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***Brüstle* and the Charter: A Cause of Europeanisation?**

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Around the beginning of the new millennium, the EU Charter of Fundamental Rights was solemnly proclaimed as a new fundamental rights standard, and this new document became legally-binding as a result of the Lisbon Treaty. Over a decade later, the European Court of Justice delivered a judgment revolving around a longstanding ethical question – at what point does humanity begin? With the biotechnology industry growing rapidly², should limits be placed on its rise? In the late 90s, the EU legislature chose to apply a uniform standard, bringing the EU rules more in line with the US and Japan³ and preventing fragmentation within the internal market⁴. Concerns about the scope of embryonic technology led to limits on its patentability⁵ and in *Brüstle*⁶ it fell to the Court to determine the exact scope of these limits.

Law has long been studied as a driver of change within the EU⁷, famously credited with the ‘transformation of Europe’⁸. Following a well-documented turn towards evidential studies of the EU’s effects on Member States’ laws, politics, and societies⁹, studies began to group changes in these states together as ‘Europeanisation’ or ‘Europeanization’. Whilst it is now rare to see a study of policy change in a Member State without the EU being discussed as a factor¹⁰, the effects of the Charter within this framework remain mostly undocumented due to its novelty and unique legal status. In a world where the proper role of EU law is subject to intense political scrutiny, it is useful to understand the precise policy effects of the Charter, as this allows more nuanced debates on the EU as a whole.

This paper will argue that the Charter has caused Europeanisation within the UK and Germany,

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² Plomer, Torremans, *Embryonic Stem Cell Patents: European Law and Ethics*, (OUP, 2009), 7.

³ *Ibid*, 4-5.

⁴ *Ibid*, 8.

⁵ *Ibid*, 18-22.

⁶ Case C-34/10, *Brüstle*, ECR [2011] I-09821.

⁷ Scheingold, *The Rule of Law in European Integration: the Path of the Schuman Plan*, (Yale University Press, 1965).

⁸ Weiler, ‘The Transformation of Europe’, 100 *The Yale Law Journal* 8, (1991).

⁹ Ladrech, *Europeanization and National Politics*, (Palgrave MacMillan, 2010), 9-11.

¹⁰ Ladi, ‘Policy Change and Soft Europeanization: The Transfer of the Ombudsman Institution to Greece, Cyprus, and Malta’, 89 *Public Administration* 4, (2011), 1643.

focusing specifically on the *Brüstle* case as a mechanism of change. These two countries are particularly worthy of study when looking at this specific mechanism – the referral for the case was German, and the UK is the source of much scepticism directed towards the Charter and the *Brüstle* judgment.

After this introduction, the paper will provide a theoretical overview and hypothesis, explaining how the institutionalist nature of Europeanisation leads to an expectation for the Charter to drive policy change. Section two will explain the research design. Section three will explain the *Brüstle* ruling and how it was influenced by the Charter. Subsequently the paper will analyse how this led to Europeanisation within Germany and the UK by comparing the situation in these Member States before and after the ruling. The final section will consider the implications of the findings on academia, as well as the broader political debate.

1. Theory and Hypothesis

‘Europeanisation’ has been quite variably defined. Taking the broadest possible definition, Europeanisation is ‘a process of change affecting domestic institutions, politics, and public policy’ as a result of membership of the EU¹¹. Traditional theoretical debates around the EU focused on EU integration¹². However, studies shifted to analysing the EU as a political system as opposed to an international organisation *sui generis*¹³. This was subsequently accompanied by an increase in evidential studies on the effects of the EU on various aspects of Member States¹⁴. In the 1990s, a series of articles combined these two shifts in discussion of the EU, forming some of the earliest research on ‘Europeanisation’– studying how the unique nature of the EU was shaping changes in Member States¹⁵. Early pioneers defined Europeanisation as ‘an incremental process reorienting the direction and shape of politics to the degree that EC political and economic dynamics become part of

¹¹ Radaelli, ‘Europeanization: The Challenge of Establishing Causality’, in Exadaktylos, Radaelli, *Research Design in European Studies. Establishing Causality in Europeanization*, (Palgrave MacMillan, 2012), 1.

¹² Ladrech, *supra* note 9, 8.

¹³ As stated in *ibid*, and exemplified by Hix, ‘The Study of the European Community: The challenge to comparative politics’, *17 West European Politics* 1, (1994) and Bulmer, ‘Domestic Politics and European Policy-making’, *JCMS* 21, (1983).

¹⁴ Ladrech, *supra* note 9, 9-11.

¹⁵ Eg. Olsen, ‘European Challenges to the Nation State’, Working paper number 14, Oslo, (1995); Olsen, ‘Europeanization and Nation State Dynamics’, working paper no. 9, Oslo (1995); Andersen, Eliassen, *Making Policy in Europe: The Europeanification of National Policy-making*, (Sage, 1993); Kohler Koch, Eising, *The Transformation of Governance in the European Union*, (Routledge, 1999).

the organizational logic of national politics and policy-making¹⁶. The basic idea of Europeanisation emerges from this - that the EU shapes events in Member States.

Whilst the term 'Europeanisation' has been subject to a number of competing definitions¹⁷, concerning topics including the expansion of the EU's geographic boundaries¹⁸, the formation of new EU-level bodies¹⁹, or the exporting of EU institutions²⁰, this paper chooses to focus on 'top-down Europeanisation' – the process through which EU-level actions shape Member States. This framework most clearly focuses on the main objects of study. The Charter is a relatively new EU-level document, and the paper seeks to study its effects on Member States. Given this, it is illogical to use other conceptualisations of Europeanisation, as these concern the interactions between the EU and third countries as opposed to Member States. Furthermore, a framework designed to study new EU-level bodies being created would not provide useful analysis of the top-down effects of the Charter.

The following section will explain how law, and more specifically the Charter, fits within this model of top-down Europeanisation. This will be pursued in several sections: firstly explaining why law has been studied as a factor in Europeanisation; secondly, explaining the process by which law effects change within Member States.

1.1 Law as an independent variable

ECJ judgments such as *Ruiz Zambrano*²¹, *Centros*²², and *Rüffert*²³, have been subject to

¹⁶ Ladrech, 'Europeanization of Domestic Politics and Institutions: The Case of France', 32 *JCMS* 1, (1994).

¹⁷ Best summated in Olsen, 'The Many Faces of Europeanization', 40 *Journal of Common Market Studies* 5, (2002), 921-52.

¹⁸ Eg. Jönsson, Tägil, Törnqvist, *Organizing European Space* (Sage, 2000).

¹⁹ Eg. Checkel, 'The Europeanization of Citizenship?', in Cowles, Caporaso, Risse, *Transforming Europe: Europeanization and Domestic Change*, (Cornell, 2001).

²⁰ Eg. Mjøset, 'The Historical Meanings of Europeanization', Oslo, Arena Working Paper number 24, (1997).

²¹ Case C-24/09, *Ruiz Zambrano*, ECR [2011] I-01177.

²² Case C-212/97, *Centros*, ECR [1999] I-01459.

²³ Case C-346/06, *Rüffert*, ECR [2008] I-01989.

Europeanisation analysis²⁴, and the effects of the ECJ have been widely noted²⁵. Going beyond previous pieces of individual research, which focused either too narrowly on the individual case in question or too broadly on integration as a whole, the following sections will explain why the institutionalist nature of Europeanisation as a theoretical framework means that law will have an unavoidable role as it is itself an institution. This explanation will also be applied to the Charter, in order to analyse if and why it would have a similar effects.

1.1.1 Law as an institution

Europeanisation originates from theories of institutionalism, and it is law's role as an institution that explains its effects within the Europeanisation model.

'Institutionalism' refers to a focus on formal structures and systems of governance as the predominant factor in explanatory theories of politics²⁶. Institutions are 'multifaceted, durable social structures, made up of symbolic elements, social activities, and material resources'²⁷. They are thus durable features of social life, providing "solidity" across time and space'²⁸.

Institutions are said to require a regulatory element, a normative element, and a cultural-cognitive element²⁹: the regulatory element provides coercive structures such as rules and sanctions; the normative element creates binding social obligations; and the cultural-cognitive element creates

²⁴ Schmidt, 'Judicial Europeanisation: The Case of Zambrano in Ireland', 37 *West European Politics* 4, (2014); Blauburger, Krämer, 'Europeanisation with Many Unknowns: National Company Law Reforms after Centros', 37 *West European Politics* 4, (2014); Sack, 'Europeanization Through Law, Compliance, and Party Differences – the ECJ's 'Rüffert' judgment (C-346/06) and Amendments to Public Procurement Laws in German Federal states', 34 *Journal of European Integration* 3, (2012).

²⁵ Eg. Weiler, 'A Quiet Revolution: The European Court of Justice and its Interlocutors', 26 *Comparative Political Studies* 510, (1994); Blauburger, 'With Luxembourg in mind...the remaking of national policies in the face of ECJ jurisprudence', 19 *Journal of Public Policy* 1, (2011); Stone Sweet, 'Judicialization and the construction of governance', 32 *Comparative Political Studies*, 2, (1999); Panke, 'The European Court of Justice as an agent of Europeanization? Restoring compliance with EU law', 14 *Journal of European Public Policy* 6, (2007); Smochina, Cernei, 'The Process of Europeanization Reviewed: The Implication of the Court of Justice of the European Union', 18 *Economics Science Series*, (2012); Radaelli, 'Whither Europeanization: Concept Stretching and Substantive Change', *European Integration online Papers (EIoP)* Vol. 4 (2000) N° 8.

²⁶ Scott, *Institutions and Organizations*, (Sage Publications, 2001, 2nd Edition), 6.

²⁷ Ibid, 49

²⁸ Giddens, *The Constitution of Society*, (University of California Press, 1984), 24.

²⁹ Scott, *supra* note 26, 51.

shared understandings that surround the institutions³⁰. Law itself is an institution, as seen in multiple pieces of work³¹ and in 'law and society scholarship' as a whole³². Its durability over time, combined with the regulatory, cognitive, and normative elements - seen in people's belief in a binding legal system - means that law fulfils the required elements for an institution.

Within this model, change is driven by institutions. Law's institutional status provides a theoretical grounding for why Europeanisation literature focuses on law— law forms one of the theory's eponymous drivers of change. Law is thus a sensible focus for Europeanisation, and particularly as an independent variable.

Moving to a prediction, the Charter should have caused Europeanisation. As part of the institution of law within an institutionalist model, it should have effects. Furthermore, certain elements of institutions mean that there is potential for the Charter to have effects even beyond practical doctrinal application. The normative element of an institution creates the perception that it should be followed, and this has the potential to change the behaviour of actors, in a way that is discussed below.

1.2 Law effecting change

The literature on top-down Europeanisation offers several different models to explain the effects the EU has on its Member States, stemming from 'new institutionalism' or 'neo-institutionalism'. The three types of new institutionalism consist of historical institutionalism, rational-choice institutionalism and sociological institutionalism³³. Rational-choice institutionalism was prominently described as a 'logic of consequentialism'³⁴. What this means is that actors seek to maximise their resources in a rational manner, and the way they do this is shaped by institutions³⁵. In contrast,

³⁰ Ibid; Greenwood, Royston, Hinings, 'Understanding Radical Organizational Change: Bringing Together the Old and New Institutionalism', 21 *Academy of Management Review* 5, (1996).

³¹ Oeter, 'Toward a Richer Institutionalism for International Law and Policy', *University of Illinois Law Review*, (2008); Lacey, 'Jurisprudence, History, and the institutional quality of law', *Virginia Law Review* 101, (2015).

³² See for example Suchman, Edelman, 'Legal Rational Myths: The New Institutionalism and the Law and Society Tradition', 21 *Law and Social Inquiry*, (1996), 907; Scott, *supra* note 26, 1.

³³ Hall, Taylor, 'Political Science and the Three New Institutionalisms', 44 *Political Studies*, (1996), 947.

³⁴ March, Olsen, *Rediscovering Institutions: The Organizational Basis of Politics*, (New York, 1989).

³⁵ Hall, Taylor, *supra* note 33, 943-5.

sociological institutionalism is based on a 'logic of appropriateness'³⁶, in that actors' responses are shaped by what is expected of them³⁷. Historical institutionalism focuses on the broad relationships between institutions and individuals, and looks at the path these relationships take over time through various power asymmetries³⁸. This generally combines elements of both rational-choice and sociological institutionalism without definitively falling within either model.

The way law effects change within the Europeanisation framework can be explained in several steps: some sort of clash between EU and Member State level; explaining reactions to that clash; and categorising the various outcomes. This section will detail these three areas, and then outline how law fits within the explanatory models.

1.2.1 Clash between EU and Member State level

Europeanisation focuses on reactions of Member States to differing events taking place at an EU level³⁹. The first step is a clash between the EU and Member State level, described as 'goodness of fit'⁴⁰, 'misfit'⁴¹, or 'mismatch'⁴². The lower the compatibility between the EU and Member State level, the bigger the misfit and higher the pressure to adapt⁴³. Misfit is regularly further broken down – institutional misfit and policy misfit. Institutional misfit represents a clash of 'administrative structures and procedures that are embedded in the member state's respective state, legal and political traditions'⁴⁴. Policy misfit involves clashes between different policies at an EU and Member

³⁶ March, Olsen, *supra* note 34.

³⁷ Hall, Taylor, *supra* note 33, 548.

³⁸ *Ibid*, 938.

³⁹ Ladrech, *supra* note 16.

⁴⁰ Eg. Risse, Cowles, Caporaso, 'Europeanization and Domestic Change: Introduction', in Cowles, Caporaso, Risse, *supra* note 19, 6; Schmidt, Radaelli, 'Policy Change and Discourse in Europe: Conceptual and Methodological Issues', 27 *West European Politics* 2, (2006), 183-210.

⁴¹ Duina, *Harmonizing Europe. Nation States within the Common Market*, (New York, 1999); Ladrech, *supra* note 9, 31.

⁴² Heretier et al, *Differential Europe – New Opportunities and Restrictions for Policy Making in the Member States*, (Lanham MD, 2004).

⁴³ Börzel, Risse, 'Conceptualizing the Domestic Impact of Europe' in Featherstone, Radaelli, *Politics of Europeanization*, (OUP, 2003), 69-73.

⁴⁴ Knill, Lenschow, 'Adjusting to EU Environmental Policy: Change and Persistence of Domestic Administrations', in Cowles, Caporaso, Risse, *supra* note 19.

State level. It has been said that policy misfits essentially equal ‘compliance problems’⁴⁵, as Member States face pressure to comply with EU level policies.

Law and the Charter cause and influence both of these misfits. Differing legal norms, including differing fundamental rights norms potentially caused by the Charter, cause institutional misfit and lead to adaptational pressure for the Member State to change. Policy misfit can also be created by law and the Charter, to the extent to which policy is determined by law. Where policy is implemented by law or altered through a court case, the results could differ from Member State policy, thus creating adaptational pressure to implement the EU-level policy. This policy misfit could be created by a case involving the Charter or any other legal instrument.

While misfit is the beginning of the top-down Europeanisation process, it is merely a ‘necessary, but not sufficient’⁴⁶ condition. In order for Europeanisation to take place, there needs to be a specific national reaction to the misfit. This is explained differently in rational-choice and sociological institutionalism.

1.2.2 National Reactions to misfit

Within rational-choice institutionalism, misfit creates ‘an emerging political opportunity structure which offers some actors additional resources to exert influence, while severely constraining the ability of others to pursue their goals’⁴⁷. Actors base their response to the misfit on new opportunities or constraints, and the result of this process is conceptualised as a redistribution of resources between different actors.

Sociological institutionalism relies on actors’ responses to what is expected of them in certain circumstances. In this model, misfit creates new expectations and norms surrounding how institutions and actors ‘should’ behave – what is expected of them. If this changes because of misfit (representing a change in what is expected of them), then actors adapt through the process of ‘arguing, persuasion, and social learning’, meaning discourse leads them to change their actions to better meet expectations, and to remain ‘in good standing’⁴⁸. The more European norms fit with domestic-level norms, the less likely the domestic change.

⁴⁵ Börzel, Risse, *supra* note 43.

⁴⁶ *Ibid* 60.

⁴⁷ Börzel, Risse, *supra* note 43, 63.

⁴⁸ *Ibid*, 66.

How do these models explain the effects of law? Explaining law's impacts using rational-choice institutionalism, the risk of legal sanctions alters the cost-benefit calculations of states. The Charter could cause Europeanisation through this same mechanism, for example by providing applicants new ways to challenge certain laws. In *Brüstle*, the Charter could have created a new mechanism for applicants to challenge policies using fundamental rights law. Subsequently, states are incentivised to change, as not doing so risks sanctions.

Within sociological institutionalism, compliance with law is a norm expected for many actors⁴⁹, therefore a change in the law brings about a change in expectations. They will want to remain 'in good standing', which creates a likelihood of behavioural change. The Charter could cause change by altering what is expected from actors by providing a new fundamental rights standard that they are expected to follow. Given the Charter's stronger normative element as an institution, this seems a more plausible explanation for any Charter-driven change.

1.3 Hypothesis

Looking at the theory described above, it seems possible that the Charter has caused Europeanisation through the mechanism of the *Brüstle* judgment.

The Charter, as part of law as a whole, is likely to have institutional influence on the Europeanisation process due to the institutionalist nature of Europeanisation as a research framework. This paper hypothesises that the *Brüstle* judgment will have functioned as the specific mechanism through which Europeanisation change took place. Normative institutional elements, combined with the Charter, mean it is likely to be used in a judgment concerning fundamental rights, leading to a substantive change in the outcome and subsequently a misfit between EU level policy and Member State policy – creating the adaptational pressure that caused change. The final outcome will be

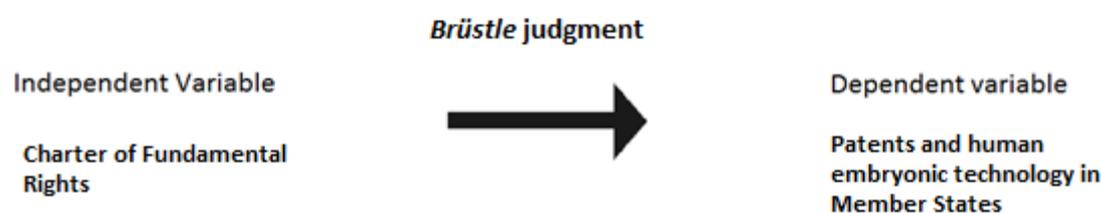
⁴⁹ Berglund, Gange, van Waarden, 'Mass production of law. Routinization in the transposition of European directives: a sociological-institutionalist account', 13 *Journal of European Public Policy* 5, (2006), 701; Falkner, Treib, Hartlapp, Leiber, *Complying with Europe: EU Harmonisation and Soft Law in the Member States*, (Cambridge: 2005); Sverdrup 'Compliance: a matter of ability?'. Paper presented at 'Transposition and Compliance in the European Union'. June 11–13, Leiden; Börzel, Hofmann, Sprungk, 'Why do states not obey the law? Non-compliance in the European Union'. Paper presented at the workshop 'Transposition and Compliance in the European Union'. June 11–13, Leiden.

transformation in the position of patents and human embryonic technology in Member States.

2. Research Design

The paper will analyse national responses to *Brüstle* to look for any evidence for the hypothesis. The independent variable will be the Charter of Fundamental Rights. For a dependent variable, the paper will analyse the effects the Charter has had on a specific part of health law - the position of patents and human embryonic technology within Member States. The judgment itself represents the mechanism of change through which the independent variable affects the dependent variable.

Fig 1: The research design



Source: Author

There are multiple outcomes within Europeanisation literature. The most common⁵⁰ are: absorption – Member States adopt European-level policies with minimal domestic change; accommodation – some domestic change in order to accommodate changes at a European level; transformation – ‘Member States completely replace existing policies, processes, and institutions by substantially different ones’; inertia - lack of action from the Member State. These can be divided fairly simply into those that represent change and outcomes that do not represent change. Another outcome has been added⁵¹. This outcome is known as ‘retrenchment’, and represents active resistance to the

⁵⁰ Börzel, Risse, *supra* note 43.

⁵¹ Eg. Radaelli, ‘Europeanization of Public Policy’, in Featherstone, Radaelli, *supra* note 43, 38; Jordan, Liefferink, *Environmental Policy in Europe: The Europeanization of national environmental policy*, (Routledge, 2004), 8; Börzel, ‘How the European Union Interacts with its Member States’, in Bulmer, Lequesne, *The Member States of the European Union*, (Oxford, 2005); Héritier, ‘Differential Europe: National Administrative responses’ in Cowles, Caporaso, Risse, *supra* note 18;

Europeanisation process, the result of which is the policy is less Europeanised. This leaves a total of five commonly used outcomes, and it is these outcomes against which change will be measured in this paper.

3. Empirical Analysis of Europeanisation

The following sections will analyse whether the Charter, through its influence on *Brüstle*, has caused Europeanisation in the UK and Germany. Section 3.1 will discuss the judgment and the Charter, with section 3.1.1 explaining the ruling and section 3.1.2 arguing that this was influenced by the Charter. Section 3.2 will explain Europeanisation within Germany, and section 3.3 will explain Europeanisation within the UK.

3.1 *Brüstle*

The Biotechnology Directive, passed on 6 July 1998⁵², constituted a substantial development in EU health law⁵³. As mentioned in the introduction, the Directive is designed to harmonise biotechnological patents in Europe, applying general principles of patent law to biotechnological inventions⁵⁴. ‘Biotechnological inventions’ in the Directive refer to inventions involving biological material which includes: material that contains genetic information; and material capable of replicating itself as part of a reproductive function ‘Biotechnological inventions’ also includes the processes by which these materials are obtained.⁵⁵ Given the ethical sensitivity of some related topics such as stem cells and embryonic technology and disagreements between Member States, certain areas of health law and health-related research were considered to be beyond the pale when drafting the Directive, and so were excluded from patentability.

Certain inventions were unpatentable due to contravening ‘ordre public or morality’⁵⁶. This phrase

Radaelli, *supra* note 25; Kostera, ‘Europeanizing Healthcare: Cross-border Patient Mobility and Its Consequences for the German and Danish Healthcare Systems’, Bruges Political Research Paper No. 7, (2008).

⁵² Directive 98/44/EC of the European Parliament and of the Council of 6 July 1998 on the legal protection of biotechnological inventions, *Official Journal L 213*, 30/07/1998 P. 0013 - 0021

⁵³ See ‘The Regulation of Clinical Research’, in Hervey, McHale, *Health Law and the European Union*, (Cambridge, 2004).

⁵⁴ Plomer, Torremans, *supra* note, 2.

⁵⁵ Biotech Directive, *supra* note 52, Art. 2

⁵⁶ Article 6(1), *ibid*.

originates from a prohibition on patents that might reflect poorly on the British crown⁵⁷, and similarly -phrased prohibitions proliferate in national and international patent law⁵⁸ representing rejection of things considered morally 'unacceptable' by society. Within the Biotechnology Directive, and within health law in general, it represents an embodiment of the aforementioned ethical concerns as well as wider morality questions⁵⁹. The Directive gives examples of exclusions from patentability on grounds of public morality, and specifically mentions 'uses of human embryos for industrial or commercial purposes'⁶⁰.

The German scientist *Brüstle* obtained a patent covering neural precursor cells, and the process through which they were obtained. The patent was challenged in front of the German Federal Patent Court, and was held invalid so far as it covered neural precursor cells obtained from human embryonic stem cells⁶¹. The Federal Patent Court felt that obtaining these precursor cells from human embryonic stem cells constituted 'use of a human embryo for industrial or commercial purposes', contrary to the German law transposing the directive⁶². Following an appeal to the Federal Supreme Court, a referral was made under Article 267 TFEU in order to clarify several issues.

3.1.1 The ECJ decision.

The ECJ was called upon to determine: firstly, the precise meaning of 'human embryo' for the purposes of the directive, whether it included neural precursor cells as used by *Brüstle*; secondly, the precise meaning of the phrase 'industrial or commercial purposes'; thirdly, the status of patents that do not mention human embryos, but where destruction of human embryonic stem cells are involved in the process⁶³. If the Court held that the *Brüstle* patent cells were human embryos for the purposes of the directive and were being used for industrial or commercial purposes, the invention would be unpatentable. The ECJ held⁶⁴:

⁵⁷ Witek, 'Ethics and Patentability in Biotechnology', *Science and Engineering Ethics* 11, (2005), 106.

⁵⁸ Gold, Gallochat, 'The European Biotech Directive: Past as Prologue', 7 *ELJ* 3, (2001), 345.

⁵⁹ *Ibid*, 339-340.

⁶⁰ Article 6(2)(c), *supra* note 52.

⁶¹ Bundespatentgericht, 3 Ni 42/04, Verkundet am 5. Dezember 2006, Teil 2, Abs. 2; Garvey, <<http://www.bristows.com/articles/patentability-of-human-embryonic-stem-cells-by-shauna-garvey>>, first accessed 15/04/2015.

⁶² BGH, Xa ZR 58/07, 17. December 2009, paras. 56-58.

⁶³ *Brüstle*, *supra* note 6, para. 23.

⁶⁴ *ibid*, para. 35-36.

‘any human ovum must, as soon as fertilised, be regarded as a ‘human embryo’ within the meaning and for the purposes of the application of Article 6(2)(c) of the Directive, since that fertilisation is such as to commence the process of development of a human being.

That classification must also apply to a non-fertilised human ovum into which the cell nucleus from a mature human cell has been transplanted and a non-fertilised human ovum whose division and further development have been stimulated by parthenogenesis. Although those organisms have not, strictly speaking, been the object of fertilisation, due to the effect of the technique used to obtain them they are, as is apparent from the written observations presented to the Court, capable of commencing the process of development of a human being just as an embryo created by fertilisation of an ovum can do so.’

Having thus defined ‘human embryos’ for the purposes of the directive, the Court held that inventions involving the destruction of such cells were unpatentable under the Article six provision excluding ‘uses of human embryos for industrial and commercial purposes’⁶⁵, and that the research in *Brüstle* constituted such an industrial or commercial purpose⁶⁶. Several questions were referred back to the German court, specifically whether blastocysts fitted the above definition of human embryo⁶⁷. The overall conclusion of the judgment is the specific given definition of human embryo given, and its application to the sort of scientific research at stake in the case. Finally, destruction of the embryos at any stage renders the invention unpatentable⁶⁸.

3.1.2 Influence of the Charter

The Court’s renewed focus on human dignity as a fundamental right inspired the specific definition of a human embryo. The Court isolates the fact that human dignity needs to be fully considered when analysing patentability, and it is this importance of dignity that leads to the above wide definition of human embryo⁶⁹.

The Charter was not explicitly cited in the judgment, but several authors think that despite its absence, the Charter had noticeable effects. Aidan O’Neill noted that the Charter was ‘conspicuous

⁶⁵ Ibid, para. 53

⁶⁶ Ibid, para. 46.

⁶⁷ Ibid, para. 37.

⁶⁸ Ibid, para. 53.

⁶⁹ Ibid, paras. 33-34.

in its absence⁷⁰, indicating that it was odd that the effects of the Charter went unmentioned, and Fontanelli has also described this as an intentional omission – the judgment being motivated by the Charter, but the judges having chosen to avoid explicit mentions of the Charter to avoid polarising public opinion against the document in a controversial decision⁷¹. Both of these academics believe that despite its omission, the Charter influenced the judgment, and McCrudden describes dignity in the context of the Charter as being ‘the subject of considerable debate and litigation’, citing *Brüstle* as an example⁷².

Furthermore, the European Commission also acknowledged the Charter’s effect on the case in their report on the impacts of the Charter⁷³. Wider reports on the case acknowledged the Charter’s role in the decision of both the Court and the Advocate General⁷⁴, an opinion supported elsewhere⁷⁵. Den Exter and Földes described the court as pointing out that the ‘Charter emphasises that patent law must be applied so as to respect fundamental principles safeguarding the dignity and integrity of the person’, a sign of the Charter’s influence on the decision⁷⁶.

Most importantly, Gärditz contrasts the Court’s approach to dignity in this case with cases that took place before the Charter became legally binding. He argues that in previous dignity cases such as *Omega Spielhallen*, the Court was ‘reluctant to develop an autonomous concept of dignity’, which resulted in a ‘decentralized’ concept of dignity specific to each individual Member State⁷⁷. He argues that the court subsequently had the ‘resolution’ to develop an autonomous conception of human dignity as they implicitly accepted the duty to protect human dignity created by Article 1 of the

⁷⁰ O’Neill, <<http://eutopialaw.com/2011/10/21/eu-law-human-dignity-and-the-human-embryo-the-decision-of-the-cjeu-grand-chamber-in-Brüstle-v-greenpeace-ev-c%E2%80%91913410/>>, first accessed 01/05/2015.

⁷¹ Fontanelli, ‘The European Union’s Charter of Fundamental Rights two years later’, 3 *Perspectives on Federalism* 3, (2011) 36.

⁷² McCrudden, ‘Labour Law as Human Rights Law: A Critique of the Use of ‘Dignity’ by Freedland and Kountouris’, in Bogg, Costello, Davies, Prassl, *The Autonomy of Labour law*, (Hart, 2015), 278.

⁷³ REPORT FROM THE COMMISSION TO THE EUROPEAN PARLIAMENT, THE COUNCIL, THE EUROPEAN ECONOMIC AND SOCIAL COMMITTEE AND THE COMMITTEE OF THE REGIONS 2011 Report on the Application of the EU Charter of Fundamental Rights, page 6; Annex I, *ibid*.

⁷⁴ Gärditz, ‘Human dignity and research programmes using embryonic stem cells: An analysis of *Brüstle*/Greenpeace-judgment of the European Court of Justice’, (Bonn, 2011).

⁷⁵ Puppinck, ‘Synthetic analysis of the ECJ case C-34/10 *Oliver Brüstle v Greenpeace e.V.* and its ethical consequences’, (European Centre for Law and Justice, 2013).

⁷⁶ Den Exter, Földes, *Casebook on European Union Health Law*, (Maklu, 2014), 21.

⁷⁷ Gärditz, *supra* note 74, 4.

Charter⁷⁸. This argument illustrates how the existence of the Charter as a document led to the judgment in *Brüstle*, as opposed to merely the pre-existing general principle of human dignity within EU law.

This logic can be seen when looking at other pre-Charter cases involving human dignity. In the challenge to the Biotechnology Directive brought by the Netherlands⁷⁹, the Court acknowledges that it is its duty to safeguard the fundamental right to human dignity⁸⁰. However, it does not establish an EU-level definition of what this means in the context of EU law, which would have made clear the substantive standard to be applied in the future. Similarly in even earlier cases on dignity⁸¹, the Court declined to lay out a centralised meaning, restricting the application to the case at hand. These cases provide further evidence for Gärditz's argument, by showing the Court's non-centralised practice preceded *Omega*, and that the Charter brought an end to a well-established practice in *Brüstle*.

It is an unsurprising outcome for several reasons that many academics⁸² will, focusing more carefully on the strict doctrinal application of the law, have neglected the influence of the Charter noted by this paper. Firstly, given the lack of existing literature on the Charter in its new form, it is easier and simpler within academia to rely on existing explanations as opposed to relying on new theories. Secondly, the case was frequently analysed through a doctrinal lens, which would tend towards only analysing the exact arguments laid out by the Court as opposed to the Courts role within a wider institutionalist system. The interdisciplinary approach of this paper allows wider analysis of the Court's actions, highlighting the influence of the Charter as part of the institutionalist framework of Europeanisation.

It is a widely acknowledged view that the Charter directly contributed to the judgment. Should this ruling subsequently be a cause of Europeanisation, the overall outcome will be one of Europeanisation caused by the Charter through the mechanism of the *Brüstle* judgment.

⁷⁸ Ibid, 4-5.

⁷⁹ Case C-377/98, *Kingdom of the Netherlands v European Parliament and Council of the European Union*, ECR [2001] I-07079.

⁸⁰ Ibid, para. 70.

⁸¹ Case C-13/94, *P v S and Cornwall County Council*, ECR [1996] I-02143.

⁸² Eg. Staunton, '*BRÜSTLE V GREENPEACE, EMBRYONIC STEM CELL RESEARCH*', 21 *Medical Law Review* 2, (2013), 310-319; Baeyens, Goffin, '*ECJ 2011/01, Oliver Brüstle v Greenpeace E.V., 18 October 2011 (caseC-34/10)*', 19 *European Journal of Health Law* 1, (2011), 101-113.

3.2 Europeanisation in Germany

In order to fully understand any change following the *Brüstle* ruling, it is first important to understand the existing state of German law preceding the ruling.

The Directive, following initial resistance and infringement proceedings⁸³, was eventually implemented in Germany⁸⁴. The provisions of the Directive excluding ‘uses of human embryos for industrial and commercial purposes’ was directly transposed into German law, which inserted the German-language version of that provision into Article 2(2)(3) of the German patent law⁸⁵. The transposition of this provision led to the judgment that is the focus of this paper. This initial transposition could be considered a case of Europeanisation – the Directive created a misfit between the EU-level policy and the German-level policy, and enforcement proceedings and the threat of sanctions created adaptational pressure to change. However, the adaptation being studied in this paper constitutes a separate change beyond the initial implementation of the Directive, which itself is worthy of study.

The decision of the German Federal Patent court, mentioned at the beginning of section 3, indicates that German law prior to the *Brüstle* cases included the obtaining and usage of neural precursor cells within the definition of ‘uses of human embryos for industrial or commercial purposes’. It is also important to note that this remained true regardless of whether destruction of embryos took place.

Following an appeal, the case was subsequently referred to the ECJ for an authoritative interpretation. The details of this ruling are discussed in section 3.1.1. To establish the effects this ruling had in German law, the first source is naturally the ruling of the Federal Supreme Court applying the ECJ decision⁸⁶. This judgment allows us to see the full effects of the ECJ ruling on the German legal position and analyse any change that took place.

Brüstle’s patent was partially upheld by the German Supreme Court. Where the patent did not

⁸³ Case C-5/04, *Commission v Bundesrepublik Deutschland*, nyr.

⁸⁴ Gesetz zur Umsetzung der Richtlinie über den rechtlichen Schutz biotechnologischer Erfindungen, Bundesgesetzblatt Jahrgang 2005 Teil I, Nr. 6, ausgegeben zu Bonn am 28. Januar 2005.

⁸⁵ Para.2, Abs. 2., S. 2, PatG. – ‘die Verwendung von menschlichen Embryonen zu industriellen und kommerziellen Zwecken’

⁸⁶ BGH, X ZR 58/07, 27. November 2012.

involve the destruction of human embryos, this fell outside of the ECJ's interpretation of the directive⁸⁷. Human embryonic cells taken *without* destroying the embryo itself were patentable, as they did not fall within the specific definition of embryo.

Where previously the German legal position was that the inventions using the precursors to human embryonic stem cells constituted a prohibited 'use' of human embryos for industrial and commercial purposes, following the application of the *Brüstle* case, inventions were (in this context) only excluded from patentability if they involved the destruction of human embryos. Even if they used the same type of cells as in the original patent, they were now patentable so long as it did not involve the destruction of the human embryo – something which the German Supreme Court was satisfied was now technologically possible⁸⁸. This involved changing the definition of human embryo that previously existed in the German interpretation of the Directive, i.e. in the relevant provisions of the Patent Law.

This change represents a liberalisation in that it 'opens up the prospect of patents on embryonic stem cell technology that did not involve destruction of an embryo'⁸⁹. The eventual outcome was a judgment from the German Federal Supreme Court which allows the patent at stake in *Brüstle*. In addition to this, it opens up the possibility for other similar cells and processes to be patented, provided they did not involve destruction of the embryo. This latter development could be significant, depending on future scientific innovations, but was met with muted reaction from within Germany, as it was perceived as merely representing a small change⁹⁰. These facts in combination demonstrate that a liberalisation took place, but merely a small one, as a more substantial liberalisation would likely have been met with a broader reaction.

Looking at the framework laid out in the research design, the changes in German law would most likely be described as absorption. There is no concrete change to statute, but definitional change has taken place and is noticeable. As a result of a Charter-inspired decision, a definition developed at an EU level (by a supranational body as opposed to one more heavily influenced by Member States), has been applied to national law, changing it in a noticeable way. The consequences of this is a

⁸⁷ Ibid, page 1.

⁸⁸ Oser, <<http://www.lexology.com/library/detail.aspx?g=00bf462b-c485-4c40-8716-c01cc1281ee9>>, first accessed 08/07/2015.

⁸⁹ Moran, 'Brüstle patent holds up in Germany', 31 *Nature Biotechnology* 94, (2013).

⁹⁰ Eg. <<http://www.sueddeutsche.de/wissen/bundesgerichtshof-urteil-zu-stammzellen-hat-begrenzte-wirkung-1.1536530>>, first accessed 20/05/2015.

change to when patents will or will not be granted for inventions coming from certain types of cells. This change is evidence of the Charter causing Europeanisation in the way hypothesised earlier in the paper.

The mechanism through which the Charter has caused change matches the hypothesis of this paper. Law caused policy misfit, which leads to adaptational pressure. In this case, the Charter resulted in Article 6(2)(c) of the Directive being defined in a way that clashed with the German policy, as expressed by the initial ruling of the German patent court. This misfit created pressure for the German Court to apply the ECJ's definition, leading to change in German policies in the extent to which they are regulated by law. In this case, the policy is determined by the interpretation of the German Federal Supreme Court, so the Charter causing policy misfit leads to change. The fact that this Europeanisation took place despite the Charter not being explicitly cited in the ECJ judgment illustrates that normative elements of institutions can also contribute to this change, as discussed in the theoretical section of the paper.

3.3 Europeanisation in the UK

When looking at the UK, it is again logical to start with the legal position pre-dating the *Brüstle* judgment and compare it to the subsequent legal position, to establish if change has taken place.

British patent law is laid down in the Patent Act 1977. This was amended in the year 2000 in order to implement the directive, and the statutory instrument⁹¹ doing so added a schedule to the Patents Act⁹² explaining what may or may not be patented in the area of 'biotechnological inventions'.

This schedule included the provision from the Directive relative to *Brüstle*. Article 3 of Schedule A2 states that 'the following are not patentable inventions', and Article 3(d) applies this to 'uses of human embryos for industrial or commercial purposes'. This latter phrase reflects word for word the prohibition in the Directive⁹³.

There was no judgment or case law directly applying this provision, so we do not have a clear judicial statement of the law in this case. However, the exact nature of the patent law can be clarified by

⁹¹ Article 8(2), The Patents Regulations 2000, 2000 No. 2037.

⁹² Schedule A2, Patents Act 1977.

⁹³ Article 6(c), *supra* note 52.

looking at the actions of the patent-granting body. This will establish the practical application of the law preceding the *Brüstle* ruling, and how Article 3 of Schedule A2 was defined at that point.

The relevant body is the Intellectual property office (IPO). Pre-*Brüstle*, the practice notice issued by the IPO stated their position by assessing three categories: human embryos; human totipotent cells; and human embryonic pluripotent stem cells⁹⁴. Totipotent cells can form any cells, both embryonic and extra-embryonic, and are developed in the first few cell divisions following fertilisation⁹⁵, whereas human embryonic pluripotent stem cells will develop into a specific aspect of the human body⁹⁶.

Processes for obtaining stem cells from human embryos were not patentable due to breach of paragraph 3(d) of Schedule A2 of the Patents Act 1977 – the provision directly transcribing the contested provision in *Brüstle*. Human totipotent cells were unpatentable due to their potential to develop into the human body, as prohibited by a provision unrelated to the *Brüstle*. Embryonic pluripotent stem cells, cells which do not have the potential to develop into a whole human body, were patentable, as on balance they were not deemed contrary to public policy or morality in the United Kingdom, despite widespread opposition.

In order to establish the scope of any changes, it is necessary to compare the previous practice note issued by the IPO to the corresponding note⁹⁷ issued after the *Brüstle* decision. In this newer note, the guidance on human embryos is more detailed, and includes several changes.

Firstly, a more specific definition of embryo is provided for the purpose of patents. In the Pre-*Brüstle* guidance, no specific definition is given of embryo, and the guidance merely states that ‘the Office will not grant patents for processes of obtaining stem cells from human embryos’. Following *Brüstle*, an ‘embryo’ is defined in three different ways with regards to patents.

- A human ovum as soon as fertilised, if that fertilisation is such as to commence the process of development of a human being;

⁹⁴ <<http://webarchive.nationalarchives.gov.uk/20140603093549/http://www.ipo.gov.uk/pro-types/pro-patent/p-law/p-pn/p-pn-stemcells-20120517.htm>>, first accessed 12/04/2015.

⁹⁵ Bosch, *Stem Cells: From Hydra to Man*, (Springer, 2008), 61.

⁹⁶ Han, Zhao, Fu, ‘Induced Pluripotent Stem Cells: The Dragon Awakens’. 60 *Bioscience* 4, (2010), 278.

⁹⁷ <<http://webarchive.nationalarchives.gov.uk/20140603093549/>>, first accessed 12/04/2015; <http://www.ipo.gov.uk/pro-types/pro-patent/p-law/p-pn/p-pn-stemcells-20120517.htm>, , first accessed 12/04/2015.

- A non-fertilised human ovum into which the cell nucleus from a mature human cell has been transplanted, insofar as it is capable of commencing the process of development of a human being;
- A non-fertilised human ovum whose division and further development have been stimulated by parthenogenesis, insofar as it is capable of commencing the process of development of a human being.⁹⁸

This is a far more specific definition than previously existed, and constitutes a noticeable change.

Secondly, the IPO will now not patent an invention if at any stage it involves the destruction of a human embryo. In the previous statutory guidance, the prohibition dealt specifically with ‘processes of obtaining stem cells from human embryos’. Now however, even if the invention does not involve an embryo itself, it is prohibited if the destruction of human embryo is involved anywhere in the process. This definition is not only more specific, but excludes a greater number of inventions from patentability.

There are several indications that this change is a result of the *Brüstle* judgment. Firstly, the definition above now reflects almost word for word the definition given by the ECJ in *Brüstle*, which gives a reasonable indication as to the definition’s source. It would seem an implausibly unlikely coincidence for the IPO to have adopted such a similar definition without at least some ECJ influence. Secondly, the case itself is mentioned in the practice note, which would indicate the IPO wish the changes to be read in the light of the judgment. This inclusion would subsequently indicated the change itself was influenced by the ruling. Thirdly, both academics and lawyers practicing in the field have noted that the judgment caused changes in the actions of the IPO⁹⁹.

Looking back at the hypothesis, Europeanisation has taken place similarly between the two cases. The Charter, in influencing the result of the *Brüstle* case, created a policy misfit between EU-level definitions and the definition at a Member State level. This created adaptational pressure to change, backed up with the implicit threat of sanctions for non-compliance, which led to change being transferred down to the British level – to the point where a term that was not previously defined is given a specific definition.

⁹⁸ Ibid.

⁹⁹ Bentley, Sherman, *Intellectual Property Law*, (Oxford, 2014), 524; Scott York < http://www.scott-york.com/index.php?action=content&content_id=309>, first accessed 09/07/2015; < Fazal, Ingram, < https://www.ashurst.com/publication-item.aspx?id_Content=8309>, first accessed 09/07/2015

Looking at the changes in the UK and looking at the framework laid out in the research design, these changes would initially be described as absorption. There is no concrete change to statute, but a new definition of ‘embryo’ has been passed down from the EU-level, changing the actions and practice of the patent-granting body within the UK.

However, whilst the legal change initially seems to only constitute absorption in the Europeanisation framework, the consequences of this definitional change lead to a much larger level of change. Given such research was permitted under previous practice, scientists within Britain spoke out in concern at the extent of the change and the harms it would pose for future research and research funding, given it would no longer be patentable¹⁰⁰. So whilst under the traditional Europeanisation framework, the change seems to only represent absorption, the practical effects of the change indicate it would be better classified as ‘transformation’.

4. Conclusions

The Charter represents a new era in fundamental rights protection within EU law. Analysis of the impact of the *Brüstle* case provides evidence for this paper’s hypothesis as to the practical impact of the Charter. Despite not being explicitly cited in the judgment, the presence of the Charter is acknowledged by both academics and the Commission as having had an impact on the judges’ decision-making process. The Charter’s existence and normative weight led to it having an impact on the Court’s decision-making in the case of *Brüstle*, as its existence altered fundamental rights norms.

The change and Europeanisation combined this normative element and the mechanism of change outlined in section 1.2. The Charter led to an EU-level definition (and policy, in that a specific definition of ‘human embryo’ constitutes a policy) which caused policy misfit due to different policies within the Member States. This policy misfit subsequently generated the adaptational pressure that leads to change within the Europeanisation framework. The Charter caused Europeanisation by causing the creation of these policy misfits. Therefore, looking at the overall picture, the existence of the Charter influenced a decision in a specific way, which subsequently led to Europeanisation. Therefore it can be said that the Charter caused Europeanisation in this specific area.

¹⁰⁰ <<http://www.theguardian.com/science/2011/oct/18/european-patents-embryonic-stem-cells>>, first accessed 04/06/2015; <<http://www.telegraph.co.uk/news/science/science-news/8834171/Stem-cell-research-thrown-into-disarray-by-European-patent-ruling.html>>, first accessed 04/06/2015.

These findings carry great significance, given the EU and the Charter are frequently discussed. Within the UK, there is significant debate as to the exact effects of the Charter, and it is widely believed that the UK enjoys an 'opt-out' from the Charter¹⁰¹. This paper has demonstrated that in spite of this, the mere existence of the Charter has led to substantive policy change within the UK, on an issue that raised substantial objections¹⁰². This finding is a significant contribution to debate around the impact of the Charter on the UK, in that it contradicts the existing political wisdom on the matter.

The findings of this paper carry different, if not unrelated, significance within Germany. For a legal system traditionally very attached to its own interpretation of fundamental rights, and the implementation of fundamental rights policy, it is significant that the Charter led to a more 'centralised' fundamental rights conception, leading to Europeanisation. It is another significant contribution to the debate when the Charter is leading to a more EU-level conception of dignity influencing policy, something seemingly anathema to the German legal community, as evidenced by repeated challenges to EU treaties on German fundamental rights grounds.

In finding that the existence of the Charter has led to Europeanisation of an area of health law, this paper has made a significant contribution beyond the above-mentioned discursive impacts in the UK and Germany. With health and health law remaining a deeply significant issue within states as well as of increasing importance in academia, this paper has demonstrated that there is a new factor to be considered when studying the development of health law – the Charter. This paper renders the Charter an ongoing concern within the field of health law backing up previous claims of its influence with empirical findings.

Furthermore, this paper has provided a theoretical analysis of the role of law within Europeanisation, backed up with some empirical evidence. Specifically it has analysed the role of the Charter within this framework. This finding brings the Charter within Europeanisation literature in a novel way. Whilst this paper is limited to a narrow assessment of the Charter's Europeanising effects in some areas, the finding that the Charter causes Europeanisation at all is noteworthy, and opens up the prospect for future research on the Charter using this framework.

¹⁰¹ <<http://www.theguardian.com/politics/2013/nov/19/chris-grayling-clarification-eu-charter-rights>>, first accessed 16/06/2015.

¹⁰² *Supra* note 100.

This paper has demonstrated that the Charter has caused Europeanisation within the UK and Germany, in a way that is notable for political and legal discussion in both countries. It remains to be seen whether these effects extend beyond the area of biotechnology and patents to wider areas of health law and policy, but this paper has certainly demonstrated this possibility. Given the political significance of both health and the Charter, it is an important area for future investigation.

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