Courts and the Biotechnology Revolution:

Policy-making in Canada, the USA and Switzerland

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Abstract

By radically expanding our scientific capacities, the "biotechnology revolution" offers the promise of new therapies to treat diseases or new types of food of higher nutritional quality, but it also raises a number of ethical, health and ecological concerns. Countries around the world, as well as supra- or international institutions, are adopting and implementing *public policies* that regulate the concrete applications of biotechnologies. Courts are also involved in the governance of biotechnologies. The implication of courts is not surprising, when we consider the global expansion of judicial power. However, political scientists have so far neglected the question of how courts have contributed to the governance of biotechnology. The implication of courts in biotechnology policy-making raises a number of important questions. Have courts primarily acted as safeguards against the risks of biotechnology and hence indirectly supported interests critical towards biotechnology, or have they promoted research and application and thus strengthened the position of industry and research? Following Galanter's argument that the "Haves come out ahead" one might suspect that industrial, business and governmental interests have been more successful in employing litigation as a strategy to influence policies. This paper analyses from a comparative perspective which interests have successfully mobilised courts and how the court decisions have influenced public policies in Canada, the USA and Switzerland.

Introduction

By radically altering and expanding our scientific capacities in the life sciences, the "biotechnology revolution" has offered the promise of new medical therapies or new types of food of higher nutritional quality. But it has also raised many concerns in terms of its potential impact on everyday life, namely the risk of eugenic medical applications and the unpredictable negative effects on the ecosystem. The question of how biotechnology should be governed thus is a salient issue on the public agenda. There is a growing debate on what the adequate regulatory answers are, how to promote research and development in the life sciences in an ethical way, and who should participate in these decision-making processes. The state is confronted with rapid changes and technological developments. Furthermore, biotechnology applications are value-loaded and initiate strong ethical debates rendering decision-making processes demanding and time consuming. Further complications arise, as biotechnology issues, e.g. embryonic stem cell research, do not divide along traditional party lines, leaving political parties dived into different camps, which in turn contributes to deadlocks and non-decisions. In addition, the economic potential of these applications is important, which enhances conflicts about regulatory strategies. Thus, courts are solicited to clarify questions that have not yet been resolved, where deadlocks have occurred, and also to secure the economic interests of actors who have made investments in developing biotechnology applications in specific fields. For example, courts have had to decide whether genetically modified organisms or animals are eligible for patent protection. Courts had to review the process of authorizing genetically modified food and the commercialization of genetically modified crops. Regulations on assisted reproductive technologies were challenged in courts and courts had to settle questions of paternity.

Policies adopted to govern biotechnology vary considerably across sectors of application and across countries. Best known are the differences between the EU and US/Canada in terms of agro-food applications (Montpetit, Rothmayr et al. forthcoming). There are, however, also striking differences when it comes to medical applications, for example, assisted reproductive technology (Bleiklie, Goggin et al. 2004). This paper compares policy-making in the field of biotechnology across three countries that have adopted different policies with respect to genetically modified organisms (GMOs) in the agro-food sector and assisted reproductive technologies (ART). While the US policies are permissive for both sectors of application, Canada has set clear limits to ART, while pursuing a rather permissive path with respect to GMOs in the agro-food sector. To the contrary, Switzerland has restrictive policies for both fields of application. The following analysis discusses whether and how courts have contributed to adopting these different policy solutions. Are courts primarily acting as safeguards against the risks of biotechnology and hence indirectly supporting interests critical towards biotechnology, or have they promoted research and application and thus strengthened the position of industry and research? Following Galanter's (Galanter 1974; Galanter 2003) argument that the "Haves come out ahead" one might suspect that industrial and business interests have been more successful in employing litigation as a strategy to influence policies. This paper first asks which interests have mobilized courts and with what success. The second question raised in our analysis is whether the successful mobilization has contributed to

policy change, and if so change in which direction, towards more stringent regulations or less state intervention.

Theoretical framework

Galanter (1974, 2003) has argued that the "Haves" tend to come out ahead. The "Haves" are more frequently "repeat players" and enjoy a number of advantages compared to "one shooters". They dispose of the economic resources and the expertise to pursue long-term strategies through repeated litigation and thus shape precedent in the long run. They strategically approach litigation and choose which cases to bring to court, and when to settle, and they also dispose of the necessary financial resources to delay decisions and go through lengthy procedures. The research on party capability in the US, in Canada (McCormick 1993) and Europe (Mattli and Slaugther 1998) reveals mixed results, only partly under specific conditions supporting Galanter's proposition (Flemming and Krutz 2002; Glenn 2003). Interests traditionally labeled as disadvantaged, like minorities, women groups or gay interest groups have been successful in using courts to promote their policies (Brodie 2001; Brodie and Morton 2004; Smith 2005). Other research points to the fact that government tends to come out ahead during the last decades (Kritzer 2003).

With respect to the two fields of application chosen for our analysis –assisted reproductive technologies (ART) and genetically modified organism in the agro-food sector (GMOs), potentially a broad range of actors might turn to court, ranging from multinational companies, over environmental interest groups and patient associations, to individual litigants depending on the issue at stake. These actors might defend or pursue varying interests, such as liability claims against companies or doctors, contestation of patents, questioning administrative decisions on authorizing genetically modified plants, seeking financial coverage for fertility treatment or challenging denied access to such resources. We would expect companies to be repeated players, but also interest groups of varied background, such as medical and research interests, environmental interest, pro life groups, or religious interest groups. Thus, our research will first analyze who are the repeated players and who are the one-shooters, and whether we actually can observe patterns of repeated litigation. In terms of organized interests, we will distinguish between *proponents* of biotechnology, i.e. interests in favor of as little regulatory restrictions as possible, and *opponents*, that are interests seeking state intervention and more or less strict regulations of research and application. Opponents of GMOs in the agro-food sector, such as environmental interests or organic farmers, for example would fight for policies strongly based on the precautionary principle, with labeling, traceability and strict authorization requirements guaranteeing the choice of consumers. Proponents of stem cell research, to add another example, would lobby for proper funding and no or little restrictions on therapeutic cloning and research on embryos, while pro-life groups and religious interests demand strict protection of the embryo and thus to impose strong limits on research. Our analysis will, thus, also look at whether proponents or opponents have been more successful in court.

As research in the past has shown, success in court does not automatically translate into the desired policy changes as court decisions need to be implemented and

various political actors react to the court decision and continue trying to influence the policy-processes. Our research, therefore, is also interested in reconstructing the impact of court decisions on public policies. Court impact studies have generated a vivid discussion on what the possible impacts of court involvement are (Rosenberg 1991; Feeley and Rubin 1998; McCann 1998). Court decisions contribute to mobilizing and empowering certain interest groups in policy-making processes and influence rules of access and participation to arenas where policy choices are deliberated and decisions are taken. Thus, they can change the actor constellation, which in turn can lead to policy change. Interest groups also search for and try out different venues for influencing policies, litigation being just one of the possible venues (Olson 1990; Baumgartner and Jones 1993), and the timing and sequence in which the different venues are activated is of importance. In order to analyze court impact we therefore need to situate the court decisions within overall decision-making process. Court impact studies have shown that court decisions might influence different dimensions of the policy-making process. They affect the content of public policies *(substantial effect)* through declaring laws, regulations and administrative decisions unconstitutional or unlawful. Judges might also formulate what norms or policies need to be adopted in order to not violate the constitution or the law (judicial policy-making). Furthermore, court decisions can have an impact on actor constellations (*mobilization effect*). Court decisions can contribute to mobilizing and empowering certain interest groups in policy-making processes (McCann 1994). They might furthermore influence rules of access and participation to arenas where policy choices are deliberated and decisions are taken (*procedural effect*). In addition, court decision can play a role in agenda-setting and framing of an issue, for example by framing an issue as a rights issue. This might particularly be the case when courts intervene early in the policy-making process or address issues that have so far been kept off the political agenda (*agenda-setting and framing effect*). The following analysis, hence, asks whether the court decisions have had any such direct or indirect effects on the policy-making process. We are particularly interested in analyzing whether court decisions have contributed to or triggered policy-change, and if so in which direction, in the direction of more strict regulations or rather preventing additional state intervention.

Despite the general tendency of a "global expansion of judicial power" (Tate and Vallinder 1995) courts play a more important role in some countries than others. According to the literature, court involvement and activism is determined by national institutions that are themselves the products of historical circumstances and social characteristics (Shapiro and Stone 1994; Kagan and Axelred 2001). Obvious differences in the jurisdiction of the highest court are a first and basic factor to consider. Within a similar type of jurisdiction, however, courts can be more or less active and engage or not in judicial policy-making, i.e. courts "exercise power on the basis of their judgment that their actions will produce socially desirable results" and not just on the basis of existing legal sources (Feeley & Rubin 1998: 5). Different legal traditions, for example common law versus civil law traditions, and different traditions with respect to parliamentary supremacy and court deference, are further variables to consider. It has also been argued that the decentralization of power through a federal system or the division of power in presidential systems is more conducive to court activism. In addition, how easily legislation can be adopted in a political system and how difficult constitutional changes are to bring about, is of relevance. Systems where the adoption of new legislation or

constitutional changes is very costly and difficult to achieve tend to show a greater amount of court activism. Thus, we expect that the importance and impact of court decisions will vary across the three countries studied. In fact, solely from an institutional perspective we would expect the US to be the most litigious case with the highest court activism (Kagan 2001; Kagan and Axelred 2001).

Methodological remarks

The present research builds upon a project comparing policies for assisted reproductive technologies and GMOs in the agro-food sector across 9 countries (Montpetit, Rothmayr and Varone forthcoming; Bleiklie, Goggin and Rothmayr 2004). Based on interviews with key actors and documentary research this project analyzed the decision-making processes in a comparative perspective. The present project analyses the importance and contribution of courts and litigation to policy-making and policy outcomes. The research is work in progress, and so far the documentary research has been conducted and will be completed through interviews with the parties involved and other key actors later on.

Court cases have been identified through a combination of literature review, systematic research in the Quicklaw database for the USA and Canada (until December 2005), and reports in the media. Two rounds of systematic research in Quicklaw based on the results of the literature review and media reports and an extensive list of key words[1] allowed us to identify most likely the large majority of cases, but for sure the important cases on the federal as well as the state and provincial level. For Switzerland, there is no single comprehensive database to search for cases.[2] We relied on literature review, interviews and systematic media research in this case. The cases found were entered into a database classifying issues, parties and outcomes.

The three countries involved in this comparison were chosen for four reasons. First of all, the policy solutions adopted vary across the three countries as detailed below. This allows us to compare whether and to what extent courts have contributed to adopting diverging solutions. Second, according to the literature the three countries vary in terms of litigiousness and court activism, as explained above. Third, the three countries share some important features. The biotechnology sector is important in the three countries, although there are differences across the sectors, namely the agricultural sector is of little importance in Switzerland. Fourth, all three countries are characterized by a federal structure, in the case of the USA and Canada a jurisdictional federalism, in the case of Switzerland a mix between functional and jurisdictional model, thus rising the question

[1] Anticrop, arracheur+champ, biotechnologie,cCell+modification, clonage, cloning, crop+vandalism, désobéissance civile +champs (+OGM), eco-vandalism, eco-warriors, environmental groups, food+biotechnology, food+genetically, gene, genetically, genetically engineered, genetically modified, genetically modified organism, in vitro, in vitro fertilization, IVF, labelling+food, labelling+genetically, Monsanto, OGM (GMO), patent (brevet), procréation assistée, procréation médicalement assistée, stem cell, regenerative medicine.

[2] The Swiss Federal Supreme Court disposes of a searchable online database. However, the Court has only recently changed its policy of publishing decisions. Thus, only since 2000 the majority of the decisions are published. Before that date, the publication was limited to "Leitentscheide" (cases creating precedence).

of on which level what type of question should be addressed and whether states, provinces and cantons might adopt different solutions.

In order to contextualize the court cases described below and to explain their contribution to the shaping of policies in the three countries, we start out with a short comparative description of the policy developments in the three countries. We then turn to the analysis of court cases for assisted reproductive technologies and GMOs in the agro-food sector.

Policies for assisted reproductive technologies: prohibitions, criminal sanctions or anything goes?

Canada and Switzerland have both adopted federal legislation for assisted reproductive technologies. In Switzerland, ART is even regulated by a constitutional article, due to the instrument of popular initiative amending the federal constitution. The policies adopted, however, contrast considerably.

Swiss policies mainly aim at preventing the abuse of ART (Federal Constitution Art 119, Federal Law on Assisted Reproduction, FmedG: SR: 814.90) through a number of prohibitions and restrictions. Federal policies strongly limit the autonomy of the medical community by prohibiting a number of techniques such as egg and embryo donation, pre-implantation diagnostics, cryopreservation of embryos, surrogate motherhood, genetic engineering on gametes, germ cells and embryos, therapeutic and reproductive cloning. To produce an embryo solely for research purposes is prohibited and stem cells for research might only be derived under specific conditions from left-over embryos (Federal Law on Stem Cell Research, StFG, SR 810.31). For the techniques that are not fully prohibited, the policies prescribe licensing requirements, define medical indications and how certain techniques have to be practiced. It proscribes also inspections and controls, specify reporting duties and formulates information and counselling requirements towards patients. Access to ART is limited, as only heterosexual couples, and for certain techniques only married couples are admitted and that access depends on the financial capacities of the patients to cover the respective costs of treatment (Rothmayr and Serdült 2004).

Canada has also adopted comprehensive policies on the federal level (Assisted Human Reproduction Act, March 2004). Details of the policies are however delegated to the newly created Assisted Human Reproduction Agency of Canada (AHRAC), which started working end of March 2004. Canadian policies with respect to stem cell research and embryo research are similar to Swiss policies. Canada prohibits the creation of embryos for research purposes and all forms of cloning (including therapeutic cloning). Thus embryonic stem cell research is limited to left over embryos and is subject to authorisation and depending on additional conditions like the consent of the donating couple. When it comes to the application of ART, however, Canadian and Swiss policies differ considerably. There are no barriers to access ART services in Canada, than financial ones. In fact, the legislation even protects the right of unmarried and homosexual couples to have access to fertility treatments. Furthermore, there are no prohibitions of specific techniques in general, like for embryo donation or surrogacy, as

is the case in Switzerland. In short, while there is a regulatory framework for the application of ART including licensing, authorisation and data collection requirements, the overall policies remain permissive in comparison to the Swiss design.

In contrast to Switzerland and Canada, in the USA all attempts to comprehensively address ART on the federal level have failed, and legislation on the state level has remained limited in scope and and nature. In fact, policy debates and policies in the USA have mainly focused on the question of embryo and stem cell research (Goggin and Orth 2004; Garon and Montpetit forthcoming). The policies on the federal level are limited to restricting public funding for stem cell research and reporting requirements for fertility clinics. The Bush government has limited in 2001 federal public funding of embryonic stem cell research to stem cells derived before August 2001 from left over embryos that were created for procreation and donated with informed consent by the couple without financial compensation. In terms of ART practice, policies have remained very limited and self-regulation is mainly guiding the field. The Fertility Clinic Success Rate and Certification Act dating from 1992 simply requires Fertility Clinics to report success rates to the Department of Health and Human Services (Center for Disease Control and Prevention) and leaves regulating ART practice to self-regulatory mechanism. Attempts to prohibit reproductive or therapeutic cloning on the federal level have all failed so far. To the contrary, on the state level, some states have introduced bans on cloning[3]. With respect to research issues and cloning, some states prohibit not only reproductive, but also therapeutic cloning together with certain forms of embryo research. Therapeutic and reproductive cloning are prohibited (by the time of writing) in Arkansas, Indiana, Iowa, Michigan, North Dakota, South Dakota, and Virginia.[4] Only reproductive cloning is prohibited in Rhode Island, Massachusetts, Connecticut, California and New Jersey. Few states address questions of ART practice, such as informed consent, donation and parentage issues.[5] Typically state regulations address problems of parentage after death or divorce for frozen embryos, embryo donation and informed written consent for certain procedures. None of the states prohibits certain techniques, such as egg donation or embryo donation, as it is the case for Switzerland. The policies adopted also don't limit access to married or stable heterosexual couples.[6] Thus, the policy design for ART practice is permissive in all the states.

Policies for GMOs in the agro-food sector: from moratorium to general approval

Swiss policies for *GMOs in the agro-food* sector are comparable to EU policies (Federal Law on Gene Technology, SR 814.91, Constitutional Article 120). As for ART, the

[3] Source for state regulations: National Conference of State Legislation , last consulted 20 October 2005: http://www.ncsl.org/programs/health/genetics/charts.htm, http://www.ncsl.org/programs/health/genetics/geneticsDB.cfm.

[4] In the case of Virginia, it is not clear whether therapeutic cloning is prohibited, or only reproductive cloning. Louisiana prohibits research on IVF embryos: further investigations are needed to interpret this prohibition.

[5] These states are California, Colorado, Florida, Louisiana, North Dakota, Oklahoma, Texas, Utah, Virginia, Washington and Wyoming.

[6] Limiting the access to married heterosexual couples has been considered in some states, recently for example in Indiana.

policies aim at protecting humans, animals and the environment from the misuse of biotechnology, and Swiss policies rely strongly on the precaution principle. Contained use, deliberate releases, production, distribution of GMO and products containing GMOs are submitted to strict procedures of authorisation, labelling (1% threshold)[7] and traceability, guaranteeing free choices and transparent information to consumers. In addition, the new Swiss liability requirements in the field of GMO are, according to experts, much more far reaching than provisions in other countries. To genetically modify vertebrates for commercialisation in the food market is also prohibited.[8] The implementation of the policies has so far been particularly restrictive with respect to deliberate releases. Since the introduction of authorisation requirements with the revision of the environmental protection act in 1995, until 2003 no deliberative release of genetically modified crops had been authorised. A small experimental release for research purposes by the Swiss Federal Technical Institute was authorized in 2004. In December 2005, however, the Swiss people accepted an initiative installing a provisional moratorium on GMOs in Swiss agriculture, which took effect immediately and making Switzerland the only European country banning GMOs from its agriculture.

In contrast to Switzerland, Canada relied on existing regulations and agencies in order to address GMOs in the agro-food sector (Montpetit 2005; Montpetit forthcoming). In the mid 1990s, different acts and regulations were amended to also address questions related to biotechnology, namely the Feed, Fertilizers, Seeds, Health of Animals and Plant Protection Acts. The commercialization of cultivars and novel food has to be approved on a case to case basis by Canadian Food inspection agency and Health Canada respectively. Experimental field trials are also subject to approval. There is no mandatory labelling or traceability requirement; voluntary labelling is possible for products which ingredients contain 5% or more GMOs. Attempts to ban genetically modified organisms on the provincial level have so far failed (for example in P.E.I. last December)

As the Canadian policies, the US solution contrast sharply with the strong state intervention prevailing in the Swiss case. Federal and state policies have so far remained permissive, even more permissive than in Canada (Sheingate 2004; Taylor, Tick et al. 2004; Garon and Montpetit forthcoming). Policy programs, adopted prior to biotechnology becoming a salient issue, regulate GMOs in the agro food sector on the federal and state level. As in the case of Canada, these programs are for plant protection, pesticides and food safety. In contrast to the Canadian situation for case authorisation procedure, for almost all GM plants, simply a notification procedure applies, whereby developers inform the United States Department of Agriculture about their releases. Government permits are only required for products listed as plant pest (Environmental Protection Agency and Animal and Plant Health Inspection Service). With respect to GM food, the Food and Drug administration implements a voluntary notification procedure for GM Food prior to commercialization. State policies,[9] with the exception of few

[7] Swiss norms also allow for 'negative' labelling, i.e. using the fact that a food product does not contain GMO for marketing purposes.

[8] Swiss legislation also covers uses of GMO in fertilizer and pesticides, and establishes for feed authorisation, labelling and traceability requirements.

[9] A number of states also adopted bills raising the criminal charges for activists destroying GM crop fields. A few states issue their own authorizations for field trails (Minnesota, Oklahoma, Vermont), taking into account, however, prior decisions of the APHIS (U.S. Department of Agriculture). In the case of pesticides,

California counties, so far have remained very limited and overall permissive. Noteworthy is the ban of GM crops by several Californian Counties, which moves them to the camp of restrictive regulators. Because of the California experience, several states have in the meantime prohibited local regulation and reserved the power to regulate biotechnologies to the state level.[10] Vermont's new policy shifting liability in case of contamination from the farmers to manufacturers also constitutes policy change into a more restrictive direction, yet overall is not sufficient to consider this State as an intermediary or restrictive regulator. With respect to food safety, two states have adopted regulation on labelling food. In Maine GMO free foods (1% threshold) can be labelled as such. Alaska has passed a bill for the mandatory labelling of genetically engineered fish, a novelty for the US. It remains to be seen, whether these latest changes are the beginning of development leading to several states adopting intermediary designs, or whether these remain punctual events with no lasting influence.

The question of labelling was already on the political agenda in the mid 90s, when the Food and Drug Administration issued guidelines for labelling of milk and milk products in relation with rBST, a genetically modified bovine growth hormone that basically stated that labels have to specify that milk comes from cows not treated with rBST (and not BST free milk) and also provide the information that "no significant difference has been shown between milk derived from rBST-treated and non-rBST-treated cows." (Runge and Jackson 2000) According to Runge and Jackson (p 60), the states have the primary enforcement responsibility and reacted in different ways:

> "Most states simply accepted the federal guidelines, but three precluded any labelling. Nevada, Illinois and Texas all concluded that such labelling might lower milk consumption, and could mislead consumers. Vermont, in contrast, mandated labelling in 1994 […] Nine states delineated additional labelling guidance in the mid-1990s, and eight of these developed substantiation and verification requirements, including record-keeping, and certification."

In short, the three cases share some features with respect to biotechnology policies, but distinguish sharply when it comes to other issues. While Switzerland and Canada have comparable policies with respect to embryo research and embryonic stem cell research, Switzerland is much more restrictive in terms of application and access. The US clearly has the most liberal policies, mainly limited to funding questions. Canada and the US GMO policies share a rather liberal approach to authorisation, while Switzerland has chosen to adopt a moratorium for GMOs in Swiss agriculture. Did courts contribute to these different outcomes? And who mobilised them to successfully influence public policies?

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with some exceptions, states base their decisions and also the registration on the EPA's decision and registration. California runs its own authorisation and registering program with respect to pesticides (Taylor, Tick et al. 2004).

[10] South Dakota, Pennsylvania, Giorgia, Idaho, Lousiana, Iowa, Kansas, and North Dakota.

Assisted Reproductive Technologies in Court

In the field of ART, litigation involving leftover embryos after separation or divorce of a couples surrogate motherhood contracts (e.g. Baby M) and parentage issues in general have been frequently addressed in court. In the context of this analysis, we have so far not included questions of filiation and parenthood, but concentrate on cases reviewing statutory law and administrative regulations and decisions, in order to see how and whether proponents or opponents of biotechnology directly challenged regulatory activities and if so, whether successfully.

Courts and the Coverage of ART by insurers and health care plans

The majority of the court cases found related to ART pertain to questions of insurance coverage, and where brought before court by couples having seek treatment and finding coverage refused by their health insurance or the provincial health plan. The organization of the health care system varies considerable across the three countries studied, with only Switzerland and Canada offering universal coverage, the first through a mandatory health insurance system and the second through provincial health care plans. Despite these differences, the similarities in the court cases and the outcomes are striking as the following comparison reveals.

In Switzerland, the Swiss Federal Court of Insurance, part of the Swiss Federal Supreme Court, and highest and final court of appeal in matter of insurance questions had to decide on several occasions on the coverage of in vitro fertilization by the mandatory private health insurance. Couples challenged the refusal of their health insurer to cover IVF without success.[11] Despite the fact that IVF is now recognized as a standard procedure, it is still not included in the list of treatments to be covered by the mandatory health plan.

Couples have not been any more successful in Canadian courts. None of the provinces fully covers IVF[12], even though some of the related procedures and medication are billed to the provincial plans. In Ontario in 1998 (*D.R. and L.R., B.C. and L.A.C., B.L. and R.F., L.E. and M.E., J.H. and K.H. v. Ontario*)[13] and in Nova Scotia in 1999 (*Cameron v. Nova Scotia*)[14] couples challenged the decision of the provincial health plans to cover intracystoplasmatic sperm injection (ICSI), a special technique related to IVF in order to overcome male infertility problems. The Canadian Human Rights Tribunal accepted to proceed to a full hearing in 2005 for a couple challenging the non-coverage of IVF treatment by the Canadian Armed Forces (*Terry Buffet v. Canadian Armed Forces*)[15].In short, court cases in Canada have so far not initiated any policy change on the federal or provincial level. The Canadian Health Act does not render coverage of IVF

[11] Eidgenössisches Versicherungsgericht: BGE 113 V 42, 2.2. 1987; BGE 119 V 26, 10.3.1993; BGE 121 V 289, 13.12.1995; BGE 121 V 302, 13.12.1995; BGE 125 V 21, 4.2.1999.
[12] Coverage limited to very specific, and overall not frequent indications.
[13] *D.R. and L.R., B.C. and L.A.C., B.L. and R.F., L.E. and M.E., J.H. and K.H. v. Ontario*. 1998. Ontario Health Services Appeal Board.
[14] *Cameron and Smith v. Nova Scotia* N.S.J. No. 297 CA 153793 (1999).
[15] *Terry buffet v. Canadian Armed Forces.* 2005. Canadian Human Rights Commission.

and related treatments mandatory, and none of the provinces generally covers IVF. Given the considerable costs of assisted reproductive technologies and the current crisis of health care, the lack of success in litigating is not very surprising.

In the USA, in 2005 the Family building Act was introduced by Rep Anthony Weiner. The Act demands insurance coverage of infertility treatment by amending the Employee Retirement Income Security Act (ERISA). Self-insured health plans are currently exempt from state benefit mandates. In a number of states, legislation has been adopted with respect to insurance coverage for fertility treatment, but not necessarily mandating insurers to cover infertility treatments, and there is so far no federal law requiring any coverage. Our research into the USA cases does not yet allow us to draw any conclusions on whether, some of the policy changes on the state level might have been triggered directly through court rulings or indirectly through agenda setting effects of litigation. Nevertheless, we can say that in the majority of the court cases found, insurers won the cases[16] and so far no changes have been made the ERISA.

In short, with respect to insurance coverage we can conclude that the Haves, i.e. government and insurance companies, have so fare come out ahead, and no federal policy changes have been induced in the three countries studied.

Challenging ART regulations on the federal and subnational level

Insurance questions are, however, not the only cases brought before court with respect to ART. In all three countries, we found cases challenging state or federal regulation in the matter. Federal regulations are currently and have been challenged in court in Canada and the USA. With respect to ART, the Bush administration's policy on financing embryonic stem cell research has been challenged in court. Religious interest challenged the NIH guidelines for public funding of embryonic stem cell research (*Nightlight Christian Adoptions, et al. v. Thompson*)[17]. Religious interests also unsuccessfully challenged California's policy of embryonic stem cell research funding, adopted by referendum (People's Advocate and al./California family bioethics council v. Independent citizen's oversight committee/California Institute for regenerative medicine).

Pro stem cell research interests also tried to promote their policy preferences in court. Scientists filed a lawsuit against the policy for withholding federal funding (*Thomson v. Thompson*)[18]. In both cases, the plaintiffs did not succeed in influencing the current policies on financing embryonic stem cell research in the direction of their preferences. In fact, courts have generally been rather cautious in attacking presidential executive orders.

Another court case initiated by organized interests in the field of ART, was launched by the American Association of Bioanalysts that wanted to see licensing

[16] See: Margaret S. v. Edwards (1986); Michael v. Metropolitan Life Ins. Co (1986).; Reilly v. Blue Cross & Blue Shield United (1988); Egert v. Connecticut General Life Ins. Co (1990); Lifchez v. Hartigan(1990); Maciosek v. Blue Cross & Blue Shield United (1991); Ravenscraft v. Hy-Vee Emple. Benefit Plan & Trust (1996); Saks v. Franklin Covey Co.(2000); Stumpf v. Med. Benefits Adm'rs (2001).
[17] *Nightlight Christian Adoptions et al. v. Thompson* Civ. No. 1:01CV00502 (D.D.C. March 8. 2001).
[18] *Thomson v. Thompson* 344 F. Supp. 1378 U.S. Dist. LEXIS 13097 No. 5651 (1972).

requirement extended to all laboratories working on embryos in vitro (*American Ass'n of Bioanalysts v. Shalala*)[19]. The case was dismissed, and the licensing requirements have so far and to our knowledge not been extended.

Given the lack of federal policies in the USA and the rather recent adoption of federal law in Canada, it is not surprising that courts have so far played a limited role. In the near future, this might however change. In Canada, the Quebec government has asked the Quebec's provincial Court of Appeal to verify the constitutionality of the Assisted Human Reproduction Act, alleging that the federal government is interfering into provincial matters. The matter is pending.

In the case of Switzerland, the Swiss Federal Supreme Court (and any other court) has no power to overturn federal laws, i.e. its power of nullification is limited. However, the Swiss Federal Supreme Court has the power to overturn cantonal law. In the case of ART, the Supreme Court declared two cantonal laws unconstitutional[20] and indirectly influenced policy-making on the federal level.

In the case of ART, the policy-making process started out at the cantonal level. The Swiss health care system is decentralized and characterized by a mixture of public and private health care providers. The cantons play a major role in formulating and implementing health policies and they are important health care providers: they are in charge of cantonal and regional hospitals, and they are notably in charge of University hospitals. As an important player in health care policies, as well as being a provider directly confronted, early on, with the questions provoked by the new techniques, some of the cantons did not want to wait for federal legislation and chose, rather, to adopt their own laws and regulations. The design of cantonal laws and regulations varied strongly. Three cantons, Glarus (1988), St. Gallen (1988) and Basel-City (1991), prohibited almost all-available ART, including full prohibitions of IVF and gamete donation. The cantonal laws of St. Gallen and Basel-City (BGE 119 Ia 460) were challenged in the Swiss Federal Supreme Court, which, at the time, in the case of an abstract review of a cantonal law was the court of first and final appeal. The Court ruled on the first case, the canton of St. Gallen in 1989, (BGE 115 Ia 234) before the federal government published its message concerning the 'Beobachterinitiative' and before the parliamentary debate took place. The Court ruled that general prohibitions of certain techniques in cantonal laws were unconstitutional and questioned the practice of the anonymity of donors.

The Court's decision led to policy convergence at the cantonal level, by ruling out extremely restrictive solutions. It thereby clearly influenced the starting conditions for the debate on the federal level. The arguments of the Federal Supreme Court found a strong resonance with the actors on the federal level. In particular, the opponents of total prohibitions referred to the Court's opinion that general prohibitions violate the right to

[19] *American Ass'n of Bioanalysts v. Shalala* U.S. Dist. LEXIS 2603 (2000).

[20] The Swiss Federal Supreme Court also reviewed two cantonal statutes, a statute of the Canton of Geneva, and a statute of the Canton of Vaud. In the case of the Canton of Geneva the Swiss Federal Supreme Court declared the regulation for licensing private infertility clinics be conform (BGE 2P.138/1992). In the case of the Canton of Vaud, an unmarried couple successfully challenged its non-admission to IVF on the basis that the competent authority had exceeded its competencies in regulating the question of access (BGE vom 26.10.1989, 1P.311/1989).

personal freedom. Furthermore, its jurisprudence strongly contributed to adopting the right to know one's ancestors. (Rothmayr 1999; Rothmayr 2001)[21]

In the US, with respect to state policies (Martin and Lagod 1990), some state statues have been held unconstitutional. In the case of a Louisiana statute concerning the prohibition of experiments and experimental research on "an unborn child or a child born as a result of an abortion" a federal appellate court decided that the statute was unconstitutional because of the vague language of statue (*Margaret S. v. Edwards*)[22]. In Illinois, a statutory provision banning non-therapeutic fetal experiments was also challenged successfully by medical interests (*Lifchez v. Hartigan*).[23] As in the case of Louisiana, terms such as experimentation and therapeutic were considered to be vague, asking physicians to guess whether various activities were lawful or not.

Compared to the insurance questions, were insurer and government prevailed over individual litigants the picture for the regulation of ART on the state and cantonal level is reverse. Medical interests have successfully challenged laws on the subnational level in the USA and Switzerland and prevailed over government, respectively scientific interests successfully defended state policies favorable to research against interests critical towards stem cell research. Courts have acted as safeguards against total prohibitions and against too strong state intervention. So far, only in the case of Switzerland, however, these battles have had a tangible impact on federal policies.

GMOs and the Courts: no success for environmental interests

There have been several court cases that were widely discussed in the media related to GMOs in the agro-food sector. One example is the case of StarLink corn detected in human food and product liability claims (In re Starlink Corn Prods. Liability Litigation).[24] Other examples involve Monsanto and other crop producers in patent infringement cases, or corn and soy bean farmers suing Monsanto for unlawfully conspiring to fix, raise and maintain prices for some of its GM crops and seeds (Roundup Ready, Yieldgard). Hence, a first category of cases opposes multinationals to farmers. A number of cases are patent infringement claims by Monsanto against farmers[25]. Traditionally farmers save seeds from the harvest to grow next year's crops. Monsanto,

[21] The Swiss Federal Supreme Court also reviewed two cantonal statutes, a statute of the Canton of Geneva, and a statute of the Canton of Vaud. In the case of the Canton of Geneva the Swiss Federal Supreme Court declared the regulation for licencing private infertility clinics be conform (BGE 2P.138/1992). In the case of the Canton of Vaud, an unmarried couple successfully challenged its non-admission to IVF on the basis that the competent authority had exceeded its competencies in regulating the question of access (BGE vom 26.10.1989, 1P.311/1989), for a detailed discussion see Rothmayr 1999: 107-108.

[22] *Margaret S. v. Edwards* 794 F.2d 994 U.S. App. LEXIS 27365 Nos. 81-3750, 84-3520 (1986).

[23] *Lifchez v. Hartigan* 556 F. Supp. 157 U.S. Dist. LEXIS 19483 (1983).

[24] *In re* Starlink Corn Prods. Liab. Lit., 212 F. Supp. 2d 828 (N.D. Ill. 2002).

[25] See *Monsanto Co. v. McFarling, 363 F.3d 1336 (Fed. Cir. 2004); Monsanto Co. v. Ralph, No. 03-1243, 2004 U.S. App. LEXIS 18814 (Fed. Cir. 2004) ; Monsanto Co. v. Swann, 308 F. Supp. 2d 937 (2003); Monsanto Co. v. Hartkamp, No. 00-164-P, 2001 U.S. Dist. LEXIS 25253 (E.D. Okla. 2001); Monsanto Co. v. Roman, No. 1:03-CV-068-C, 2004 U.S. Dist. LEXIS 10724 (N.D. Tex. 2004) Monsanto Co. v. Scruggs 342 F. Supp. 2d 584 U.S. Dist. LEXIS 26650 (2004) ; Monsanto Co. v. Trantham (in Re Trantham) 286 B.R. 650 Bankr. LEXIS 1446; 49 Collier Bankr. Cas. 2d (MB) 979 (2002).*

however, legally obliges farmers to buy seeds every year and has sued farmers who did breech the agreement signed on purchase of the patented seeds. Monsanto won at least seven of such cases in the US. Monsanto also won the one patent infringement case before the Canadian Supreme Court, which attracted considerable media attention, because it involved a farmer who had not previously purchased Roundup Ready Canola (*Monsanto Canada Inc. v. Schmeiser*)[26], but whose fields had been contaminated through cross pollination, and by saving and replanting seeds contained more the 90% of the patented canola.

A second category of cases involves liability issues in tort law. In the USA, Aventis StarLink maize, only approved for feed, entered the human food chain through cross-pollination of non StarLink fields and triggered a wave of court cases[27] and considerable economic losses caused by the recall of merchandise and boycotts of American corn exports. Court cases together with public outrage about the case, led Aventis to sign a formal agreement to compensate farmers for their damage and losses related to the growth of StarLink maize in 2000. Aventis also settled in the case of consumers suing for eating food not fit for human consumption (Kershen 2004).[28] The prominent Canadian case is *Hoffman v. Monsanto*[29], in which organic farmers unsuccessfully brought a class action suit against Monsanto for contamination of their crops through Roundup Ready Canola.[30]

This brief overview reveals that farmers have so far not been very successful in defending their interests, with the exception of StarLink. In the case of StarLink, however, court cases were embedded in a large public outrage and huge media coverage that certainly influenced the adoption of a settlement and compensation payments to farmers. Patent and liability issues are important battlefields in Europe and for proponents and opponents of biotechnology. A detailed analysis of the impact of all such court cases on policies and policy-making goes, however, beyond the scope of this paper and would imply considerable additional research.

A second category of cases consists of governmental authorisation procedures and practises that have been attacked in court. For Canada, we have so far not found any cases where environmental interests challenged federal or provincial policies. To the contrary, authorisation practice in the USA was attacked in court. In the case of GMOs in the agro-food sector, we identified several cases challenging federal and state regulatory activities. On the ground of the National Environmental Policy Act (NEPA), interests critical to biotechnology challenged unsuccessfully the FDA's policy that recognises genetically modified crops generally to be safe (*Alliance for Bio-Integrity v. Shalala*)[31]. To the contrary the National Institute of Health's approval of deliberative release

[26] *Monsanto Canada Inc. v. Schmeiser*, 2004 S.C.C.D. LEXIS 48 (2004).
[27] See for example: *Jemar, Inc. v. Aventis Cropscience United States Holding, Inc.; Olsen v. Aventis Crop Sci. USA Holding Inc.; Schnoebelen v. Aventis Cropscience United States Holdings, Inc.; Wolff v. Aventis Cropscience USA Holding, Inc.; In re Starlink Corn Prods. Liab. Litig.*
[28] Star Link Corn Products Liability Litigation. 2002. WL 1291790 at *1 (MDL. ND III 2002), cited after Kershen 2004, p 460.
[29] Hoffman v. Monsanto Canada, Inc., 2003 Sask. D.J. 15153 (2003).
[30] Monsanto also brought legal action against dairy producers labelling in other states (e.g. in Maine); subject to further research.
[31] Alliance for Bio-Integrity v. Shalala, 116 F. Supp. 2d 166 (D.D .C. 2000).

experiments involving genetically modified bacteria was successfully challenged in court (*Foundation on Economic Trends v. Heckler).*[32] A third case concerns International Dairy Foods Association et al v. Attorney General of Vermont (*International Dairy Foods Ass'n v. Amestoy*)[33], where the dairy industry supported by Monsanto successfully challenged a Vermont statue that required placement of blue dot on products which contained milk from cows treated with a genetically modified growth hormone in 1996 (rBST, growth hormone bovine somatotropin). To the contrary Ben&Jerrys sued Illinois for preventing them from labelling their products as rBST free, and Illinois now allows for voluntary food labelling of non-rBST food products (*Ben & Jerry's Homemade, Inc. v. Lumpkin*)[34]. On the federal level, the above-mentioned Alliance for Bio-Integrity challenged unsuccessfully the FDA's decision not to require labelling for GM food (*Alliance for Bio-Integrity v. Shalala*).[35] Challenges of federal policies in court did not succeed in pushing policies into a more interventionist and restrictive direction. On the state level, labelling requirements in one state were successfully challenged. This successful challenge might have had an influence on the enforcement practice in other states (to be confirmed). At the same time, in one state, producers succeeded in establishing the right to label if they wish to do so. This case did however not turn the policies overall more restrictive, because it did not imply a mandatory labelling. Thus, we can say that environmental and business interests seeing an advantage in labelling did succeed in initiating policy change through the courts.

In Switzerland, compared to ART, court involvement in GMO policies remained much more modest. To initiate legal action against implementation decision of the Federal Administration was one of the strategies used by interest groups critical of GM food in order to attack the policies of the Federal Office of Public Health. They filed complaints against the unauthorized use of a GM vitamin, and also against the first authorization of GM Soya by the Office (BGE 123 II 376). They also legally attacked a public campaign against a popular initiative against biotechnology ('Genschutzinitiative') that claimed that if the Swiss people would accept the popular initiative, research into currently incurable illnesses would be prohibited and hence medical progress stopped. The judicialization[36] of the conflict over biotechnology was not a successfully employed strategy with respect to GM food. All three complaints were rejected, and the implementation practice of the Federal Office of Public Health sustained. Environmental interests were not more successful in the case of deliberative releases (BGE 129 II 286). In the case of deliberative releases, one research institution that had been denied an authorization successfully appealed. The Federal Environmental Office then authorized the deliberate release, but environmental groups successfully appealed against this new decision. However, the research institutional finally won the case and was allowed to go ahead with an experimental deliberative release of very small scale. However, this change in implementation practice was of little relevance because of the already very restrictive

[32] Foundation on Economic Trends v. Heckler, 756 F.2d 143 (D .C. Cir. 1985).
[33] International Dairy Foods Ass'n v. Amestoy, 92 F.3d 67 U.S. App. Lexis 19891 (1996).
[34] Ben & Jerry's Homemade, Inc. v. Lumpkin, 1996 U.S. Dist. Lexis 12469 (N.D. Ill. 1996).
[35] Alliance for Bio-Integrity v. Shalala, 116 F. Supp. 2d 166 (D.D .C. 2000).
[36] The tradition of supremacy of parliament is still very strong in Switzerland. The Swiss Federal Supreme Court has no power to overturn federal laws, i.e. its power of nullification is limited.

authorization practice in place and also in light of the recently adopted moratorium on GMOs in Swiss agriculture rendering legal battles vain for the coming 5 years.

Conclusions

This paper analyzed the role of litigation and court decision in biotechnology policy-making, more precisely in the field of assisted reproductive technologies and in the case of genetically modified organism in the agro-food sector. We were starting out with three questions. First, we asked whether proponents or opponents to biotechnology were generally more successful in court. The data overall supports the conclusion that big business is a successful repeated player. To the list of rather successful interests, we can add medical research interests and the government. We found that environmental interests are also repeated players in Switzerland and the USA, and so are religious interests in the case of embryonic stem cell research in the USA. Both have so far not been particularly successful in court. If it comes to individuals, infertile couples and farmers, the data clearly supports Galanter's thesis that the Haves come out ahead, given that insurance companies, the state and multinationals win the majority of the cases.

A second interest of this research was the question whether court cases bring about policy-change, directly or indirectly, and whether these changes rather strengthen permissive policy approaches or to the contrary reinforce tight regulation and strong governmental intervention. In all three countries and both fields, courts have the tendency to act as a safeguard against strong state intervention and more regulation. Courts take rather side with proponents of biotechnology. Policy change initiated through litigation has, however, remained modest. Changes remain within the overall policy direction adopted by a country and we could so far not observe any basic changes of direction initiated or supported by court decisions, with the exception of ART on the cantonal level in Switzerland.

Finally, we supposed that there are considerable differences in court involvement and impact across countries. In fact, the importance of litigation as a strategy but also its impact varies across the three countries studied, but not in the way we expected. While the US clearly shows the most litigious pattern, it is only in the case of Switzerland for ART that we found court cases influencing public policy making in a larger sense on the national and sub-national level. The number of cases we found for Canada[37] has remained rather modest, and despite the case of Quebec against the federal ART legislation and the cases involving the financing of ART techniques on the provincial level, we have so far not come across any cases attacking federal regulations, procedures or authorizations, as was the case for Switzerland and the USA. We can also observe differences and commonalities with respect to the issues brought before court, indicating that litigation and litigation strategies depend on the context specific to a policy issue. In all three countries courts were solicited related to the coverage of in vitro fertilization, and federal or state regulations have been attacked in court. In the US and in Switzerland, authorization procedures and authorization for commercialization and deliberate releases were also brought to court, which seems not to be the case for Canada. Several patent

[37] Specialized administrative courts have not yet been included.

infringement and liability cases related to patented crops and seeds can be found in the USA and in Canada, but not in Switzerland. Furthermore, only in the USA embryonic stem cell research has been an issue for interest group litigation. The picture of variation across countries and issues is, however, provisional, not only because this research is work in progress, but also because of the rather recent nature of some of the legislation and debates. Nevertheless, further research might propose some explanations for these differences based on the specific characteristics of the policy making processes, the actors involved and institutional features of the three countries studied.

Cited Literature

Baumgartner, F. and B. Jones (1993). Agendas and Instability in American Politics. Chicago, University of Chicago Press.

Bleiklie, I., M. L. Goggin, et al., Eds. (2004). Comparative Biomedical Policy. London, Routledge.

Brodie, I. (2001). "Interest Group Litigation and the Embedded State : Canada's Court Challenges Program." Canadian Journal of Political Science **34**(2): 357-376.

Brodie, I. and F. L. Morton (2004). Do the "Haves" Still Come Out Ahead in Canada? Constitutional Politics on Canada and the United States. S. L. Newman. Albany, Sunypress.

Feeley, M. and E. L. Rubin (1998). Judicial Policy Making and the Modern State: How the Courts Reformed America's Prisons. Cambridge, Cambridge University Press.

Flemming, R. B. and G. S. Krutz (2002). "Repeat Litigators and Agenda Setting on the Supreme Court of Canada." Canadian Journal of Political Science **35**(4): 811-833.

Galanter, M. (1974). "Why the 'Haves' Come Out Ahead: Speculations on the Limits of Legal Change." Law and Society Review **9**: 95-160.

Galanter, M. (2003). Why the "Haves" Come Out Ahead: Speculations on the Limits of Legal Change. In Litigation: Do the "Haves" Still Come Out Ahead? H. M. Kritzer and S. Silbey. Stanford, Stanford University Press.

Garon, F. and E. Montpetit (forthcoming). Same Policy, Different Processes: Explaining Permissive Policies in the USA. The Politics of Biotechnology: A Cross-Country Comparison of Biomedicine and GM-Food E. Montpetit, C. Rothmayr and F. Varone.

Glenn, B. (2003). The Varied and Abundant Progeny. In Litigation: Do the "Haves" Come Out Ahead? K. A. Kinsey and S. Silbey. Stanford, Stanford University Press.

Goggin, M. L. and D. A. Orth (2004). The United States. National talk and state action in governing ART. Comparative Biomedical Policy. Governing assisted reproductive technologies. I. Bleiklie, M. L. Goggin and D. A. Orth. London, Routledge**:** 82-102.

Kagan, R. A. (2001). Adversarial legalism. The American Way of Law. Cambridge, Harvard University Press.

Kagan, R. A. and L. Axelred, Eds. (2001). Regulatory Encounters. Multinational Corporations and American Adversarial Legalism. Berkeley, University of California Press.

Kershen, D. L. (2004). "Legal Liability Issues in Agricultural Biotechnology." Crop Science **44**: 456-463.

Kritzer, H. M. (2003). The Government Gorilla: Why Does Government Come Out Ahead in Appellate Courts? In Litigation: Do the "Haves" Still Come Out Ahead? K. A. Kinsey and S. Silbey. Stanford, Stanford University Press.

Martin, P. A. and M. L. Lagod (1990). "The Humen Preembryo, the Pogenitors and the State." Berkely Technology Law Journal **5**(2): 258-309.

Mattli, W. and A.-M. Slaugther (1998). "Revisting the European Court of Justice." International Organization **52**: 200-216.

McCann, M. (1994). Rights at Work. Pay Equity Reform and the Politics of Legal Mobilization. Chicago, Chicago University Press.

McCann, M. W. (1998). Law and Political Struggles for Social Change: Puzzles, Paradoxes, and Promises in Future Research. Leveraging the Law. Using the Courts to Achieve Social Change. D. A. Schultz. New York, Peter Lang**:** 319-349.

McCormick, P. (1993). "Party Capability Thoery and Appellate Success in the Supreme Court of Canada, 1949-1992." Canadian Journal of Political Science **26**: 523-540.

Montpetit, E. (2005). "A Policy Network Explanation of Biotechnology Policy Differnces between the United States and Canada." Journal of Public Policiy **25**(3): 339-366.

Montpetit, E. (forthcoming). The Canadian Knowledge Economy in the Shadow of the United Kingdom and the United States. The Politics of Biotechnology: A Cross-Country Comparison of Biomedicine and GM-Food E. Montpetit, C. Rothmayr and F. Varone, Lexington.

Montpetit, E., C. Rothmayr, et al., Eds. (forthcoming). The Politics of Biotechnology: A Cross-Country Comparison of Biomedicine and GM-Food

Olson, S. M. (1990). "Interest-Group Litigation in Federal District Courts: Beyond the Political Disadvantage Theory." Journal of Politics **vol. 52**(3): 854-882.

Rosenberg, G. N. (1991). The Hollow Hope: Can Courts Bring about Social Change? Chicago, University of Chicago Press.

Rothmayr, C. (1999). Politik vor Gericht. Implementation und Wirkung von Entscheiden des Schweizerischen Bundesgerichts in den Bereichen Fortpflanzungsmedizin, Lohngleichheit von Frau und Mann und Sonntagsarbeit. Bern, Haupt.

Rothmayr, C. (2001). Towards the Judicialisation of Swiss Politics? The Swiss Labyrinth. Institutions, Outcomes and Redesign. J.-E. Lane. öpmdpm, Framl Cass**:** 77-94.

Rothmayr, C. and U. Serdült (2004). Switzerland: policy design and direct democracy. I. Bleiklie, M. Goggin and C. Rothmayr. London, Routledge**:** 191-208.

Runge, F. C. and L. A. Jackson (2000). "Negative Labeling Of Genetically Modified Organisms (GMOs): The Experience of rBST" AgBioForum **3**(1): 58-62.

Shapiro, M. and A. Stone (1994). "The New Constitutional Politics of Europe." Comparative Political Studies **26**(4, Special Issue: The New Constitutional Politics of Europe, edited by Martin Shapiro and Alec Stone): 397-420.

Sheingate, A. (2004). The Politics of Biotechnology in the United States: Medical and Agricultural Applications Compared. Annual Meeting of the American Political Science Association, Chicago, September 2-5, 2004.

Smith, M. (2005). "Social Movements and Judicial Empowerment : Courts, Public Policy, and Lesbian and Gay Organizing in Canada." Politics and Society **33**(2): 327-353.

Tate, N. C. and T. Vallinder (1995). The Global Expansion of Judicial Power: The Judicialization of Politics. The Global Expansion of Judicial Power. N. C. Tate and T. Vallinder. New York, New York University Press**:** 1-10.

Taylor, M. R., J. S. Tick, et al. (2004). Tending the Fields: State & Federal Roles in the Oversight of Genetically Modified Crops.