

Intellectual Property, Biotechnology and Process Tracing: Applying Political Research Methods to Legal Study

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This chapter explores the application of a novel research method for law to a question concerning how different legislative systems underpinned by substantially different political and institutional structures and cultures can nevertheless reach very similar regulatory outcomes. It takes the example of the limitations placed upon the patenting of human embryonic stem cell-derived inventions (or hESCs) on the basis of moral concerns in the EU and China, two systems in which the moral status of the embryo differs considerably. This chapter considers how the use of process tracing, a methodological tool from political science and international relations, can be used to explore how divergent institutional designs can identify and solve problems with very similar solutions, despite very different processes of identifying and approaching those problems. Exploring the role of institutional learning as a means of regulatory transfer, this chapter demonstrates how the use of a process tracing socio-legal method can allow lawyers to better understand the causes of legal change in a way that cannot ordinarily be uncovered using more traditional doctrinal analysis.

Introduction: Studying the politics of law-making

The study of biotechnology in the social sciences often falls into discrete disciplinary categories, whether it is in the form of doctrinal legal study of biotechnological inventions in patent law (Bonadio 2012), the consideration of social implications of these inventions in bioethics (Savulescu 2009), or the analysis of interest group interventions in areas of controversy such as genetically modified organisms and agriculture in politics and public policy (Skogstad 2003). In my research, I attempt to bring these various fields together in interdisciplinary analysis of what could broadly be called biotechnology regulation. Whereas doctrinal study of biotechnology patenting tends to focus on questions of what ‘is’ or ‘ought’ to be patented, or compares approaches under different regimes, it does so in a way that focuses very much on textual analysis of legislation and legal decisions. Similarly, bioethics is more

akin to a philosophical perspective on the ‘ought’ of biotechnology patenting (where it considers patents at all, as opposed to macro-level discussions of the morality or ethics of biotechnology research or application), comprising a more normative approach to the study of emerging technologies. Finally, public policy approaches have tended towards the study of the role of different stakeholders in making their voices heard over controversial biotechnological subject matter. My research is centred at a nexus between these approaches, seeking to better understand how different ideas, norms or beliefs (relating to the ‘bioethics’ dimension of this field of study) can influence legislative bodies or courts by focusing on how actors are able to change the approaches or perspectives of these bodies in areas considered controversial (the public policy dimension), resulting in specific legal outcomes (the legal dimension). A different way of putting this is that my research in the field of biotechnology seeks to better understand or explain legal change in areas of controversy, exploring the ways in which a multitude of different law and policy actors are able to take their vision of what law ‘ought’ to be, and effectively make it what law ‘is’. In order to do this, however, it is necessary to answer these questions in a coherent way, using an appropriate theoretical and methodological approach tailored to explaining change.

Process tracing: explaining legal change

This chapter considers the application of a change-explaining methodology, process tracing, to a project that explored the history of the patentability of inventions derived from human embryonic stem cell (hESC) research in the systems of the EU and China (Farrand 2016). Process tracing ‘attempts to identify the intervening causal process [...] between an independent variable and the outcome of the dependent variable’ (George & Bennett 2005:6), by providing an analysis of evidence of ‘processes, sequences and conjunctures of events within a case for the purpose of either developing or testing hypotheses about causal mechanisms that might causally explain the case’ (Bennett & Checkel 2014:7). To put it another way, process tracing is a method used to analyse the intermediate steps between an action and an outcome that may help us to explain or understand how a particular outcome was reached. In the context of legal study, process tracing as used in this project makes its most valuable contribution in providing a rigorous methodology for uncovering the processes by which particular norms, beliefs, ideas or ideological positions produce concrete legal results. Socio-legal scholars can apply this approach to a range of different issues or questions, going beyond purely biotechnological research. Hypothetical examples of how this could be used

include: a family lawyer seeking to explore how a change in government may result in a shift in discourses concerning how a family is constituted, and how this may impact upon legislative initiatives in fields such as equal marriage or gender recognition; a contract lawyer who wants to understand how hegemonic ideas concerning market freedoms represented in contemporary capitalism shape understandings of bargaining power and privity of contract represented in legislation; or an EU lawyer working to identify how Euroscepticism as a phenomenon works to facilitate opt-outs from particular fields of EU activity just as Justice and Home Affairs. Process tracing can of course go beyond the ideational – socio-legal scholars of a more positivist bent could instead be interested in, for example, how decision-making in House of Commons Committees may influence the content or wording of Acts of Parliament, or how the wording used by a judge in a decision is used to distinguish a new set of circumstances from an existing precedent in an interesting or controversial case, so as to achieve (and indeed, justify) a preferred outcome. In this way, process tracing can be applied to a wealth of different issues in socio-legal analysis; it is not tied to any particular subject matter or disciplinary perspective but can be used to interrogate change in a range of different areas of law, focusing on very different institutions in very different contexts, as explored further in the section of this chapter on my research on biotechnology patenting.

These causal mechanisms can be unobservable physical, social, or psychological processes through which actors are able to affect change in other entities, such as individuals or organisations, whether in terms of attitudes, behaviours or actions, until another intervening causal mechanism acts upon them (George & Bennett 2005:37). This means that it goes beyond discourse analysis as a methodological tool, or indeed doctrinal legal analysis, insofar as it does not seek to provide a descriptive account of ‘A happened, then B’, but ‘A led to change/result B, because of X’. Process tracing seeks to explore the role of ‘X’ in more detail, identifying the relationships between it and ‘A’ and ‘B’, as well as considering why ‘X’ is a more convincing explanation than ‘Y’. It is at its most useful when seeking to explain or understand a particularly interesting, unusual or puzzling outcome, or one that appears on the surface at least, to be counter-intuitive. In terms of theoretical approach, Beach and Pedersen, the ontology of process tracing is *deterministic*, insofar as it relates to the identification of necessary and sufficient causes in individual cases and *mechanistic* in that the focus of analysis is upon causal mechanisms that explain outcomes (2012:27–28). Bennett and Checkel recommend a three-part best practice standard, based in meta-theory, context and method (2014:21). Meta-theoretically, the theories used to explain the function of these mechanisms

must be ontologically consistent with a mechanism-based understanding of social reality, requiring researchers to consider carefully the hypothesised causal mechanism and underlying theoretical framework (2014:23). Contextually, researchers should place the phenomenon in its wider context with a clearly stated hypothetical causal process (2014:21), indicating the importance of conceptual clarity. Methodologically, the work should take into account the issue of ‘equifinality’ – the possibility that multiple paths may result in the same outcome, and that these alternative explanations should also be considered in order to determine whether they, or the hypothesised mechanism are more likely to have resulted in the observed effect (George & Bennett 2005:153–160; Bennett & Checkel 2014:20).

Brady, Collier and Seawright state that an essential characteristic of process tracing is making causal process observations, defined as ‘observations on context, process, or mechanism [...which] provide depth of insight [...and] are routinely used in qualitative research based on within-case analysis’ (2010:12). Through the observation of these processes, process tracing allows for qualitative researchers to more effectively explain or understand particular outcomes. For example, in ‘International Actors on the Domestic Scene: Membership Conditionality and Socialization by International Institutions’, Kelley (2004) sought to identify the causal mechanisms that resulted in Eastern European states passing ethnic minority protection legislation in the 1990s. In this work, Kelley stated that ‘socialization-based methods [...] were not very effective when used alone, and I show [...] that more rational choice-based efforts such as membership conditionality were crucial in changing policy’ (2004:426). In this explanation, Kelley both identifies the theoretical framework in which the mechanism is to be assessed, namely rational choice, and the mechanism by which this effect was achieved, that of membership conditionality, in which the desire to become part of international organisations such as the EU influenced domestic actors to pursue policy changes (2004:431–433). Furthermore, Kelley provides clear consideration of alternative explanations, including the threat of sanctions from Russia if minorities of Russian origin were mistreated, or with domestic application of principles of democracy, determining them to be insufficient in explaining the outcomes observed (2004:433–434).

Process tracing as a method of understanding the ways in which certain legal outcomes are reached is something of a novelty in legal research; indeed, its use thus far has predominantly been by political scientists and international relations scholars seeking to place legal change in a broader context of existing theoretical models or explanations for the actions of policy-

makers or judicial bodies. Examples come from different disciplinary fields: Obermaier's (2009) work on European Court of Justice (ECJ) jurisprudence, analysing the applicability of several different explanations for Europeanisation of controversial legal decisions is firmly grounded in political science. Mantilla's (2017) study of the reasons why the US and UK joined the 1949 Geneva Conventions is a key example of the application of international relations theories to why political actors make legal commitments. Yildirim's (2018) consideration of the causes of significant differences in the time it takes different WTO Members to facilitate compliance with an adverse WTO panel ruling is based in political economy. This admittedly non-exhaustive body of work nevertheless indicates that historically, the application of process tracing to law is done from an external disciplinary perspective, in which law or legal change constitutes an interesting case study or puzzle, rather than it being used as an internal means of critiquing or analysing socio-legal issues. The project I will expand on in the next section of this chapter was an attempt to bridge these disciplinary boundaries. By taking an interdisciplinary approach to legal study, using process tracing to explore an interesting question about similar legislative outcomes in very different legal regimes, new insights into legislative development could be made possible.

Process tracing in socio-legal research: theoretical and methodological synthesis

The project I applied this approach to originally began as a relatively 'simple' comparative analysis of the patentability of inventions derived from human embryonic stem cell (hESC) research in the systems of the EU and China. The initial research had been conducted as part of a workshop in 2014 exploring synergies between EU and Chinese law, bringing together scholars from the EU and China working on issues such as financial regulation, environmental protection and intellectual property law. At this point in time, debates over the extent to which hESCs constituted a form of 'life', and the extent to which the granting of a patent over inventions derived from them would be contrary to *ordre public* or morality under the EU's Biotechnology Directive Article 6 (98/44/EC) appeared to have been settled after the *Brüstle* case. In *Brüstle* the Court of Justice concluded that as hESCs could only be derived from the destruction of the embryo, which it considered to constitute life as it has the potential to develop into a human being, a patent could not be granted over the invention derived from this destruction of life (Farrand 2016:270–271). In the event of hESCs being derived from artificial electrical stimulation of an oocyte, which could not develop into a human being, then no destruction of life occurs (Farrand 2016:271). In the context of the workshop I was involved

in, I became curious about the restrictions on patentability in the field of biotechnology that may arise in the Chinese legal system, and how these may differ from those of the EU, in order to assess a potential area of legal divergence between the two regimes. On this basis, I decided to consult the official translation of the Chinese Patent Act held by the World Intellectual Property Organisation, where I made an interesting finding. While the specific language used in the Chinese Patent Act was not identical to that of the Biotechnology Directive, it was remarkably similar. While Article 6 of the Biotechnology Directive states that ‘inventions shall be considered unpatentable where their commercial exploitation would be contrary to *ordre public* or morality’, Article 5 of the Chinese Patent Act states that ‘patent rights shall not be granted for invention-creations that violate the law or social ethics, or harm public interests’. Interestingly, the 2010 Guidance accompanying the Chinese Patent Act on how this should be interpreted indicates that ‘the use of human embryos for industrial or commercial purposes is considered contrary to public morality and derived inventions not granted patent rights’ at p.131. In fact, there is compelling evidence to suggest a chain of legislative development beginning with the Biotechnology Directive and ending with the Chinese Patent Act and its Guidelines – the European Patent Convention (EPC) and the guidelines established by the European Patent Office (EPO) were directly based on the Biotechnology Directive as it relates to biotechnology-related patents, and the EPO guidelines were highly influential on the Chinese guidelines. But why was this the case? Why did the Chinese law mirror the EU and European Patent Office standards?

In order to better understand this puzzle, I used process tracing as a method to determine what causal mechanisms may help us to understand the means by which two very different legal systems nevertheless implemented very similar restrictive approaches to patenting hESC-derived inventions. Referring back to Bennett & Checkel’s best practice standards, I needed to ensure that consideration was paid to the theoretical, contextual and methodological dimensions of the research. In terms of theory, epistemologically my work is of a social constructivist nature; this epistemological position holds that ‘people do one thing and not another due to the presence of certain “social constructs”: ideas, beliefs, norms, identities or some other interpretive filter through which people perceive the world’ (Parsons 2010:80). In particular, my research is governed by the belief that in order to understand the decisions made by policymakers, it is important to consider the introduction of new ideas (see generally Beland & Cox 2010), starting from ‘the recognition that we cannot hope to understand political behaviour without understanding the ideas that actors hold about the environment in which

they find themselves’ (Hay 2002:208). But is process tracing compatible theoretically with a social constructivist perspective? Beach and Pedersen perceive process tracing as being firmly within positivist epistemology, in which the emphasis is about making observations regarding ‘facts’ in the real world, and providing clear causal *explanations* in the form of independent variable A impacting upon dependent variable B. Goertz and Mahoney take a similar position, holding that positivist qualitative analysis is concerned with ‘explaining outcomes’ (Mahoney & Goertz 2006:230–231), with Hall arguing that ultimately, process tracing is positivist in nature and therefore incompatible with a strongly interpretivist epistemology (2013). However, Hall does acknowledge that there could be benefit in considering more fully the meaning actors ascribe to their actions (that may constitute the causal mechanism itself) (2013:24), with Vennesson maintaining that process tracing can be used in both positivist and interpretivist research designs, and that the combination of the two may indeed be useful (2008:224). Constructivist approaches to causal mechanisms allow for the consideration of the reasons that actors give for their chosen actions, and to investigate relations between belief and behaviour (Vennesson 2008:233). In this respect, Wendt argues that there is a difference between ‘traditional’ considerations of causation, and constructivist considerations of ‘constitutive’ relations (1998) that help us to better understand how certain changes occur, or ‘[how] we construct certain meanings and so “constitute” certain political arenas and actions’ (Parsons 2010:87). However, as Parsons makes clear, this is not to say that constructivism does not allow for causal inference (Parsons 2010:88), only that it does so by considering how meaning is constructed by actors, which may help us to better understand why and how they take the actions that they do. Theoretically then, my approach was consistent – my intention was to consider the role of ideas in institutional settings, seeking to better understand how ideas serve to constrain or facilitate legislative approaches to controversial issues by focusing on the processes by which that legislation is created. In this instance, I wanted to understand how very different systems of legislative development in different contexts resulted in very similar outcomes, focusing on the role of ideas, beliefs and norms. Institutions, and those operating within them, work to a ‘logic of appropriateness’, in essence rules of the game that determine what is acceptable or unacceptable within a particular context, or in the case of policy and legislative development, what solutions are deemed to be appropriate and facilitated, and those which are inappropriate, and hindered or discounted. In this respect, institutional path-dependence means that the governing contexts, rules and history of decision-making bind the decision-making of the future, absent a significant rupture or external shock that results in a change in decision-making (see for example Lewis & Steinmo 2012). Therefore, in this project

I wanted to apply this theoretical approach to institutional approaches to hESC-related patents, in order to assess the role of this path-dependence on the decision-making processes resulting in similar policies.

The next consideration was context. In this project on hESC patentability, context was twofold; I needed to place the analysis in the context of IP law generally, including the position of both the EU and China as WTO members, and subsequently, party to the TRIPS Agreement, and the context of the law-making systems of the EU and China specifically. Beginning with the issue of IP law, TRIPS requires compliance with a set of minimum standards that form the basis of the international framework for IP protection. This prevents considerable divergences between states in what may be patented, with Article 27 outlining what constitutes patentable subject matter. The exceptions to patentability are listed under Article 27(2), which state that ‘Members may exclude from patentability inventions, the prevention within their territory of the commercial exploitation of which is necessary to protect *ordre public* or morality, including to protect human, animal or plant life or health or to avoid serious prejudice to the environment’. The emphasis here, however, is on the ‘may’, meaning that while states are required to conform to the patentability criteria set out in Article 27(1), the exceptions carved out in 27(2) are optional, meaning that states are not obliged to incorporate these exceptions into their national laws (see Henckels 2006). Furthermore, other states party to TRIPS, such as the US and Israel, do not impose restrictions to the patentability of hESC-derived inventions on this basis. Therefore (and as will be discussed in more detail below), the existence of this permissible exception in the TRIPS Agreement is not sufficient to explain the similarities between the EU and Chinese regimes, despite their institutional differences. This also means that a legal doctrinal approach would be insufficient in explaining the similarities, given this legal flexibility, requiring the use of a different approach, necessitating the use of interdisciplinary methodology.

In terms of institutional design, the EU and China have very different processes for legislative development. While not covering all the complexities of EU law-making (and at the risk of simplification), the Commission has the right of legislative initiative, with the Council of the European Union and European Parliament having the ability to approve, modify or reject legislation. Stakeholders can become involved in the legislative process at the stage of agenda-setting in the Commission through participation as experts (Farrand 2015), or later through the lobbying of the European Parliament (and to a lesser extent the Council of the European Union)

in a form of participative deliberation over the content of legislation (Farrand 2016; Farrand 2015; see also Coen & Richardson 2009). In China, however, the legislative process is more closed and opaque. It instead gains its legitimacy not through general participation, but instead the formalisation of processes and institutions. However, experts are still involved in law-making processes, both as a means of formulating policy as well as legitimate the decisions made, in a form of authoritarian deliberation (Farrand 2016; He & Warren 2011). Here, then, was a divergence in institutional design, but with one commonality, namely the involvement of expert groups. However, from a social constructivist perspective, the notion of expertise is in itself a constructed one – *who* is considered an expert, and *how* is expertise used? Therefore, focusing solely on the commonality of expertise and ignoring the other divergences as a means of understanding the similarities in law would also be insufficient. A deeper understanding of the processes at work in the formulation of the EU Biotechnology Directive and the Chinese Patent Act was therefore required in order to identify potential causal mechanisms for these similarities.

Methodologically, process tracing is something of a laborious undertaking, requiring review of large volumes of information, in the form of speeches, preparatory works, Commission working papers, resolutions of the European Parliament and other sources that may be of relevance in following the course of legislation from initial idea to final adopted text. By analysing these documents, and in particular, how and when these documents are modified, it is possible to gain a better understanding of the ideas or beliefs that had an impact on the finalised text of the legislation, or in other words, identifying potential causal mechanisms for legislative outcomes. Tracing the development of the Biotechnology Directive, it was possible to determine that the Directive was significantly modified during its passage from Commission proposal to finalised legislation. In particular, the first version of the Directive made no specific references to morality, and exclusions concerning the patenting of living matter were not present – in other words, the current Articles 5 and 6 of the Directive did not exist in the original proposal. This was the cause of some concern in the European Parliament, which was being heavily lobbied by interest groups representing secular and religious concerns concerning biotechnology-related inventions and patenting. Consideration of European Parliament resolutions, as well as the use of Eur-Lex as a means of reviewing each document published during the passage of the Directive, including the ultimate rejection of the first draft and the passing of a subsequent draft that included the provisions on morality and life matter was useful in determining the role of interest groups and participative processes in the

European Parliament in facilitating a significant change in the content and wording of legislation (for a more comprehensive analysis, see Farrand 2016:273–275).

In comparison, the process for the passage of the legislation and guidelines in China was a more closed process, with a notable absence of interest group representation. Instead, based on the interviews conducted by Sleeboom-Faulker (2014), the process in China was instead expert and elite-driven, with legislation and guidelines being drafted on the basis of coordination with medical scientists working in the field, who were themselves sceptical of public involvement in the legislative process. Furthermore, the authoritarian deliberation of the Chinese system was undertaken in a context in which China was investing significant resources in developing its national biotechnology and IP-intensive industries. Why then did they decide to pursue a more restrictive and limited regime for hESC-derived patents? The explanation provided in my project was the role of learned practice and internalisation. Many of the Chinese biotechnology researchers who returned to China as a result of the government's policies and were involved in the drafting of the legislation and guidelines were partly educated (either as postgraduate or doctoral researchers) in European nations, subsequently becoming involved in postdoctoral projects in these research institutions. These research institutions were required to comply with the standards of best practice, ethical compliance and adherence to the rules of the Biotechnology Directive when it came to the publication of results. Through this process of institutional learning, in which legislation dictated that inventions involving the destruction of embryos could not be patented, researchers came to internalise the appropriateness of these rules. When they returned to China, these internalised rules and understandings then guided their responses to government requests for information regarding the drafting of its own biotechnology-patenting regulations. In addition, by complying with these stricter standards, cross-state collaboration with European partners in existing research relationships could be more easily facilitated, as standards of institutional research practice would be seen as compatible (Farrand 2016:275–277). Therefore, despite significantly different institutional designs, with different means of legislating with different logics of appropriateness nevertheless drafted similarly restrictive legislation and guidelines on patenting hESC-derived inventions.

Yet could there be other more convincing explanations? With process tracing, it is important to consider the issue of equifinality - the possibility that multiple paths may result in the same outcome, and that these alternative explanations should also be considered in order to

determine whether they, or the hypothesised mechanism are more likely to have resulted in the observed effect (George & Bennett 2005:153–160). As discussed above, the requirements of the TRIPS Agreement upon the EU and China were not sufficient – any morality or *ordre public* exceptions to patenting were ultimately up to states to determine the appropriateness of, resulting in different approaches in different states, with the US taking a much more liberal approach than that taken by the EU and China. Another consideration was different moral statuses of the embryo in the different cultures. Could it be that a strong conviction that an embryo reflected the starting point of life would be sufficient for both regimes to exclude from patentability inventions that resulted in their destruction? Based on the process-tracing research, the answer was ‘no’. Not only were moral statuses significantly different *within* European states, both with regard to differing levels of religious objection between Catholic and non-Catholic countries, but secular objections based in historical atrocities also led to divergences between various EU states on the level of protection that should be afforded to an embryo. In China, where Christianity arguably holds less influence than Confucian thought, the embryo has lesser moral status than in Europe, where life is predicated on the development of social relationships, and embryonic research actively encouraged and the regime for regulating the research undertaken being much more liberal than those permitted in EU states (for a more comprehensive comparison of the different approaches see Farrand 2016:269–272). This leads, as Jiang has stated, to the ‘paradoxical’ situation in China where human embryos have low moral status in practical scientific application, but high moral status in patent law (2015:81–82). For this reason, this other competing explanation is also less convincing than the one of institutional learning and divergences in logics of appropriateness, helping to support the main argument made.

Improving the analysis: lessons learned and refining the approach

Perhaps the most interesting finding of this research project was the discovery that divergent institutional decision-making structures, with very different approaches to moral claims in the field of biotechnology research, could nevertheless design very similar regulatory solutions to perceived problems. By using process tracing to better understand the origins and development of the EU and Chinese approaches to hESC-derived invention patentability, the importance of institutional learning and the transfer of ideas as a source of regulatory best practice could be uncovered. If this analysis had been performed using a more standard comparative doctrinal legal approach, this interesting insight may have been lost. While a perfectly serviceable

comparison of the two regimes *may* have been possible, an understanding of the underlying factors resulting in such a level of regulatory similarity would not have been.

This is not to suggest that the approach used here was perfect, or that it could not be improved upon. While the application of the method was rigorous, and the adherence to the theoretical and contextual dimensions maintained, I could have been more explicit in the discussion of the use of process tracing, and clearer on the issue of equifinality. On the first issue, as noted above, the use of process tracing was informed by a social constructivist perspective in which the key independent variable was that of institutional design, with the causal mechanism linking the independent variable to the dependent variable of legislative outcome being ideational path-dependence. As Dür and De Bièvre state, it is important in process tracing work to be explicit about methodological choices, by necessity ‘spelling out the causal mechanism’ (2007:8). In my article, while I do use process tracing to demonstrate this mechanism, conceptualising and defining terms such as path-dependence and constructivism, I do not explicitly refer to the use of process tracing as the method for conducting the research, and nor do I discuss these concepts in terms of variables and causal mechanisms, leaving this implicit in the analysis. An improvement would have been to make this explicit.

As with the use of process tracing as a method, the use of equifinality as a way of demonstrating the convincingness of the identified causal mechanism was implicit rather than explicit. While independent variables such as membership of the WTO (and therefore being states party to the TRIPS Agreement) and the moral status of the embryo in the comparator regimes were demonstrated as being insufficient to explain the similarity of legislative outcomes, the analysis was not conducted using these specific terms. This is in part due to the narrative style of the work, written for a legal audience rather than a political science or international relations one. An example of a work that is more explicit in its discussion of process tracing methodology and clear use of equifinality as a means of considering and discounting competing explanations is that undertaken by Deters, which was written with the intention of demonstrating the utility of process tracing in qualitative research (2013:75, 79). Deters states that the form of process tracing used in their work combines theory generating with theory testing, seeking to explain why environmental policies in the EU are subject to a wide level of variance, with different causal mechanisms explaining the different outcomes, or complex combinations of mechanisms achieving the result (2013:79–80). There is also consideration of equifinality, in the discussion of counterfactual examples that may have changed outcomes, or alternative

mechanisms which may explain the same result. The explicit identification and explanation of the methodology of process tracing in order to explain policy decisions in a contentious area is a particular strength of this work and can improve research using process tracing as a means of identifying causal mechanisms.

It may have been interesting to consider a counterfactual in order to demonstrate the importance of ideas concerning legislative process and institutional design as an explanation for the similar regimes for the patentability of hESC-derived inventions in the EU and China. A counterfactual can be used to dispel an alternate hypothesis (Haas 2015:123), where the presence or absence of a particular causal mechanism can help to reinforce or weaken an argument regarding the importance of the identified causal mechanism to the outcome observed. For example, what may have happened in the EU regarding the passage of the Biotechnology Directive had the participative element of citizen and interest group engagement with the European Parliament been absent? As stated above, the Commission's Proposal for a Directive, there was no specific exclusion as currently contained in Article 6, and it was the involvement of interest groups appealing to the European Parliament to reject the initial proposal that resulted in the redrafting of the Directive with a specific morality exclusion to patentability. Had the role of the European Parliament been purely consultative, and if interest groups not protested the content of the Directive, then the original draft may have entered into law, with the result that inventions derived from hESCs could be patented. In the event of a case such as *Brüstle* being heard on the basis of an objection to the destruction of an embryo in order to obtain stem cells, the absence of Article 6 could have led to a different decision by the CJEU regarding patentability, if indeed the case would have been referred there to begin with. Similarly, what if the academics involved in the legislative process in China had not been educated and involved in research project in European countries? In the absence of the institutional learning and internalisation of ideas regarding best practice and the conduct of research within the context of the Biotechnology Directive and EPC, would the recommendations of the Chinese researchers have been the same? This cannot be definitively proven, but in the event of dispelling alternative explanations such as the moral status of the embryo, cannot be easily dismissed either. Would an externalised international (and potentially abstract) concept of best practice have been as influential in the event that it had not been experienced by the Chinese researchers involved in informing the legislative process of the Chinese Patent Act? From a social constructivist perspective, this would appear somewhat

unlikely. Nevertheless, these are interesting questions, and ones in which the introduction of a hypothetical counterfactual could provide additional avenues for analysis.

Process tracing and socio-legal research: the broader implications

Having considered how process tracing was used in the context of my biotechnology-related research, must now turn to considering how this approach can be used by other socio-legal researchers. Process tracing provides both a method as well as a methodology for approaching these example objects of study, allowing for scholars to conduct a robust analysis by ensuring a theoretical, contextual and methodological synthesis in the consideration of these phenomena. To be used in this form of socio-legal study, the researcher must consider the theoretical approach to be taken – is their causal mechanism compatible with their underlying epistemology? They must also take into account the broader context in which that decision to distinguish the case was made, and to consider alternative explanations. Applying this in the hypothetical example, let us assume the researcher considers that social pressures upon the judiciary to change their attitude to a particular issue is the causal mechanism linking the independent variable (the particular case in question) to the dependent variable (namely, the change in the law as a result of judicial reasoning). Epistemologically, the researcher may hold that judges are ultimately rational actors acting in the interest of ensuring the legitimacy of decision-making, requiring adherence to social norms. Therefore, when social norms change, so too will the decisions of the judiciary. The researcher must then consider the context – are there indications that society’s view of that issue *has* changed? This may require exhaustive documentary evidence, whether in the form of media reporting, opinion polling, interviews, statements by politicians or other sources that may help to identify that potential changing social norm. Methodologically, does that indication of the awareness of social change appear in the decision, and does it appear influential in the justification in the overruling of existing precedent? To be effective process tracing, the researcher should also consider the issue of equifinality, and the possibility of more convincing alternate explanations. Are the facts significantly different to demonstrate a reason to take a different position? Has the judge released a statement, or been interviewed subsequent to the decision, in which they make it clear that social pressures had no bearing on the decision? While these alternative explanations may not necessarily be exhaustive, they should nevertheless be potential avenues for a socio-legal scholar to explore. This does of course require that evidence is obtainable – this may be more difficult in the case of judicial decision-making, particularly in legal systems in which

this reasoning is not made public. For this reason, the use of process-tracing is dependent upon the ability to gather the body of information required to consider various explanations for an observed outcome.

The relevance of process tracing to socio-legal studies is that it can assist in opening up the ‘black box’ of politics that is often considered outwith the domain of legal study, or alternatively, hinted at or discussed with little in the way of methodological consideration. As Unger once stated, an approach to law founded in doctrinal formalism and a dismissal (or at the least, an absence of consideration) of the politics and contestation of law was a misguided enterprise; ‘for how could law, produced through conflict among interests and ideologies, come to look, after the fact, in the hands of professional interpreters, as if a single mind and will had conceived it?’ (Unger 2015:11–12). If, as socio-legal scholars, we wish to place law in its greater social, cultural and historical contexts, then the black box of politics and policy must be opened, rather than adhering to the use of ‘policy’ as a fashionable addition to the study of ‘law and...’, with little in the way of conscious thought behind it. Process tracing is one of the methods that can be used to carefully open that box and examine its contents, helping to link origins, causes and effects in a way that withstands scrutiny and is cognisant of the counter-arguments and competing explanations. To put it another way, process tracing can go beyond telling us the ‘what’ of law, or even the ‘why’ of law, to understand the ‘how’ of law. It allows us to go beyond saying (as one example) ‘this law is the result of lobbying’, to better explore and understand *how* different types of lobbyist (or interest group) were able to effectively lobby, *how* they were able to influence the language or scope of legislation by consideration of their strategies, and *how* this explanation is more convincing than another based in the idea of an impartial and uninfluenced parliament. Being able to unpack these processes is highly beneficial to socio-legal studies at this time of political and legal uncertainty and contestation; whether we consider the role of ‘populist’ parties and communication (for more on this see Laclau 2007) in serving to influence both general understandings of law and specific approaches to legal issues. Process tracing could be useful in considering the regulation of the Eurozone and responses to the Stability and Growth Pact) by new political parties, challenges to judicial reform in Poland and the use of ‘rule of law’ as a rhetorical device to both facilitate and hinder such reforms, or how the broader context of revelations regarding political manipulation and use of data such as in the case of Cambridge Analytica may serve to change approaches to both data protection law, as well as electoral laws concerning advertising and political communication. Process tracing could be used to explore how national developments

and concerns regarding refugees, and the knock-on effects on parliamentary politics then shape European responses to migration, such as current debates over the reform of the Dublin processes. It could also be used to search for alternative explanations, which may be as, if not more convincing, than current understandings of anti-immigrant hostility, particularly in Southern Europe. But perhaps most importantly, process tracing methodologies allow for this analysis to be done with the application of rigorous appreciation of theory, context and application of method, as a means of ensuring that the socio-legal research performed in highly contentious or controversial areas can be done in a way that withstands scrutiny.

Conclusions and further reading

In conclusion, process tracing can be a highly useful method of analysis for socio-legal scholars. It assists the researcher in unpacking political and social contexts, linking actions to their outcomes through the identification of causal mechanisms or processes, helping them to better understand *how* changes in law may come about, particularly in areas of political or moral controversy. Process tracing also helps the socio-legal researcher to explore these processes in a methodological way, requiring the researcher to carefully consider the compatibility of their approach with their epistemological position, awareness of the broader context in which their research and observed phenomena are placed, and with due consideration of equifinality and alternate explanations. Its flexibility both in terms of perspective (whether positivist or interpretivist), as well as its potential for use in a wide range of different scenarios, makes it a valuable asset in critiquing legal developments in a way not often undertaken in contemporary legal scholarship.

Suggested further reading

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