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Ethics vs. Innovation? The Impact of Embryo Research Laws on the Innovative Ability of National Economies

Simon Fink (University of Bamberg)

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Abstract

The article assesses the empirical veracity of the frequently heard thesis that strict embryo research laws can hinder innovation in embryo and stem cell research, and thereby impede the innovative ability of the medical biotech sector. Based on a comparative study of the OECD countries, and case-study material, the article argues that this thesis can only partly be confirmed. Strict embryo research laws are associated with a lower innovation quota in stem cell research. But this correlation mostly reflects stable structural differences between national innovation systems rather than dynamics triggered by policy measures. Permissive embryo research laws are not automatically associated with an innovative biotechnology sector, and the innovativeness sometimes is a partly unintended consequence, rather than the result of an active political strategy. The results of the analysis caution against undue simplified theses on the impact regulation can have on the innovative ability of national economies. If there are impacts of embryo research laws on the innovative ability of the biotech sector, they will be visible only in the long term. Short-term political steering efforts have to be judged very sceptically.

1 Introduction

Research institutions, politicians and representatives of the pharmaceutical industry alike claim that embryo and stem cell research are part of the most promising branch of medical biotechnology, and that exceedingly strict regulation of this research severely impedes innovation in the medical biotechnology sector (Standing Committee on Legal and Constitutional Affairs 2000; Deutsche Forschungsgemeinschaft 2001; Association of the British Pharmaceutical Industry (ABPI) 2004). On the other hand, opponents of stem cell research doubt the veracity of this claim. They argue that a ban of embryonic stem cell research is ethically necessary and does not inhibit innovation (Campbell 2001; Lilge 2001; Spaemann 2001).

The actors in this debate have mostly used abstract reasoning, hypothetical examples, or anecdotic evidence. Empirical studies on the consequences of permissive or strict embryo research laws on the innovative ability of national research systems are rare. This article tries to fill this gap, and analyzes empirically whose claims can be confirmed. Embryonic stem cell research is part of the scientific and political agenda since ten years (Gearhart 1998; Thomson 1998), and the first laws that explicitly deal with embryonic stem cell research date back to the same time. Laws regulating embryo research – the larger research field in which stem cell research is embedded – have been passed as early as 1987. Thus, it is not premature to conduct a first evaluation of the question whether strict embryo research laws do indeed impede innovation in stem cell research.

Methodologically, the article applies a quantitative approach and traces the relationship between the strictness of embryo research laws and innovations in the stem cell sector in the Western OECD countries from 1994 to 2006. The quantitative comparison is used to draw some general conclusions about the hypothesis, and to identify interesting country cases, which are studied in more detail. Thereby, the advantages of quantitative and qualitative approaches are combined and their weaknesses compensated (Lieberman 2005).

The article argues that the relationship between the embryo research law and the innovative ability of the medical biotech sector is complex and does not correspond to the views of either of the opponents in the debate. There is no systematic short-term effect, executed by the strictness of embryo research laws, on the innovativeness in the stem cell field. Neither do strict laws lead to a decline of innovations, nor do permissive laws automatically lead to an increase in innovations. The field is rather characterized by long-term structural differences. Case studies additionally lead to the conclusion that an increase of the innovativeness of the sector may in a few cases be the result of a political strategy, but coevally it often may be a concomitant phenomenon of regulatory inactivity. Thus, the argument that strict regulation instantly impedes the innovative ability, and permissive regulation leads to an increase in innovations is not supported. That does not exclude, however, that different embryo research laws in the long run and in a more subtle way may have such an effect.

The structure of the article is as follows. The second section outlines in short the controversy and the theoretical arguments, and additionally formulates the main hypothesis. In the third section the data and methods used to test the hypothesis will be focused on. The fourth section comprises the analysis. The fifth section summarizes the findings and hints at further venues of research.

2 The controversy: Are bioethics and innovative ability incommensurable?

Embryo and stem research are elusive notions, hence some basic definitions must be clear to get an overview of the field and to understand the major promises and ethical problems. Embryo research is here conceived as all techniques or scientific enterprises focusing on the human embryo. The embryo is the first stadium of human development, from the first division of the zygote (the fertilized egg) until it becomes a fetus (that is, major structures and organ systems begin to form).

Human embryos first came on the political agenda in 1978, when the first baby was born using in-vitro-fertilization (IVF). For IVF, eggs are fertilized – i.e. embryos created – and implanted into the womb of a woman in order to bypass certain forms of infertility. Additionally, the successful conduct of IVF showed that human embryos could be cultivated in a laboratory setting (Lauritzen 2001). For technical reasons, the number of embryos created for an IVF usually is larger than the number actually used for implantation. These surplus embryos are kept in a frozen state, but are almost never used for fertility treatment, as the donor couples have usually finished their family planning with one successful IVF treatment. Medical researchers demand to use these surplus embryos as an object of research. Another implication of IVF is that the embryos to be implanted may be screened beforehand to avoid hereditary diseases. The so-called pre-implantation diagnosis is still in its infancy. However, by the selection of the sex of the child it is possible to avoid hereditary diseases that are located on the sex-determining chromosomes. Nevertheless, screening is only a simple – and ethically contentious – selection procedure. Nobody is cured, only the "wrong" embryos are put away. If scientists would try to change the genetic endowment of the embryo, this would go under germline therapy (Stock/Campbell 2000).

The short sketch of these techniques already shows the gray area between reproductive medicine – the use of established techniques to cure diseases – and embryo research – the scientific enterprise of gaining new knowledge without immediate therapeutical implications. The line between cure and research is more clearly crossed with non therapeutic research, that is, research that uses the embryo as a raw material and without any intention of creating a child. The derivation of human embryonic stem cells is one form of such non therapeutic research. Stem cells are a very promising object for research, as they are still totipotent, which means that they can differentiate into any mature cell type. For example, they could in principle be used to create brain or nerve cells, as replacements for decayed ones (Gearhart 1998; Thomson 1998). The source for these stem cell lines can be the aforementioned surplus embryos, but scientist often demand that it should be allowed to create embryos for research purposes only, without any IVF treatment in mind. Particularly, the creation of embryos via therapeutic cloning is often seen as desirable. *Therapeutic cloning* is the creation of an embryo with the same genetic characteristics as a mature human being. This genetic identity is especially desirable for the creation of replacement tissue or organs, as the risk of rejection is much lower when the replacement tissue has the same genetic information as the recipient. If the same basic cloning technique is used to create a child, this is called *reproductive cloning*.

The ethical problems with the diverse techniques of embryo research are manifold and complex. The easiest judgment can be made about therapeutic research: there is nothing wrong with observing the develop-

ment of an embryo. The other techniques are more contentious. The most obvious problems arise with all the techniques that lead to the destruction of the embryo. If one conceives of the embryo as a human being, all these techniques are fundamentally wrong and should not be carried out. The trouble here is the word "if". Some scientists and ethicists see the embryo as equivalent to a human being (Ryan 2001), others do not (Green 2001; Steinbock 2001). Different, but similarly complex, issues arise with germline therapy and reproductive cloning – no human being is killed here. But as Habermas (2001) argues, these techniques violate the bodily and moral integrity of the cloned and/or genetically modified child (Mendieta 2004).

One of the major tenets in the debate is the question whether there is an insurmountable tension between the promises of therapeutic innovations and the ethical considerations. Can we reap the benefits of biomedical innovations, and at the same time uphold strict bioethical principles (Salter 2007)? Proponents of stem cell research claim that innovation and strict bioethical principles are incommensurable. According to them, the imposition of strict embryo research laws severely impedes the innovative ability of the medical biotech sector (Jones/Towns 2006). The argument follows two lines: First, certain research venues – e.g. research on human embryonic stem cell lines – are positively forbidden, and thus impossible to carry out in a given jurisdiction. Second, even scientists that currently do not work with embryonic stem cells might be afraid to „cross the red line", and precautiously move to another jurisdiction, where the laws are more permissive. This is all the more important, as scientific progress in the sector is rapid, and laws could be considered to be too rigid to keep pace with the scientific developments. Thus, restrictive embryo research laws should dispel researchers and therefore lower the innovative ability of a national economy. The ramifications are clear: a decline of innovative ability in biotechnology leads to economic decline of the sector, and, ultimately, to the loss of jobs. On the other hand, permissive embryo research laws should attract researchers, and, in turn, generate more innovations in medical biotechnology.

These arguments can be found in public debate all around the world. For example, the Australian parliament conducted a public hearing on the regulation of stem cell research (Standing Committee on Legal and Constitutional Affairs 2000). Sue Serjeantson, as representative of the Australian Academy of Science stated clearly „if Australia is to capitalise on its undoubted strength in medical research then it is important that research on human therapeutic cloning is not inhibited by [...] unduly restrictive legislation in some states." (ibid.: 63) And: „The academy believes that scientific progress is proceeding at such a rapid rate that, if we put in place restrictive legislation, it is quite possible that [...] we are left in an environment where we have inadvertently hindered some of the research that might go forward." (ibid.: 79) In line with this, Australian scientists threatened more or less openly to leave the country if a restrictive law would be passed. Similar arguments from scientists, industry representatives, and high-ranking politicians can be found in the French (Hénard 2001; Viville/Ménézo 2002), German (Schröder 2000; Dams 2001; Winnacker 2001), Italian (Lorenzi 2003), Norwegian (Hazekamp/Hamberger 2005), Swiss (Interpharma 2001; Interpharma 2002), or British debate (Mulkay 1997; Blair 2000; Sleator 2000), and in the debates about European Union research funding (Salter 2005).

Opponents of stem cell research, on the other hand, claim that the promises of embryonic stem cell research are widely exaggerated by the researchers. According to them, the promises of stem cell research do not justify the destruction of human embryos. Besides this, they claim that other lines of research, like the use of stem cells taken from umbilical cord blood, bone marrow or fetuses are ethically less contentious and scientifically as promising or even more promising than the use of embryonic stem cells. Thus, from the opponents' point of view, passing strict laws on stem cell research is ethically necessary. Furthermore, it does not inhibit the innovative ability, because enough other lines of research are still open for ambitious researchers.

These arguments appear in public debates frequently – though not as frequently as their counterparts, because often more basic religious arguments are submitted and the innovative ability is thought to be clearly secondary to religious reasoning. Nevertheless, many opponents of stem cell research explicitly consider the question of innovative ability, and put forward the argument sketched above, that strict ethical standards and innovative ability can be reconciled. The argument is headed by scientists (Höffe 2001; Kollek 2001; Spaemann 2001; Fukuyama 2002), religious actors (Australian Catholic Bishops Conference 2000), politicians (Lindner 2001), and even by representatives of the pharmaceutical industry (Geyer 2001).

Thus, we have two countervailing claims about the impact of strict embryo research laws on the innovative ability of the biotech sector. The purpose of the remainder of this article is to test the hypothesis brought forward by the proponents of stem cell research: „Strict embryo research laws have a negative effect on the innovative ability of the medical biotech sector; permissive embryo research laws have a positive effect on the innovative ability of the medical biotech sector."

3 The concepts: How can we operationalize embryo research laws and innovative ability?

The hypothesis stated in the last section includes two main elements: the strictness of embryo research laws as the independent variable, and the innovative ability of national economies in the biotech sector as the dependent variable. These two concepts must be operationalized in order to test the hypothesis.

For the independent variable, this article proposes a measure of the strictness of embryo research laws based on the various techniques of embryo research, that may or may not be allowed. Nine basic techniques have been identified. Data on embryo research laws of 21 OECD countries have been gathered, indicating whether these basic techniques are allowed (coded 0) or forbidden (coded 1). The techniques and their coding can be seen in Table 1. Added up, these binary variables constitute the Embryo Research Index (ERINDEX).[1] Main source for the data is the survey on the legal situation in the EU countries done by Gratton (2002) for the European Group on Ethics and new Technologies and the surveys of the Council of Europe (1998) and the UNESCO (2004). These data have been cross-checked and complemented using legal studies (Eser et al. 1990; Koch 2001), case studies (Bleiklie et al. 2004) and e-mail correspondence with the relevant ethics councils and ministries.

[1] To avoid concept stretching, only parliamentary laws that target both the private and public sector were coded. Constitutional provisions, funding guidelines etc. were not coded.

Table 1: Composition of the embryo research index *

Variable	Description of Procedure	Coding
THR	Therapeutic research: non-harming research.	0 (allowed) / 1 (forbidden)
TSS	Therapeutic sex selection: the selection of the child's sex after genetic testing in order to avoid hereditary diseases.	0/1
GLTH	Germ line therapy: the manipulation of the human germ line in order to influence genetically determined characteristics.	0/1
NTHR	Non-therapeutic research: research that destroys the embryo	0/1
NTHRAGE	The age or stage of development until which non-therapeutic research may be done.	0 (no time limit) 0.5 (up to 14 days after fertilization) 1 (forbidden in principle)
EPRES	Embryo production for research purposes: the production of embryos solely for the purpose of research.	0/1
ESCR	Embryonic stem cell research: research on human embryonic stem cells (which must necessarily have been created using human embryos).	0 (use and production of stem cells allowed) 0.5 (use of imported stem cell lines allowed, but no production) 1 (completely forbidden)

* The aim of the index is to map the abstract "possibility space" of embryo research. All of these techniques are theoretically possible, whether they are allowed or forbidden is an empirical question. The elements of the index are mostly, but not completely, logically independent from each other: if stem cell research is allowed, then, logically, non-therapeutic research has to be allowed (but not vice versa); if non-therapeutic research is allowed, then NTHRAGE cannot be 1; and if therapeutic cloning is allowed, embryo production for research purposes has to be allowed (but not vice versa, as embryos may be produced by other means).

The dependent variable is the innovative ability of a national economy in the medical biotech sector. This article proposes to operationalize the innovative ability of the medical biotech sector using the proportion of patents in microbiology[2] of the total patents; a measurement that could be loosely termed „biotech innovation quota".

There are some disadvantages of this operationalization. The time lag between patent application and the granting of a patent is sometimes

[2] EPO classification C12N („Micro organisms or enzymes, compositions thereof"), the same category that the original stem cell patents fall in. Source for the data: http://ep.espacenet.com/

very long. Combined with the relatively short time frame of the analysis, this means that at the moment long-term developments can not be analyzed adequately. The proportion of biotechnology patents does not testify anything about the importance, let alone quality, of the innovations. Neither does it tell us something about the economic importance of the innovations. And it does not distinguish between patents in "red" and "green" biotechnology. A more precise indicator would be desirable, but is at the moment not available.

However, there are reasons to believe that the indicator can serve as a good proxy measure for the innovativeness of the medical biotech sector. A growing number of patents in microbiology and genetic engineering should be the first detectable sign of an improved research environment due to permissive embryo research laws. Besides this, to measure the proportion of patents in the sector offers an intersubjective measurement, which allows to compare between countries and over time. Additionally, taking a policymakers perspective, if one would consider the biotech sector to be strategically important, the quota of biotech patents should be a good benchmark to assess whether the sector prospers, or not. In conclusion, given the scarce supply of cross-country and time series data about biotechnology research performance (Van Beuzekom 2001; Arundel 2003), using the proportion of medical biotech patents is a reasonable proxy for the innovative ability of the sector.

4 The analysis: A complex relationship

A first descriptive analysis of the data reveals a considerable variation of the independent variable, the strictness of embryo research laws. Table 2 shows that, so far, no regulatory model has become universally accepted. Instead, we observe a variety

Table 2: Regulatory situation in the OECD countries in 2007**

Country	THR	TSS	GLTH	NTHR	NTH-RAGE	EP-RES	ESCR	REP-CLON	THER CLON	ERIN-DEX
BEL	0	0	0	0	0,5	0	0	1	0	1,5
GBR	0	0	1	0	0,5	0	0	1	0	2,5
SWE	0	0	1	0	0,5	0	0	1	0	2,5
NZL	0	1	1	0	0	0	0	1	0	3
AUS	0	0	0	0	0	1	0	1	1	3
DEN	0	0	0	0	0,5	1	0	1	1	3,5
FIN	0	0	0	0	0,5	1	0	1	1	3,5
GRC	0	0	0	0	0,5	1	0	1	1	3,5
NEL	0	0	1	0	0,5	0	0	1	1	3,5
CAN	0	0	1	0	0,5	1	0	1	1	4,5
FRA	0	0	1	0	0,5	1	0	1	1	4,5
SPA	0	0	1	0	0,5	1	0	1	1	4,5
SUI	0	1	1	0	0,5	1	0	1	1	5,5
AUT	0	1	1	1	1	1	0,5	1	1	7,5
GER	0	1	1	1	1	1	0,5	1	1	7,5
ITA	0	1	1	1	1	1	1	1	1	8
NOR	1	0	1	1	1	1	1	1	1	8

**The USA, Ireland, Luxemburg and Portugal are missing, as they have no law regulating the public as well as the private sector as of 2007.

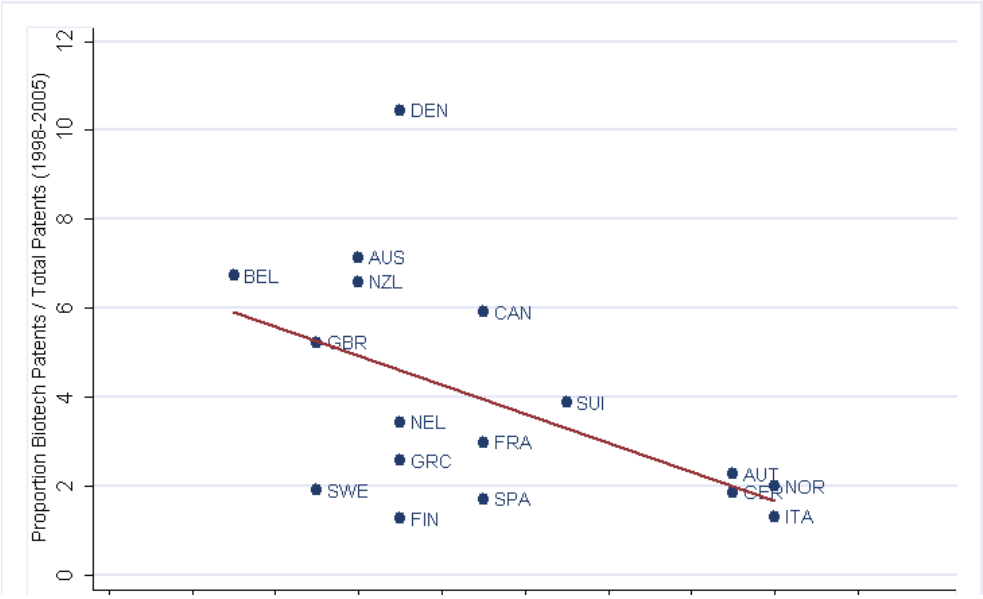
of embryo research laws. Using a rough classification, one may distinguish three categories of countries. First, a group of *permissive regulators*, comprising Belgium, the United Kingdom, Sweden and New Zealand. This group is characterized by the fact that all members allow the so-called therapeutic cloning.[3] Second, a group of *restrictive regulators*, comprising Austria, Germany, Italy and Norway. This group is characterized by its ban on non-therapeutic research. All the other countries are *intermediate regulators* that try to find a middle way between the two extreme groups.

The question posed in the theoretical part is: does the considerable variety of embryo research laws translate into a systematic variety of the innovative ability of the respective countries? An analysis of this question may start with the most simple form of cross-sectional plot. Figure 1 plots the average proportion of biotech patents (1998-2005) against the strictness of national embryo research laws (2007).

Figure 1 shows that restrictive embryo research laws are indeed interrelated to a lower innovative quota in stem cell research. The cross-sectional graph clearly shows that the countries with the most restrictive embryo research laws – Austria, Germany, Norway and Italy – have the lowest biotech innovation quota. This finding resonates with the available case studies in the field (Körtner 2002; Burrell 2005: 22). On the other hand, a permissive law does not guarantee innovations in the medical biotech sector. A comparison of Denmark and Finland shows that even countries with very similar embryo research laws exhibit considerable differences in their biotech innovation quota.

However, a cross-sectional perspective may obscure more than it reveals. A comparison of average values may simply reflect stable long-term level differences.

Figure 1: Relationship between strictness of embryo research laws and innovative ability



[3] In terms of overall strictness, the Australian law is similar to the law of New Zealand. However, as therapeutic cloning is scientifically and politically of supreme importance I use the admission or non-admission of this technique in order to differentiate between permissive and intermediate regulators.

From a political and strategic – as well as scientific – point of view, the more intriguing question is whether a correlation between permissive embryo research laws and a high innovative ability can also be shown *over time*. If the introduction of a liberal embryo research law is followed by an increase in the biotech innovation quota – or vice versa, the introduction of a restrictive law is followed by a decline of the biotech innovation quota – the case for the strategic importance of embryo research laws – and the incommensurability of innovation and ethics – would be strengthened.

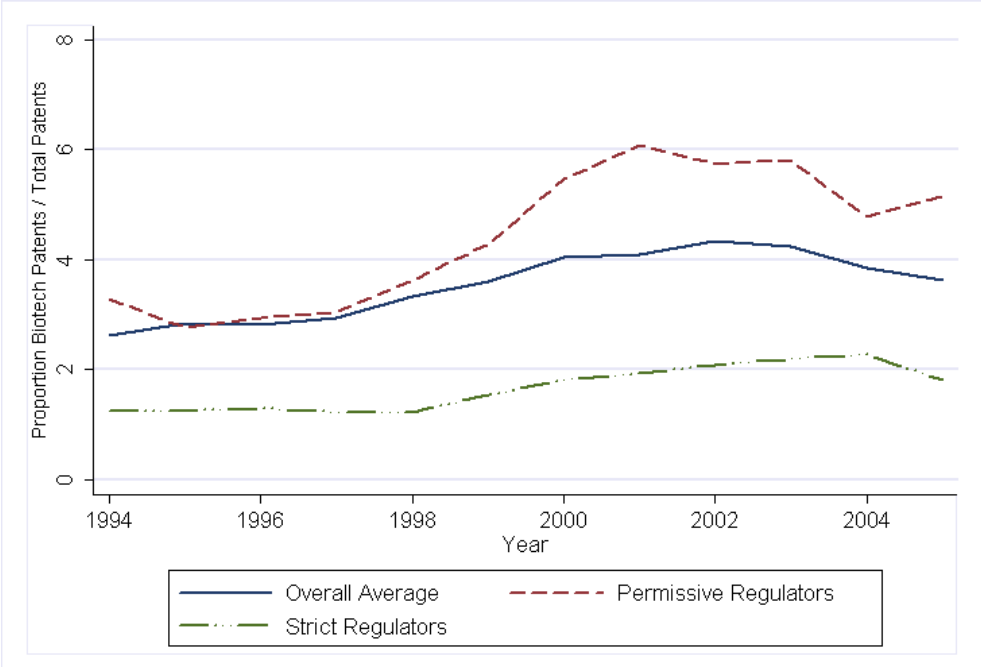
Thus, a longitudinal analysis is needed to complement the cross-sectional picture. Figure 2 offers a longitudinal perspective, disaggregated to show the development of the biotech innovation quota in different country groups.

Figure 2 allows some further conclusions. On the one hand, the data underline that Figure 1 does partly reflect stable structural differences. The group of restrictive regulators has a lower biotech innovation quota than the group of permissive regulators from the outset. On the other hand, the data show that these level differences have increased. After 1998 – after the breakthroughs in stem cell research – the biotech innovation quota increased in all countries, but most markedly in the group of permissive regulators.

In conjunction, Figure 1 and Figure 2 thus suggest that permissive embryo research laws indeed contribute to a higher innovative ability in the medical biotech sector.

Or, to interpret the data more cautiously: Permissive embryo research laws might be a necessary condition for a high biotech innovation quota, but no sufficient condition (see for example Sweden or Finland in Figure 1).

Figure 2: Development of the biotech innovation quota over time for permissive and strict regulators, compared to the overall mean.***



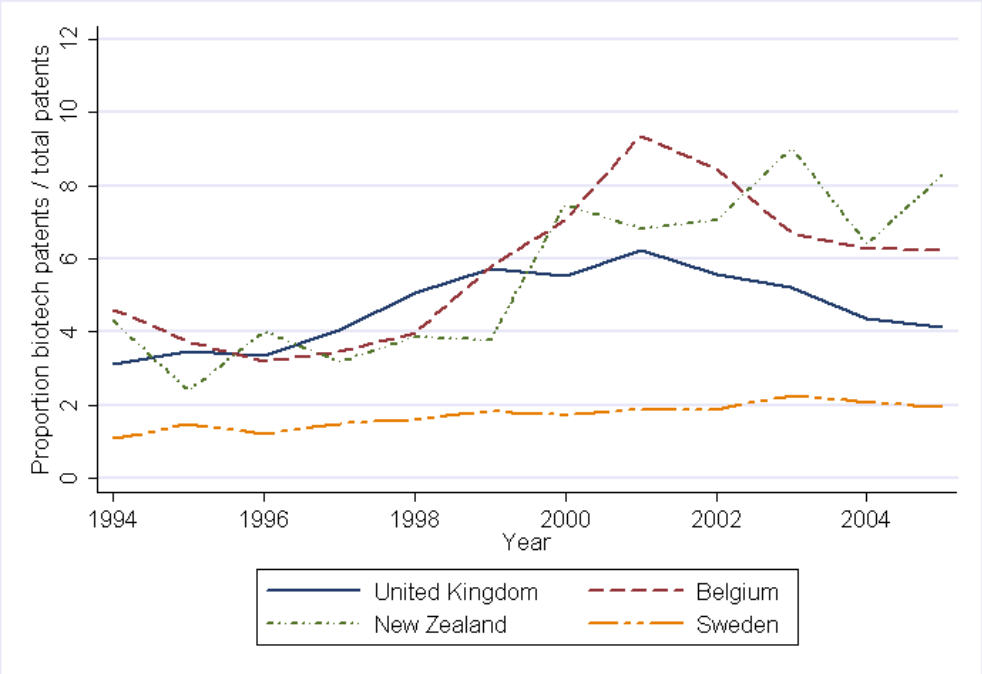
*** As outlined in the text, the United Kingdom, Sweden, New Zealand and Belgium can be considered permissive regulators, while Austria, Germany, Italy and Norway are strict regulators.

A further step of disaggregation plots the biotech quota for single countries against the time dimension, thus allowing conclusions about which countries might deliver further evidence for or against the hypothesis.

Figure 3 plots the biotech quota for the group of permissive regulators: Belgium, New Zealand, the United Kingdom, and Sweden. In all other countries under study, the quota remains more or less stable. This implies that there is no sharp decline in the biotech innovation quota in the countries that have passed strict laws on embryo research.[4] These findings further caution against the hypothesis that permissive embryo research laws have an short-term effect on the innovative ability of the sector.

The disaggregation into country trajectories cautions our interpretation even further, especially concerning the active political intervention and steering abilities governments can have. There are only three possible examples for "heroic innovation policy" that can be found in the country sample studied: Belgium and New Zealand have passed very liberal laws on stem cell research (see Table 2), and both countries have seen a considerable rise of their biotech innovation quota (see Figure 3). Furthermore, the United Kingdom has passed a very liberal law, but its increase in biotech innovation quota is not as marked as in Belgium or New Zealand.[5] The fourth country in the permissive group, Sweden, has not

Figure 3: Development of the biotech quota in the group of permissive regulators



[4] One might argue that the quota was so low from the outset that there was no room for a sharp decline. Another implication of this finding is that Denmark, which outstands in Figure 1, has always been strong in biotechnology patents, with no major impact of the embryo research laws.

[5] A possible explanation for this example is the fact that the United Kingdom's research profile is more heterogeneous, with more innovative sectors than in Belgium or New Zealand. Thus, changes in the proportion of biotech patents are harder to achieve.

experienced a change in the biotech innovation quota.

These results of the quantitative overview allow us to identify interesting country cases and pose more specific research questions. Especially the four cases presented in Figure 3 merit our attention. The sharp increase of the biotech innovation quota in Belgium and New Zealand (and the more smooth increase in the United Kingdom) raises the question whether these cases can be characterized as evidence for the thesis that permissive embryo research laws lead to innovations, or if we see only statistical artifacts. Additionally it will be to discuss, if these countries prove to be evidence for the thesis, what are the mechanisms and policy measures that lead to the success? On the other hand, the case of Sweden raises the question why the country was not able to capitalize on its permissive embryo research law. A closer investigation of these cases will allow more nuanced conclusions about the *conditions* under which liberal embryo research laws lead to a higher innovation quota in the medical biotech sector.

Belgium is a difficult case to interpret. On the one hand, Belgium confirms the thesis; it has been one of the leading countries in artificial reproductive technology. Thus, when the stem cell research breakthroughs occurred, Belgium already had an established research base in applied medical biotechnology (Varone /Schiffino 2004). As it had no special law regulating embryo research up to 2003, it was considered a "bioethical paradise" (Varone/Schiffino 2004: 85). Public opinion was very positive towards biotechnology (Schiffino /Varone 2004). Together with the United Kingdom, Belgium is considered to be one of the most research-friendly environments for stem cell research in Europe, and is either co-coordinator or project partner in a large share of EU-funded research projects involving stem cells (European Commission 2005). On the other hand, this Belgian success story is rather a by-product of political struggle and not the result of an active political strategy to promote life sciences. The boom in biotech patents in Belgium occurred from 1998 to 2001. However, the very permissive *Loi relative à la recherche sur les embryons in vitro* was passed only in 2003. Up to this time, the lack of a law in Belgium cannot be considered a part of a coherent political strategy. Rather, intense political struggle within a coalition comprising Christian democrats prevented the passage of a law on embryo research. The secular parties in government preferred a liberal law; Christian democrats preferred a strict law, the result was a deadlock situation in which no law could be passed (Schiffino/Varone 2004; Varone/Schiffino 2007). The secular parties could accept this deadlock as a second-best solution, because the lack of a law partly coincided with their preferences. However, they preferred the passage of a law to a lawless space, and when the Christian democrats left the coalition due to electoral defeat, a law was quickly passed. Thus, the biotech boom in the lawless space from 1998 to 2001 occurred to some extent "behind the backs" of the political actors.

Thus, Belgium confirms the thesis that liberal embryo research laws are associated with a prospering and innovative medical biotech research sector, although this cannot be attributed to an active political strategy, and is rather the (partly) unintended consequence of policy deadlock.

New Zealand's success story is similarly equivocal. New Zealand has an ethics committee regulating embryo research since 1993.[6] As early as

[6] The National Ethics Committee on Assisted Human Reproduction (NECAHR).

1996, a bill regulating embryo research – the Human Assisted Reproductive Technology (HART) bill – came into the parliamentary arena, but lay dormant for a long time in the Health Committee (Barr 2003b). Under the impression of the stem cell research breakthroughs, the Labour government re-animated the bill in 2003. Due to the Westminster system with few veto points, the government was able to push through the liberal bill (Barr 2003a), and the HART act was passed in 2004. Public opinion towards medical biotechnology and stem cell research is generally positive (Warren/Osborne 2006), supported with headlines like "Stem cells could end need for heart transplants" or "Blind could see again with new medical breakthrough", "'Incurable' illness falls to gene therapy", or "World on the edge of a new era of drug discovery" in the New Zealand Herald.[7] New Zealand Universities are amongst the leading research institutions in stem cell research, with a particular record in neurological research (Futurewatch 2006). What makes the increase in stem cell related patents even more intriguing is that the amount of state funding is comparatively low. Only NZ$2.3 million per annum are allocated to stem cell projects (Futurewatch 2006: 53).[8] However, similar to the Belgian case, the increase in innovations in stem cell research occurred *before* the permissive law was passed in 2004. In the New Zealand case, the delay of the law was not due to coalition struggles, but rather to conflicts and hesitation within the governing party. However, the conclusion remains the same: the success of the sector seems to have been a partly unintended consequence rather than the result of a political strategy.

Thus, the case of New Zealand leads to a similar conclusion as in the Belgian case. On the one hand, the liberal regulative situation seems to have been supportive for the increase in innovations in the stem cell field. On the other hand, this does not entirely reflect the intended consequence of a political strategy.

The United Kingdom was the first country to liberalize its embryo research law after the breakthroughs in stem cell research. The Human Fertilisation and Embryology Regulations from 2001 allowed therapeutic cloning, and were part of an explicit strategy to promote biotechnology as an integral element of the knowledge society (Blair 2000; Banchoff 2005). As a traditional leader in biotechnology (Gottweis 1998), with a strong role of the Royal Society as a policy advisor (Krönig 2001), and an already established overview and licensing system (the Human Fertilisation and Embryology Authority HFEA), the United Kingdom was in an ideal position to build on its experience and strengthen its innovativeness in the biotech sector. However, as Figure 3 shows, the bulk of the increase in biotech innovations occurred from 1996 to 2001, under the old Human Fertilisation and Embryology Act, dating from 1990. This act was permissive from the outset[9], and, at its time, introduced with the explicit aim to strengthen the United Kingdom's research base in biotechnology (Mulkay 1997). Hence, the United Kingdom could capitalize on the stem cell research breakthroughs because the regulatory framework that was already in place was liberal enough to keep researchers in the country.

Thus, the case of the United Kingdom fully confirms the thesis that permissive embryo research laws lead to an increase in the innovative ability of

[7] http://www.nzherald.co.nz

[8] This is about €1.2 million. The state of California alone spends $300 million a year on stem cell research (Schwägerl, 2004).

[9] Though not as permissive as its successor, with an ERINDEX of 4.

the biotech sector; although the case suggests that the effects are to be assessed on a more long-term time frame.

Sweden at first contradicts the thesis. Sweden had a relatively liberal embryo research law since 1991[10], that was changed in 2005 to allow therapeutic cloning, and with the explicit aim to strengthen the Swedish research position in biomedical applications (Kulawik 2003). However, as exemplified in Figure 3, the relatively liberal law of 1991 was not accompanied by an increase in the biotech innovation quota. But the Swedish case may illuminate the limits of a quantitative approach to innovativeness. The quota of patents may not have increased, but according to all observers, Sweden is a world leader in stem cell research (Torgersen et al. 2002; Kulawik 2003; Burrell 2005). The funding of 257.3 Mio SKR (27 Mio €) from 2003 to 2008 expresses the high priority that stem cell research has in the Swedish innovation system (Hague 2006), and the Karolinska Institute in Stockholm and the Sahlgrenska Academy in Gothenburg are amongst the leading suppliers of stem cell lines. Thus, the quality of the Swedish innovations in the biomedical sector is high, though its proportion compared to total patents is low. This may reflect a distinct "patenting culture" (Packer/Webster 1996), focusing more on quality than on quantity.

Thus, the case of Sweden is illustrative for two reasons. First, it confirms the thesis that permissive embryo research laws can lead to innovations. Second, it illustrates the limits of a quantitative approach to the field and the usefulness of qualitative in-depth material.

To sum up the conclusions of this analysis: There seems to be an interconnection between strict embryo research laws and a low innovation quota in stem cell research in cross-country comparison, which would confirm the thesis outlined in the theoretical section. However, this statistical interconnection has to be interpreted very cautiously. First, the same does not apply vice versa. Permissive embryo research laws are not consistently associated with a high innovation quota in stem cell research. The variation of the innovation quota increases as the embryo research laws get more permissive, but there are countries with permissive or intermediate embryo research laws and a low innovation quota in stem cell research. Second, the disaggregation of the data and the study of country trajectories reveals that there are only very few countries in which the innovation quota in stem cell research has changed substantially in the last 13 years. This illustrates as well that the countries, which have passed strict laws, have not experienced a decline of their innovation quota. Third, in the countries that did experience a sharp increase of the innovation quota in the stem cell area, there is some evidence that this increase is causally linked to a permissive regulatory situation. However, there is less evidence that this is due to a conscious political strategy. If one considers the temporal dimension, the increase of innovations in the medical biotech sector did often occur *before* political actors had decided on how to regulate the sector. Only in two countries of the examined – Sweden and the United Kingdom –the prospering of the biotech sector can be attributed to a distinct political strategy. Fourth, the time frame of the analysis is still rather short. At this moment, all we can safely conclude is that embryo research laws have no large systematic effect in the short term. What the long-term effects are – possibly in the form of path-dependent or self-reinforcing dynamics (Pierson 2000) – is open to speculation. Finally, all

[10] ERINDEX of 4.5.

the results must be interpreted in light of the used indicator. The quota of microbiology/stem cell patents is only a proxy measure for the innovativeness of the sector. It does not say anything about the *total* number of patents in the sector – here, e.g. Germany can easily outshine Belgium. And it does not say anything about the importance or the quality of the patents (as the case of Sweden indicates). Thus, all the conclusions from this analysis must be read with some caveats as to their generalizability.

5 Conclusion

Taking together the results of the analysis and all the caveats, this article depicts a sector in which stable-long term differences in the innovativeness are dominant, and government interventions in the form of permissive laws do not have a predictable and stable effect in the short term. The cases of Sweden and the United Kingdom, where such a strategy did succeed, must be weighed against the large number of other cases, in which the biotech innovation quota remained stable, or cannot be causally linked to the strictness of the embryo research law. Innovativeness of the medical biotech sector seems to be in considerable parts determined by stable structural differences. Policy measures, like permissive or strict embryo research laws, seldom have a short-term impact on the innovativeness of the sector.

This finding cautions the hopes – and promises – of many actors that claim to introduce permissive embryo research policies in order to reap short-term gains in innovative ability. This strategy may work, but more often, changes in the innovativeness of the sector cannot be attributed to strategic political decisions. This finding also casts doubts on the ability of states to steer scientific developments and sectors and to force innovations by policy measures.

However, proponents of strict laws on bioethics should not draw the conclusion that embryo research laws do not matter at all for the innovative ability of a national economy. First, the analysis has revealed that none of the countries that have passed strict regulation was able to raise its biotechnology innovation quota, while at least some of the permissive regulators were able to increase their biotech innovation quota. Second, due to the relative youth of the research and policy field, this article could only illuminate a relatively short time frame. What the long-term consequences of different embryo research laws will be is an open question. Recent theorizing about the self-reinforcing nature and nonlinear dynamics of social processes (Mayntz/Nedelmann 1987; Pierson 2004) suggests that small differences in innovative ability may add up at an increasing rate, thereby generating path-dependent developments. Maybe the question of how to regulate stem cell research proves to be a critical juncture, and 20 years from now, the countries that chose a permissive law today will have a lead in the sector the other countries are unable to catch up with.

A final caveat is that all conclusions must be seen in the light of the limitations of the indicator used for innovative ability. As discussed in the methodological section, the proportion of biotech patents cannot precisely represent the quality or economic importance of the innovations, the time lag between patent application and patent grant means that long-term developments may not appear in the data, and the indicator does not distinguish between "red" and "green" microbiology. Thus, the picture painted in the quantitative analyses is not – and cannot be – as fine-grained as the picture from in-depth case studies. More detailed case studies are needed to uncover

the social mechanisms that link the regulatory framework and the innovative ability of the biotech sector. But the conclusions from the quantitative analyses are a rough map of the relationship between the regulatory situation and the innovativeness of the biotech sector. They can serve as a starting point for case selection, and can be useful to embed the insights from case studies in a larger context.

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