ECJ) on the legal definition of 'human embryo.' The following questions were referred:

> 1. What is meant by the term 'human embryos' in Article 6(2)(c)?
> 2. What is meant by 'uses of human embryos for industrial or commercial purposes'? Does it include any commercial exploitation within the meaning of Article 6(1) especially for the purposes of scientific research?[116]

In answer to question one, the ECJ defined 'human embryo' as:

> Any human ovum after fertilisation, any non-fertilised human ovum into which the cell nucleus from a mature human cell has been transplanted and any non-fertilised human ovum whose division and further development have been stimulated by parthenogenesis.[117]

In answer to question two, the court held that:

> …[T]he exclusion from patentability concerning the use of human embryos for industrial or commercial purposes also covers use for purposes of scientific research.[118]

Finally, it is relevant to consider the case of *International Stem Cell Corporation v Comptroller General of Patents, Designs, and Trade Marks*[119] (hereafter *ISCC*), which concerned the rejection of a patent application concerning a particular stem cell technology: parthenogenesis (the process of reproduction from an ovum without fertilisation).[120] The resultant organism is a 'parthenote', which behaves like an embryo in the early stages of division but is unable to develop into a viable foetus[121] due to the absence of paternal DNA. In recognising the therapeutic potential of stem cells[122] and the purpose of the Directive in encouraging biotech research, it was concluded that the balance between this and the need to respect human integrity was not affected by excluding processes of development which are incapable of leading to a human being.[123] Accordingly, the patents court referred the following question to the CJEU:

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[115] *Brüstle v Greenpeace (Brüstle)* (C-34/10) [2012] 1 C.M.L.R. 41.
[116] ibid [23].
[117] ibid [38].
[118] ibid [46].
[119] *International Stem Cell Corp v Comptroller General of Patents* Chancery Division (Patents Court) [2013] EWHC 807 (Ch).
[120] Meaning of parthenogenesis in English (LEXICO) <https://www.lexico.com/definition/parthenogenesis> accessed 9 March 2020.
[121] J Galef, 'You Say Embryo, I say Parthenote' (Scientific American, 2011) <https://www.scientificamerican.com/article/you-say-embryo-i-say-parthenote/> accessed 29 February 2020.
[122] International Stem Cell Corp [57].
[123] ibid [58].

> Are unfertilised human ova, whose division and further development have been stimulated by parthenogenesis and which in contrast to fertilised ova, are incapable of developing into human beings, included in the term 'human embryos' in Article 6(2)(c)?[124]

The CJEU ruled that:

> Article 6(2)(c) must be interpreted in the sense that an unfertilised human ovum whose division and further development have been stimulated by parthenogenesis, does not constitute a 'human embryo' under the proviso that in light of current scientific knowledge, it does not, in itself, have the inherent capacity of developing into a human being, this being a matter for the national court to determine.[125]

Though this decision ultimately retains the fundamentals of *Brüstle*, it places its scope within parameters to some extent. While this is a welcome development, it remains correct to say that even after *ISCC*, a broad interpretation of morality unfortunately still stands.

3.4 Summary

It has been demonstrated above that historically, the morality provisions were subject to a narrow interpretation; however, recent EPO jurisprudence has brought this approach into question. Embryonic stem cells are now a leading development, not only intellectually but also commercially in respect to patent law. The granting of hESC patents has initiated challenge and caused the morality provisions to be considered in a different way. Ultimately a broad interpretation of Article 6(2)(c)/Rule 28(1)(c) inherently broadens the scope of Article 53(a), which deals with morality generally. There is much to critique in the broadening interpretation; this will be the focus of the next chapter. For now, it is appropriate to submit the preference of the narrow approach.

It seems that the adoption of such a narrow reading stemmed primarily from the practice of a repressive slant to the morality concept in the context of biotechnological innovation. According to Drahos,[126] multinational corporations – those with the largest financial stake in the patent system – clearly influence how the rules of the system have been applied in practice. For example, the role of pharmaceutical internationals in shaping the patent provisions of the TRIPS agreement has been well documented.[127] But is this institutionalisation necessarily wrong? I submit that it is only natural that those with the most at stake should have a correspondingly sizeable influence. Others, such as pressure groups with a political agenda, may have less influence; but that may not be unfair: they simply have less 'skin in the game' in a system essentially designed to protect the economic rights of patentees. Thus, it can be argued that the traditional narrow approach is both favourable and reasonable.

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[124] ibid [59].

[125] Judgement of the Court (Grand Chamber) of 18 December 2014, *International Stem Cell Corporation v Comptroller General of Patents, Designs and Trade Marks,* C-364/13 ECLI:EU:C:2014:2451 (*ISCC*).

[126] Peter Drahos, *The global governance of knowledge: Patent offices and their clients* (Cambridge University Press 2010).

[127] Peter Drahos, '"Trust me": Patent offices in developing countries' (2007) Centre for Governance of Knowledge and Development Working Paper.

Chapter 4: Criticism of the Broadening Approach

4.1 Introduction

The previous chapter demonstrated the new liberal approach to the interpretation of morality in patent law that has developed through a number of cases specifically concerned with inventions based on human embryonic stem cells. This chapter analyses each of those decisions in turn.

4.2 Criticism of *Edinburgh*

The TBA in *WARF/Stem cells*[128] reviewed the *Edinburgh* judgement and concluded that the 'redundancy argument' based on Article 5 was incorrect and that such a broad interpretation, based on the reasoning presented, was ethically artificial.[129] In this deduction, the Board referred to the fact that the relevant provisions overlapped in both purpose and subject matter per se.[130]

Moreover, the Board distinguished between cases in which the invention is undoubtedly immoral and those whose concerns remain abstruse. Where it is apparent that a provision could be interpreted in two ways, one resulting in rejection of the patent on moral grounds (broad interpretation) and one which authorises the grant (narrow interpretation), the correct approach is the latter.[131] The reasons for this relate to the need to conform to EPO jurisprudence and the Guidelines of the EPC.[132] Moreover, the Board commented that such a narrow interpretation would avoid the EPO acting as a moral censor of controversial technologies, when its expertise is in the field of patents.[133] This supports the proposition argued previously: that patent adjudicators are ill-suited to this area.[134]

As a final point, the Board noted that where moral concerns arise, any decision following from them should be based on facts as substantiated at the current time.[135] It is apparent that, at the relevant date, numerous Member States allowed and endorsed the development of hESC from superfluous embryos.[136] Such embryos cannot, at least not immediately, return to the uterus, either because they have developed in excess of what was required, or because they are genetically defective.[137] The only other option would be to discard them, which is arguably unreasonable considering their potential advantage to healthcare. Thus, without a consensus

[128] *WARF/Stem cells* (T13174/04) [OJ EPO Published 07 April 2006].
[129] ibid Summary of Facts and Submissions, X.
[130] ibid.
[131] ibid.
[132] ibid.
[133] ibid.
[134] Siew-Kuan (n 41).
[135] ibid.
[136] ibid.
[137] Practical details of the PGD treatment > What happens to supernumerary embryos? (Centrum voor Medische Genetica 2017) <http://www.brusselsgenetics.be/pgd-destiny-of-supernumerary-embryos?doscroll=true#NavL3> accessed 10 March 2020.

on the moral correctness of hESC amongst Member States, the broad interpretation adopted in *Edinburgh* seems increasingly irrational.

Aside from this, it should be considered that the Directive must be interpreted consistently with the European Convention on Human Rights (ECHR); consequently, as stated in decision R19/12,[138] case law of the European Court of Human Rights (ECtHR) can be used as a supplementary means of interpreting the EPC.[139] This is reinforced in the EU Charter[140] and Article 6(3) of the Treaty on the European Union. Even in the pre-EU Charter era, *Nold v Commission*[141] asserted that Community law can be guided by international human rights treaties.[142] Thus it is relevant to now review the jurisprudence ECtHR in relation to the rights and protections afforded to the human embryo under the Convention and to observe how this reconciles with the *Edinburgh* decision. Article 2 ECHR, which asserts that everyone's 'right to life shall be protected by law'[143] and that 'no one shall be deprived of his life intentionally'[144] is of particular relevance here.

Of initial weight is the judgement in *Vo v France*,[145] which permitted Member States a wide margin of appreciation[146] in the context of human embryos by leaving open the question of whether an embryo in utero may have a right to life under Article 2. This ruling was then extended in *Evans v UK*[147] and *A.B. & C. v Ireland*.[148] In *Evans*, the court discussed the question of whether the embryo in vitro has a right to life. The court said no, reasoning that:

> …[I]n the absence of any European consensus on the scientific and legal definition of the beginning of life, the issue of when the right to life begins comes within the margin of appreciation which States should enjoy in this sphere. Under English law…an embryo does not have independent rights or interests and cannot claim a right to life under Article 2.[149]

Consequently, the jurisprudence of the ECtHR establishes that there is no European consensus in relation to the extent of legal and moral protection that the human embryo is entitled to; furthermore, where this divergence of moral cultures exists, the court should be mindful to avoid imposing a universal norm.[150] Hence, under the Convention, it can be said that there is no legal basis to support the application of the broad, unqualified moral norm on human embryos invoked by the OD in the Edinburgh patent.[151]

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[138] *IXETIC/Verletzung des rechtlichen Gehors* (R0019/12) (Unpublished) [12 April 2016].
[139] Case Law of the Boards of Appeal – Interpretation of the EPC - The European Convention on Human Rights (European Patent Office 2016) <https://www.epo.org/law-practice/legal-texts/html/caselaw/2016/e/clr_iii_h_3.htm> accessed 3 March 2020.
[140] Charter of Fundamental Rights of the European Union [2012] OJ 326/02 (EU Charter).
[141] *Nold v Commission* Case 4/73 [1974] ECR 491.
[142] *Nold v Commission* [13].
[143] European Convention on Human Rights, Article 2.
[144] ibid.
[145] *Vo v France* ECHR 2004-VIII [2004]
[146] ibid [82].
[147] *Evans v UK* [2007] ECHR 264.
[148] *A.B. & C. v Ireland* [2010] ECHR 2032.
[149] ibid [46].
[150] A Plomer, 'Stem Cell Patents: European Patent Law and Ethics Report' 2006, <https://www.nottingham.ac.uk/~llzwww/StemCellProject/project.report.pdf> accessed 27 February 2020.
[151] ibid.

4.3 Criticism of *WARF*

The significance of the ruling in *WARF* lies in the notion that moral concern goes far beyond the patenting and extends to general instrumentalisation.[152] It is disappointing that the Board was unable to separate the use of human embryos from the claimed subject matter, despite the fact that the patent would not have been granted over such use or over the embryos themselves.[153] To apply this logic generally to the whole biotech sector would be to conclude that where a step in the development process of a product is classed as unethical, the end result will be denied a patent.[154] I counter that where information or biological materials are obtained 'unethically', sound consideration must be given before discarding such materials in situations where the end product can be used therapeutically or for scientific studies which are ethically defensible. Such a determination can be seen as a balancing exercise which would arguably appear favourable to non-destruction of material where hESCs are concerned, given their numerous health benefits.

In light of the caveat discussed above, it is now the applicant who must assert that the source they have used is acceptable for moral purposes. This runs counter to what the drafters of the EPC intended,[155] as established in *Plant Genetic Systems*, whereby it was concluded that the legislative intention is that the exception *only* be applied where *commercial exploitation* is objectionable.[156] It should also be remembered that exceptions are usually negative in nature and thus are likely to be raised in opposition to the applicant;[157] in other words, the general rule of burden of proof would dictate that confirmation of non-compliance should come from the party who complains of immorality.[158]

As a final point, the criticisms of *Edinburgh* in relation to the jurisprudence of the ECtHR also apply to *WARF*.

4.4 Criticism of *Brüstle* and *ISCC*

From an institutional perspective, the decision in the *ISCC* case is less controversial than *Brüstle*,[159] which is why the latter will be the focal point here. Despite the minor change *ISCC* introduces with respect to parthenotes, nothing is different in relation to fertilised human ova; so the two decisions will be analysed together, with a warranted closer look at *Brüstle*.

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[152] Brown and others (n 45).
[153] Amanda Odell-West, 'The absence of informed consent to commercial exploitation for inventions developed from human biological material: a bar to patentability?' [2009]I.P.Q. 373-390.
[154] Ana Nordberg and Timo Minssen, 'A "ray of hope" for European stem cell patents or "out of the smog into the fog"? An analysis of European case law and how it compares to the US' (2016) 47(2) IIC 138-177.
[155] ibid.
[156] *PLANT GENETIC SYSTEMS* (n 67).
[157] Nordberg and Minssen (n 154).
[158] ibid.
[159] A Faeh, 'Judicial activism, the Biotech Directive and its institutional implications: is the court acting as a legislator or a court when defining the "human embryo"?' (2015) 40(4) E.L. Rev. 613-627.

4.4.1 Definition of human embryos

In *Brüstle*, notwithstanding the ECJ's acknowledgement that the social issue of what constitutes a human embryo is determined by the diverging value systems of Member States,[160] the court adopted a uniform definition for the purposes of giving the Directive a 'legal interpretation'.[161]

Two points are important here. First, paragraph 8 of the recitals of the Directive states that it does not 'necessitate the creation of a separate body of law in place of the rules of national patent law'.[162] Arguably, this is traversed through the adoption of a judicially constructed 'autonomous' definition of the term 'human embryo,' particularly where the circumstances are such that there is no legal (or even moral) consensus amongst Member States as to a definition.[163]

Second, through the simple denial that it was being asked a 'medical or ethical question',[164] the ECJ evaded any engagement with moral debate, in spite of the fact that the provision in question was overtly moral.[165] What is more, the ECJ inexplicably did not consider any legal authorities.[166] For instance, there was no reference to the jurisprudence of the ECtHR on the status of the human embryo (similar to *Edinburgh* and *WARF*), which would surely be relevant.[167] The court merely stated that where a term in EU jurisprudence does not mention the law of any Member State, it must be uniformly interpreted throughout the Union (a notion expressed in the cases of *Ekro*[168] and *Infopaq International*[169]). The court accordingly determined that the term 'embryo' falls within this general rule.[170]

Following from this, ECJ continued to rely on human dignity in saying the purpose of Article 6 necessitated a wide interpretation of the term.[171] But this approach is hardly meritorious when one considers the court's indifference to any theoretical, moral, or legal inquiry into the concept of human dignity.[172] Furthermore, by then saying that human dignity should apply to something that does not bear a resemblance to human beings, or even fertilised embryos, the ruling equates cells with embryos.[173] This is a definitional fault that contorts our common understanding of developmental biology.[174] While human dignity is a noble concept, it is useful insofar as it is concerned with the well-being of actual human beings.[175] Moreover,

[160] *Brüstle* [30].
[161] ibid.
[162] The Biotech Directive Recitals paragraph 8.
[163] Shawn Harmon, Graeme Laurie and Aidan Courtney, 'Dignity, Plurality, and Patentability: The Unfinished Story of Brüstle v Greenpeace' (2012) 38 European Law Review 92-106.
[164] *Brüstle* [30].
[165] Harmon, Laurie & Courtney (n 163).
[166] ibid.
[167] ibid.
[168] *Ekro BV Vee-en Vleeshandel v Produktschap voor Vee en Vlees* (Case 327/82) [1984] ECLI:EU:C:1984:11.
[169] *Infopaq International A/S v Danske Dagblades Forening* (Case C-5/08) [2009] ECLI:EU:C:2009:465.
[170] *Brüstle* [25]-[29].
[171] *Brüstle* [34].
[172] Harmon, Laurie and Courtney (n 163).
[173] Katja Vrtovec and Christopher Scott, 'The European Court of Justice Ruling in Brüstle v Greenpeace: The Impacts on Patenting of Human Induced Pluripotent Stem Cells in Europe' (2011) 9 Cell: Stem Cell 502-503.
[174] ibid.
[175] ibid.

aside from the concept per se, I suggest that the court should have analysed it in further socio-legal contexts, which could have had a positive impact on science and commercialisation. For instance, there was no consideration of how hESC-based treatments could benefit the human dignity of those in ill health.[176] On this basis one could argue that Europe should focus more on protecting the human dignity of such patients who anticipate novel stem cell treatments, rather than on safeguarding the dignity of cells not generally recognised as constituting human beings.[177] It is apparent that human dignity is increasingly being used as a form of general condemnation and as a blanket justification for regulatory restraints.[178] I assert that the sole concept of human dignity is doubtful justification for policies that are aimed at constraining controversial biotechnologies.[179]

From a comparative perspective, it is interesting to note the US decision of *Sherley v Sebelius*,[180] which concluded that the amendment in question, which forbade the funding of research involving embryo destruction,[181] did not extend to the preclusion of hESC research funding.[182] It is notable that the relevant amendment was passed in 1995, three years prior to the development of the first embryonic stem cell line. Therefore, it would be incorrect to assert with confidence that the amendment intended to exclude the funding of hESC research.[183] On this basis, the decision in *Sebelius* has much to be commended in its recognition of the uncertainty that exists within the amendment.[184] Likewise, the Biotech Directive was passed absent of any announcement of embryonic stem cell lines, yet the ECJ failed to account for this fact.[185] Furthermore, it should be recalled that since 2004, hESC research has been funded by the EU under the 6th Framework Programme for Research and Technological Development (FP6) and has been continued under FP7, while the funding of embryonic destruction remains prohibited under Council Decision 2002/834/EC.[186] Thus, comparable to the court's finding in *Sebelius*, the EU does separate embryo destruction per se from hESC research.[187] By doing so, the EU adopts a literal interpretation of the funding application and does not purport to scrutinise prior actions required for the research to proceed, a strategy the court disappointingly failed to consider in the *Brüstle* case.[188]

[176] Harmon, Laurie and Courtney (n 163).
[177] Vrtovec and Scott (n 173).
[178] Timothy Caulfield and Roger Brownsword, 'Human Dignity: A Guide to Policymaking in the Biotechnology Era?' (2006) 7 Nature Reviews Genetics 72-76.
[179] Ibid.
[180] *Sherley v Sebelius* 704 F. Supp. 2d 63 2010 US Disct.
[181] Section 509 Consolidated Appropriations Act 2011.
[182] *Sebelius* [71].
[183] Ciara Staunton, '*Brustle v Greenpeace*, embryonic stem cell research and the european court of justice's new-found morality' (2013) 21(2) Medical Law Review 310–319.
[184] ibid.
[185] ibid.
[186] 2002/834/EC: Council Decision of September 30 2002 adopting a specific programme for research, technological development and demonstration: 'Integrating and strengthening the European Research Area' (2002–2006) at para 1.1.
[187] Staunton (n 183).
[188] ibid.

4.4.2 Meaning of uses for industrial or commercial purposes

In response to question two, which asked for a consideration of the meaning and scope of industrial or commercial purposes, the ECJ responded by saying that the phrase includes the purposes of scientific research.[189]

To explain, the ECJ restated that the Directive is hermetically sealed within the context of the *patentability* of biotechnological inventions, and thus any definitions assignable to the Directive are not intended to facilitate the regulation of embryos in research within Member States.[190] To restate simply, the regulation of science is distinct from the commercialisation of products.[191] The court then goes on to state that although the object of scientific research is separate from industrial or commercial purposes, the use of human embryos in research, which constitutes the subject matter of a patent application, cannot be separated from the patent itself and the rights assigned to it.[192] Undoubtedly, this view expresses an awareness of the essential distinction between patent law and science regulation; however, it is disappointing that the court did not take up any further engagement with the issue.[193] It is arguable, therefore, that the court displayed a narrow-minded, entrenched view of the operation of patent law in practice.[194] For instance, it is well-known that the movement of research organisations into an area largely rests on potential commercial monopolies, i.e. a patent.[195]

In addition, the ECJ's view does not adequately consider how human rights interact with patent law. For example, Article 1 of the First Protocol of the Human Rights Act,[196] which protects the right to enjoyment of property, has been held to include intellectual property and patents in Europe, as seen in the cases of *Smith Kline and French Laboratories Ltd. v Netherlands*,[197] and *Lenzing AG v UK*.[198] As a fundamental human right, the doctrine of proportionality must be applied upon any limitation to it; however, the ECJ did not acknowledge this and has arguably contravened the doctrine with its restriction on property rights.[199]

Furthermore, Porter's assessment of the drafting history of the Directive[200] demonstrates that the exclusion on industrial and commercial uses of human embryos was intentionally narrowly drawn by the legislature, in order to limit its reach and ensure that inventions and uses of

[189] *Brüstle* [46].
[190] ibid [40].
[191] Harmon, Laurie and Courtney (n 163).
[192] *Brüstle* [42]-[43].
[193] Harmon, Laurie and Courtney (n 163).
[194] ibid.
[195] ibid.
[196] Human Rights Act 1998.
[197] *Smith Kline and French Laboratories Ltd. v Netherlands*, No. 12633/87, 4 October 1990.
[198] *Lenzing AG v UK*, No. 38817/97, 9 September 1998.
[199] Harmon, Laurie and Courtney (n 163).
[200] Gerard Porter, 'The Drafting History of the European Biotechnology Directive', in Aurora Plomer and Paul Torremans (eds), *Embryonic Stem Cell Patents: European Law and Ethics* (Oxford University Press 2009) 3–26.

human embryos which are lawful in Member States would not be rendered unpatentable by the exclusion.[201] The ECJ appears to have dismissed this understanding.[202]

Additionally, the ECJ inaccurately considers 'industrial or commercial application' as interchangeable with 'industrial or commercial purposes'.[203] Article 57 EPC states that 'an invention shall be considered susceptible of industrial application if it can be made or used in any kind of industry, including agriculture.' The EPO guidelines reveal that 'Article 57 excludes from patentability very few "inventions" which are not already excluded by the list in Article 52(2)'.[204] These primary sources can be used to advocate an expansive interpretation of 'industrial application'.[205] As the EPC regulates the grant of patents, while the Directive guides the extent of patent rights, it can be said that to interpret 'industrial or commercial purposes' in an equally broad sense would be to run counter to the Directive's mandate.[206] Moreover, the Council of the EU expressly included the phrase with the intention to restrict the exclusion to specific uses of human embryos.[207] As only inventions with 'industrial applications' can be patented, the Council's modification could only limit the exclusion if the two phrases had dissimilar meanings.[208] Thus, by equivocating 'industrial or commercial application' with 'industrial and commercial purposes', the ECJ has rendered the Council's amendment redundant.[209]

4.4.3 Did the court act as a legislator in deciding Brüstle?

It should first be noted that the role of the ECJ is to clarify EU legislation. Thus, I do not propose that the court lacked competence to define the term 'human embryo' nor that it acted *ultra vires*.[210] Rather, and aside from the criticism of the reasoning behind the definition chosen, the question is whether the court should have arbitrated in providing such a definition. I concede that, based on the concept of *effet utile*, it is commonly reasonable for the Court to interpret Treaty provisions beyond their literal wording.[211] For instance, the doctrines of direct effect,[212] the supremacy of Union law,[213] fundamental rights[214], and state liability[215] are all well-known examples of the Court extending the scope of its authority granted in the Treaty.[216] However, via these doctrines, the Court can sometimes go further

[201] Ibid.
[202] Harmon, Laurie and Courtney (n 163).
[203] Mark Nickas, 'Discordant Harmonization: Did the European Court of Justice Interpret the Biotechnology directive's Exclusions to Patentability Too Broadly in Brüstle v. Greenpeace?' (2012) 40 AIPLA Q. J. 517.
[204] Guidelines for Examination in the EPO, Part G – Patentability, Chapter III.1 < https://www.epo.org/law-practice/legal-texts/html/guidelines/e/g_iii_1.htm> Accessed 2 February 2020.
[205] Nickas (n 203).
[206] ibid.
[207] Council Common Position (EC) No. 19/98 of 26 February 1998, art. 6, 1998 O.J. (C 110/30) 17, 37.
[208] Nickas (n 203).
[209] ibid.
[210] Faeh (n 159).
[211] ibid.
[212] *Van Gend en Loos Nederlandse Administratie der Belastingen* (26/62) [1963] E.C.R. 1; [1963] C.M.L.R. 105.
[213] *Costa v ENEL* (6/64) [1964] E.C.R 1141.
[214] *Nold/Internationale Handelsgesellschaft v Commission* (4/73) [1975] E.C.R. 985; [1974] 2 C.M.L.R. 338.
[215] *Francovich v Italy* (C-6/90) [1991] E.C.R. I-5357; [1993] 2 C.M.L.R. 66 at [33].
[216] Faeh (n 159).

than the ordinary application of previous law and can be considered to be legislating;[217] an observation present in *Brüstle*.

To decide whether the courts were too innovative in *Brüstle*, it is imperative to consider both the enactment of the Directive and its attendant content. As stated previously, the Directive was legislated as a market harmonisation instrument as emphasised in the wording and recitals of the Directive. Nevertheless, the Directive has other partially contradictory goals which can be divided between market/non-market interests,[218] of which the former includes acknowledging the important role of biotech research[219] and eliminating differences between national laws to clarify the status of protection for biotech products.[220] The non-market aims include the application of patent rules to safeguard human dignity and integrity[221] and exclusion from patentability if commercial exploitation would contravene *ordre public* or morality.[222] The issue, which was central to *Brüstle*, is how to align all of these goals. Because of the various stances taken in the legislative process of the Directive, harmonisation is confined to those issues on which the majority could agree, whereas matters not regulated by the Directive keep within the domain of Member States.[223] Thus, it is doubtful whether 'human embryo' is a Union term simply because it is mentioned in the Directive.[224] Ultimately it is of significance that during the whole legislative process, nothing was said about the definition of a human embryo.[225]

No doubt, the Directive is intended to harmonise patent law; however, it remains appropriate to ask whether some aberration is allowed or whether each and every matter must be harmonised. The arguments against the latter notion are, first, if unification was the goal then a regulation would have been more appropriate.[226] Second, directives, while requiring Member States to achieve a particular result, do not dictate the means to do so. Where there is the inclusion of a term absent a definition, such as 'human embryo,' the Member States should be able to define the term, as asserted in *Evans v UK*. Third, there is no evidence from the enactment process that the term should have been harmonised; otherwise there would have been a debate on the issue.[227] Based on this, it is unusual that the Court argued in contrary by refusing Member States any margin of appreciation. The only argument given by the Court for its decision is that the term must be uniformly applied in order to fulfil the goal of harmonisation.[228] If this was a satisfactory argument, the Court could unify each and every issue in any harmonisation Directive.[229]

There are two arguments for why the Court should have abstained from defining 'human embryo' or should have at least been more restrictive in its interpretation.

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[217] ibid.
[218] Faeh (n 159).
[219] The Biotech Directive Recitals 1 and 2.
[220] ibid, Recitals 4 and 5.
[221] ibid, Recital 16.
[222] ibid, Recitals 36, 37 and 38.
[223] Faeh (n 159).
[224] ibid.
[225] ibid.
[226] ibid.
[227] ibid.
[228] *Brüstle* [26]–[29].
[229] Faeh (n 159).

The first argument is that while the harmonisation of the internal market is a core competence of the EU, non-market issues such as biotechnology and health are not.[230] This is supported by Article 168 Treaty on the Functioning of the EU, where the scope for legislating on health issues is very limited, and Article 168(7), which assigns Member States the exclusive duty to govern matters such as healthcare and financial affairs, and explicitly states that these responsibilities should be respected by the Union.[231] Thus, it is arguable that as the definition of human embryo is not directly related to market harmonisation, it is more a matter for Member States to decide rather than the ECJ.

The second argument is that by defining the term so broadly and thus preventing the scope for national values to be considered, the Court has acted contrary to its principles and in ignorance to its acknowledgement of the diversity among the Member States.[232] In the case of *SPUC v Grogan*,[233] on the dissemination of information on abortion in Ireland, the court was asked to determine whether such an activity falls within the scope of the freedom to provide and receive services. The court held that, according to the judgement in *Luisi*,[234] it did fall within such a scope but it nevertheless also held that it was not contrary to Union law for Ireland to prohibit the student's activities because of the fact that abortion is illegal in Ireland.[235] In this instance, the Court respected the diversity of legal and moral standards within the Union and had no intention of aligning the national opinions on moral, ethical, and religious issues.[236] Of course, the two cases cannot directly be compared; but the Grogan case shows that the Court does not pursue strict harmonisation in all matters.[237]

4.5 The CJEU and ethical expertise

Article 7 of the Biotech Directive determines that 'the Commission's European Group on Ethics in Science and New Technologies (EGE) evaluates all ethical aspects of biotechnology'.[238] In Opinion 16 on stem cell patenting,[239] the EGE stated that there is no ethical reason warranting the veto of stem cell/stem cell line-based patents. To do so would run counter to the right to health and to Europe's furtherance of medical study and development as articulated in Directive recitals.[240] Moreover, the EGE differentiated modified and non-modified hESCs, with the former being patentable. The definition of 'embryo' was not contemplated and, most notably, their destruction was not thought to be a determinative moral factor.[241]

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[230] ibid.
[231] ibid.
[232] ibid.
[233] *SPUC v Grogan* (C-159/90) [1991] E.C.R. I-4685; [1991] 3 C.M.L.R. 849.
[234] *Luisi v Ministerio del Tesoro* (286/82) [1984] E.C.R. 377; [1985] 3 C.M.L.R. 52 at [16].
[235] *Grogan* [32].
[236] Faeh (n 159).
[237] ibid.
[238] Article 7 Biotech Directive.
[239] European Group on Ethics in Science and New Technologies, Opinion n∞16—07/05/2002—Ethical aspects of patenting inventions involving human stem cells, para. 2.1. (EGE Opinion 16)
[240] Nordberg and Minssen (n 154).
[241] EGE Opinion 16 (n 239).

The legislature has expressly recognised some legal interpretive value to these opinions, as is manifest from Article 7. On the contrary, the CJEU has disregarded the EGE and evaded referrals to Article 7,[242] narrowly construing the EGE's mandate and the importance of its views as a subordinate source of law.[243] This is evident from the Opposition Division's rejection of Opinion 16 in relation to the Edinburgh decision. I suggest that the OD may have been adversely disposed by the EGE's proposal for an extension of bioethics into the bureaucratic framework of patenting governance.[244] This is a disappointing result, particularly considering the EPO's self-confessed understanding of the importance of cultural diversity in patent law.[245]

I propose that the use of the 'bioethics' community (for example, examination by an ethics board) could provide courts and patent offices with beneficial moral expertise.[246] This would be a welcome development, particularly in light of the demand, present in our current political landscape, for the co-operation of new forms of governance in response to the advancement of biomedical research.[247] Bioethics can be seen as a suitable body in that it provides a fundamentally irreligious and unbiased discourse for negotiating the competing value complexes of various public interests.[248] I argue that a visible demonstration of the involvement of bioethics in science would reassure the public at large that potential ethical criticisms have been addressed.[249] Thereby, notwithstanding how ambitious or controversial, biomedical research, specifically hESC research, would then be able to progress.[250]

Summary

To summarise, I have concluded that the judgements analysed constitute the wrong approach to Rule 28(1)(c) EPC and have decisively gone too far in broadening the general approach to morality in patent law.

Defining the concept of 'human being' within the isolation of patent law accounts for a weak point in the decisions of the CJEU.[251] It produces a legal falsehood of a consensus between Member States on how the concept of human dignity extends to embryos, in complete disregard for the provision's history, the ECtHR jurisprudence, and the CJEU's own acknowledgement.[252]

Furthermore, regardless of one's opinion on the outcomes of the judgements, there is an inherent requirement to set boundaries on the level of judicial activism and to erect more

[242] Nordberg and Minssen (n 154).
[243] ibid.
[244] Salter and Salter (n 35).
[245] ibid.
[246] Nordberg and Minssen (n 154).
[247] Sheila Jasanoff, *States of knowledge: The co-production of science and social order* (Routledge 2004).
[248] Susan E. Kelly, 'Public bioethics and publics: consensus, boundaries, and participation in biomedical science policy' (2003) 28(3) Science Technology & Human Values 339-364.
[249] Salter and Salter (n 35).
[250] Klaus L. Hoeyer and Richard Tutton '"Ethics was here": studying the language-games of ethics in the case of UK biobank' (2005) 15 (4) (2005) Critical Public Health 385-397.
[251] Nordberg and Minssen (n 154).
[252] ibid.

stringent rules determining when the court can, should, and must act with discretion.[253] This analysis demonstrates that for a highly controversial issue, where religion and ethical values are involved, and where there is no consensus among Member States, it is not appropriate for the court to make such far-reaching decisions even though it may not exceed its powers by doing so.

I propose that an improved response would have been to adopt a narrower approach in setting the minimum standard for Member States to agree on, leaving the imposition of stricter rules to their discretion.

[253] Faeh (n 159).

Chapter 5: An Analysis of the Consequences of Broad Interpretation

5.1 Introduction

It remains to be seen just how the new broad approach to morality within patent law will impact the legal and commercial sectors. However, it is apparent that there are concerns and that these should be considered in order to reinforce my final stance on the issue, particularly where hESC technology is concerned. This chapter foresees such consequences, with the focus naturally being on *Brüstle* and *ISCC*. There is more apprehension commercially, as is expected due to the economic nature of patents that we have seen throughout the discourse; however, the legal consequences will also be briefly described.

5.2 Legal consequences

The area of hESC technology and its regulation has always been one of inherent uncertainty; thus, it was hoped that these rulings would have much to improve in this regard. However, arguably, the introduced standard of 'inherent capacity'[254] has not resolved any issues of uncertainty because it can be interpreted in various ways.[255] Furthermore, for the assessment of 'current scientific knowledge'[256] the court did not determine what the relevant point in time is. In *ISCC*, the CJEU has accepted arguments based on works available years after the filing date.[257] Considering the functions and nature of patents, this would cause unnecessary legal insecurity; at any time throughout the 20-year monopoly, new technological advances may render the claims non-patentable.[258] Moreover, the standard for determining such knowledge is also unclear. On one hand, it may be similar to the novelty/state-of-the-art standard in patent law (a high threshold); on the other, it could be more akin to the lesser standard of inventive step.[259]

I accept that, overall, while *ISCC* does (gladly) introduce a more nuanced approach to hESC patenting,[260] issues will continue to persevere. Considering the importance of *Brüstle* and *ISCC* to such imperative areas like regenerative medicine and cellular therapy, the continued legal ambiguity and the absence of coherent guidelines are especially regrettable and run counter to the objective of a cooperative and efficient legal framework for biotech advancement in Europe.[261]

[254] *International Stem Cell Corporation.*
[255] Nordberg and Minssen (n 154).
[256] *International Stem Cell Corporation.*
[257] ibid.
[258] Nordberg and Minssen (n 154).
[259] ibid.
[260] ibid.
[261] ibid.

5.3 Commercial consequences

First of all, it is important to note that the rulings discussed in chapter 4 only cover patent law and not hESC research as such, irrespective of a patent claim.[262] Nonetheless, it is still likely that funding for such research will decrease, as is evident from the draft opinion issued in the Horizon 2020 programme, which states that 'research which either involves the destruction of human embryos or which uses hESC should be completely excluded from EU funding'.[263] This is regrettable considering that investment is a necessary prerequisite for broadly applicable hESC technologies to be developed.

With fewer hESC patents, Europe will find it difficult to compete against other economies such as the US and Asia, where morality exclusions to patentability are either absent or of liberal application.[264] For instance, Japanese patent law excludes inventions liable to injure public order, morality, or public health;[265] however, it is apparent from an inventory by the Hinxton group that Japan does not closely observe the exclusion in relation to hESC patents.[266] Alternatively, in the US there is no such exclusion, as stated in *Diamond v Chakrabarty*,[267] in which the Supreme Court ruled that 'anything under the sun made by men' is patentable.[268] Instead of confining patentability, the US addresses the morality of stem cell use by strict legislation on public funding. This approach, favourable to the patentee, may encourage them to pursue intellectual property rights in the US.[269] Indeed, this may not have a direct adverse effect on academic research in Europe, as of course research serves (primarily) to provide innovations, not patents.[270] Yet the restraints on stem cell patents in Europe may be an impetus for industries such as the pharmaceutical sector to prefer collaborations with academic partners in the US, where the results of work are better protected.[271]

Further issues may arise where translational hESC research is concerned as, at this stage of development, revenue-focused biotech and pharmaceutical companies are more actively involved.[272] To the extent that the lack of patent protection following the court's rulings decreases the profit available, for instance because the right to commercially exploit the invention cannot be assigned or licensed, these companies may be less incentivised to invest in European hESC research. This effect could be worse for start-up companies.[273]

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[262] M G Nielen, S A Vires and N Geijsen, 'European stem cell research in legal shackles' EMBO J (2013) VOL 32 NO 24.
[263] European Parliamentary Committee on Legal Affairs, *Draft Opinion on the proposal for a regulation establishing Horizon 2020 – the Framework Programme for Research and Innovation (2014-2020)*, 2011/0401(COD), at 3.
[264] Nielen, Vires and Geijsen (n 262).
[265] Article 32 Patent Act (Act No.121 of 1959).
[266] Nielen, Vires and Geijsen (n 262).
[267] *Diamond v Chakrabarty* 447 U.S. 303 (1980).
[268] ibid.
[269] Nielen, Vires and Geijsen (n 262).
[270] ibid.
[271] ibid.
[272] Nancy J Koch, Elona Baum and Alan Trounson, 'European Court Ruling on Embryonic Stem Cells: Ripple Effects' (2011) 9 Cell Stem Cell 499-500.
[273] ibid.

One must concede that emerging technical developments may weaken the extremity of the court's rulings.[274] For example, in 2006/7 it was demonstrated that adult skin cells, involving neither ova nor embryo, can obtain a pluripotency comparable to hESCs.[275] However, hESCs remain the 'gold standard' for regenerative medicine research[276] and many technical and governing questions continue to be unaddressed for new techniques, particularly their appropriateness for clinical use.[277] I expect that scientists conducting basic research will be reluctant to focus exclusively on adult stem cells given the unique advantages offered by hESCs.[278]

Nevertheless, it should be noted that it is not anticipated that there will be a complete absence of European commercial investment in the hESC sector due to the fact that protection via trade secrets[279] or clinical data exclusivity is available. However, it is arguable that the level of protection afforded here is considerably weaker when compared with patents. Consider clinical data exclusivity, for example, which permits that upon the arrival of a new medicine, no generic/biosimilar version of that product can be approved using the same clinical data that is used to support the original medicine until eight years have transpired.[280] The question is whether national authorities accept that there could be a biosimilar version of an hESC-based product.[281] It does not appear likely that highly complex hESC-based advanced therapy medicinal products could be considered biocompatible in the near future, as more simple biological products such as monoclonal antibodies are currently facing this difficulty.[282]

5.4 Summary

First of all, it is discouraging that, even after *ISCC*, broad legal uncertainty remains in the area of stem cell therapy patents. It is unfortunate that both the courts and patent offices will continue to have difficulties when faced with applications based on hESC technology. But what is even more discouraging is the expected commercial consequences. Arguably, in our present economic state, it seems imprudent to withdraw large potential investment in such a pioneering sector through the denial of patents.[283] Such investment not only ensures economic development and increased employment, but moreover advances healthcare.[284] These aims should have been considered equally in the court's judgements, instead of allowing extreme moral and religious views to decide the future of hESC research and its commercial significance to the Union's economy.[285] Now the US will lead developments and the EU will

[274] Harmon, Laurie & Courtney (n 163).
[275] Kazutoshi Takahashi and Shinya Yamanaka, 'Induction of Pluripotent Stem Cells from Mouse Embryonic and Adult Fibroblast Cultures by Defined Factors' (2006) 126 Cell 663-676.
[276] Kelly P. Smith, Mai X. Luong and Gary S. Stein, 'Pluripotency: Toward a gold standard for human ES and iPS cells' (2009) 220 Journal of Cellular Physiology, 21.
[277] Harmon, Laurie & Courtney (n 163).
[278] Koch, Baum and Trounson (n 272).
[279] ibid.
[280] Juli Mansnérus, 'Brüstle v Greenpeace: Implications for Commercialisation of Translational Stem Cell Research' (2015) 22 European Journal of Health Law 141-164.
[281] ibid.
[282] ibid.
[283] Faeh (n 159).
[284] ibid.
[285] ibid.

lose economically and academically, due to the court's failure to foresee the consequences of its judgements.[286]

Conclusion

From an observation of EPO jurisprudence and academic commentary, it is clear that historically, the morality exclusions within patent law were narrowly construed, in a stance favourable towards the patentee. It is apparent that this has now considerably changed, and it is appropriate to suggest that the general morality provision found in Article 53(a) EPC now has a broader meaning. This change from a narrow to a more expansive approach has been introduced and sustained through case law, specifically on Rule 28(1)(c) of the Implementing Regulations to the EPC concerning inventions based on human embryonic stem cells. The decisions of *Edinburgh* and *WARF* can be seen as the beginning of the deviation. I submit that these decisions lacked merit for reasons such as an absence of consensus on the ethical acceptability of hESCs, and also a lack of recognition of ECtHR jurisprudence. The standout judgement is *Brüstle v Greenpeace*, which strengthened the former decisions and then went further in its extremely wide interpretation of the term 'human embryo' in particular. I contend that the court went too far and now has excessively constrained not only embryonic stem cell research, but biotechnological innovation in general, as the widening of Rule 28(1)(c) bears on the interpretation of Article 53(a) EPC. I predict that this will leave legal uncertainty and also have profound commercial consequences. Whether one agrees with the judgements or not, there is a need to set limits to the court's judicial activism, particularly in the context of biotechnological patents. The courts deciding on issues of morality with regard to biotech innovation, represents an unwarranted extension of their role and is inappropriate when one considers the competing policy complexes that must be taken into account in such an area. Ultimately, patent law is not the place for these extensive moral reflections and the courts should not act as a moral censor; rather such ethical consideration is better suited to the role of bioethics. I suggest that a more appropriate response would have been to adopt a narrower approach in setting the minimum standard for Member States to agree on, leaving the imposition of stricter rules to their discretion. This approach would not naturally lead to maximum harmonisation of the rules set out in the Directive; but neither does it conflict with what was agreed in the Directive.

[286] ibid.