Federalism, New Biotechnologies & Fundamental Rights in Europe

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Introduction

The aim of this paper is to explore the role of judicial policies relating to research in and patenting of the life-sciences and new health technologies in the EU in the light of renewed calls for greater European Integration. Legal regulation of new biotechnologies reflects a plurality of conflicting national policies and laws on controversial issues, such as stem cell research, which often involve deeply held moral and religious beliefs that reflect the diversity of values and cultural identities in Europe. Our argument involves three steps. First, EU regulation of new biotechnologies is undertaken under conditions of what is widely perceived as a ‘democratic deficit’ in the Union. Secondly, the Union’s fundamental values, which are contained in the Treaties as well as key texts such as the Charter of Fundamental Rights of the EU, are based on open-ended principles such as human dignity to accommodate this moral diversity (Plomer & Tsarapatsanis, 2013). Thirdly, the CJEU (hereinafter ‘the Court’) plays a critical role in the determination of the balance between the Union’s central values and the diversity of national values. Yet, the role and fitness of the Court to discharge the role of arbiter in this constitutionally charged field has been little scrutinized. We suggest that the political and legal tensions between the Union and Member States are particularly acute in the field of biotechnology and require fundamental reforms of EU institutions, notably the Court, to protect the democratic ideal.

The Federal problematic

In the midst of what seems to be the most important ‘existential’ crisis of its history, to wit, the crisis of the common currency, the EU still represents a legal and political enigma. The Union is frequently characterized as a ‘sui generis’ entity which is stranded uncomfortably in the conceptual space between international law and national constitutionalism. In terms of the classical doctrine, the EU is neither an international organization, nor (yet) a Federal state (Mason, 1955). Its constitutional identity is still
indeterminate and, in any event, is hotly contested (Schütze, 2012). Some speak of a ‘Federalism without constitutionalism' (Weiler, 2001), alluding to what appears as an odd combination of strong doctrines of supremacy and direct effect of EU law, marshaled by the Court in a series of landmark decisions, with the continuing lack of a ‘European demos'. Others accept this analysis *de lege lata*, but point to the future and call for an ever closer unification. Their basic argument is that the creation of tighter political democratic federal structures, along with the gradual strengthening of the ties between Europeans in a European-wide public sphere, could provide the means to counter the forces of globalization and neoliberalism (Habermas, 2001). Still others think that it is possible to disentangle the legal concept of ‘federation’ from those of state and sovereignty, thus producing a conception of a ‘federation of states’ that strikes some form of balance between ‘international’ and ‘national’ elements (Beaud, 2007 and Schütze, 2012).

Whatever the right answer to the abstract question of the legal nature of the EU might be, the above debates point to a major feature of the European experience, to wit, the pressing practical need to constantly reconcile the sovereignty and autonomy of Member States with federal centralizing tendencies and the ‘democratic deficit’ or ‘disconnect’ between EU and national institutions (Lindseth, 2010). The expansive reach of the Union is most famously expressed by the constitutionalizing jurisprudence of the Court (Craig and De Burca, 2011). As expected, constitutional tensions are particularly acute in areas in which there exists little or no European consensus, as well as in those that pose threats to what is commonly perceived as the hard core of state sovereignty. According to one widely accepted view, and given the current distribution of powers between EU institutions, the centralizing movement unfolds in the form of a dialectic between the Court and the political process of the Union. At moments of political stagnation, the Court typically steps in to salvage and to accelerate European integration, thus prompting the political process to further crystallize the constitutional *acquis* by intergovernmental legal means (Weiler, 2012).

**Democracy, the EU and the Court**

Three features of this dialectic stand out. *First*, the Court clearly takes on the role of a major driver of the integration process. Its famous constitutionalizing jurisprudence in the 1960s and 1970s is only the most obvious facet of this process. A less obvious but
equally crucial one is to do with the impact of the proliferation of EU law, whether primary or secondary, on whose interpretation the Court is the ultimate arbiter. In this respect, the Court yields enormous interpretive power. This is even more so when the adopted texts contain abstract principles of indeterminate content such as human dignity, enshrined in the Lisbon Treaty as a fundamental value of the Union for the first time in 2007, as well as the Charter of Fundamental Rights of the EU which contains a whole chapter under this heading (Plomer & Tsarapatsanis, 2013). Second, the strong impetus towards a constitutionalization of EU law, prompted by the case-law of the Court itself, goes hand in hand with a persistent democratic deficit on the level of EU legislative institutions. The two primordial features of any functioning representative democracy – the grand principles of accountability and representation – in the words of Weiler, are missing (Weiler, 2012). First, there is no coherent process of accountability on an EU level, since there is no ‘Government’ of the EU that could be ousted by means of popular vote. European governance is, in Weiler’s words, ‘governance without Government’. Second, political representation of European citizens in the European Parliament is also skewed in the sense that ‘it is impossible to link in any meaningful way the results of elections to the European Parliament to the performance of political groups within the preceding parliamentary session’ (Weiler, 2012). This means that the constitutionalization process which resulted from the Court’s bold jurisprudential initiatives in the 1960s whereby EU law was declared by the Court to have supremacy over national laws, has resulted in a quasi-federal legal structure in the fields of competence of the EU that cannot be adequately justified on democratic grounds. Third, the Court has consistently interpreted provisions that confer powers to the EU in a teleological manner to further (its own perception of) the aims of the Union, that goes far beyond what Member states thought they were agreeing to when they conferred those powers to the EU in the first place (Schütze, 2012, at 156-157; a classic example from the case-law of the Court in this regard includes the Casagrande case [Case 9/74, Casagrande v. Landeshauptstadt München]).

There are longstanding concerns about the potential for illegitimate interference by courts with elected parliaments in national legal systems (Ewing, 2007; Campbell, 2001; Hiebert, 2011). These concerns are amplified in federal systems, where supreme or constitutional courts are called upon to make decisions which strike at the heart of the constitutional balance between the federal centre and the autonomy/sovereignty of the federation's states. For instance, Tushnet (2005) argues for a more 'populist constitutional law' as an alternative to the US' heavy reliance on judicial review to
resolve conflicts of constitutional norms. On a similar note, Kramer (2004) calls for recognition of “the democratic pedigree and superior evaluative capabilities of the political branches”.

In our view, these generic concerns are even more compelling when it comes to the quasi-federal structure of the European Union in its present form. The concerns specifically extend to the operative mechanisms and structures, notably the role of the Court, as regards the balance of power among EU institutions as well as among the EU and Member States themselves. The endemic clash of moral, political and religious values over the use of biomedical technologies in Europe and the diversity of national policies and laws makes the role of such a transnational constitutional court particularly sensitive in the existing union and even more so in any closer union.

**Enter Biotechnology**

EU policy on biotechnology has been the source of ongoing moral, religious and political controversy in Europe between secular, catholic, liberal protestant, green, Christian Social Democrats and socialist parties in Europe (McRae, 2010; Jasanoff, 2005). Legislative settlements such as the EU Directive on Biotechnological Inventions 1998 (hereinafter the Directive), adopted after a ten year long battle between the Commission, Council and Parliament (Porter, 2008), were referred to the Court for a declaration of incompatibility with the Treaties immediately after the legislation was adopted (*Netherlands case*, 2001). The Court was further called upon by the Commission in infringement proceedings against a substantial number of Member States which had failed to implement the Directive several years later (Nottingham report, 2006). The landmark ruling of the Grand Chamber of the Court in the Brüstle case (2011) is the latest intervention of the Court in a field where moral, religious and political controversy continues unabated (Plomer, 2012). MEP opponents of stem cell research in Europe (Peter Liese (EPP, Germany), Miroslav Mikolasik (EPP, Slovakia), Gerald Häfner (Greens-EFA, Germany) and Konrad Szymanski (ECR, Poland) announced on the 12th of September 2012 that they would challenge the legality of Horizon 2020 if funding is approved, as it has. So the Court may well be called upon, yet again, to intervene in the longstanding battle over EU policy and funding of hESC research, as it has over other contested technologies (Scott, 2007). Whether the EU evolves towards a closer federalist union or not, and whatever the precise form such a closer federal union may take,
role of a Court which has hitherto exercised “unparalleled transnational power” (Lord Mance) will be critical to judicial review of the European divisions over moral, religious and political values on biotechnology. Yet, whilst the Court is called upon to play such a critical role as constitutional arbiter, there has hitherto been little scrutiny of the Court and its role in the legal architecture of the Union (Chalmers, 2012).

Differences over moral and religious values on biotechnology in Europe are captured in different national laws and policies reflecting differences on the meaning and scope of protection of fundamental rights in Europe (Plomer & Tsarapatsanis, 2013). The autonomy of Member States of the European Union to reflect in their national laws their respective moral and religious cultures is formally respected through the limitations of EU competences and the principle of subsidiarity, set out in the Treaties. The principle of subsidiarity, central to democratic self-government within the European Union, requires that all decisions should be made at the lowest feasible level. Yet, despite formal recognition of this principle in the Treaties, the Court has yet to annul a measure because it violates ‘subsidiarity’ (Chalmers, 2012). Instead, the Brüstle ruling illustrates the dramatic potential for judicial overreach. In an extraordinary ruling, the Court proceeded to impose on the whole of the EU a ‘unified’ definition of the human embryo, seemingly upholding a religious, morally conservative view of the embryo and extending ‘human dignity’ to embryos despite the absence of agreement at national level (Plomer, 2012). In so doing, the Court disregarded the jurisprudence of the European Court of Human Rights, which, for its part, has consistently over four decades adopted a stance of deference to Member States as regards the rights and level of protection owed to the embryo – mainly, though not exclusively, through its case law on abortion (see, of late, its decision in A, B and C v. Ireland). Only five years before the EU Court’s Brüstle ruling, the ECtHR had also reaffirmed the margin of discretion afforded to Member States in a case where the claimant sought to implant frozen embryos without the father’s consent claiming that destruction of the embryos was contrary to Article 2 of the Convention protecting the right to life (Evans v UK). The European Court of Human Rights disagreed and reiterated that there is no consensus in Europe as to when and what value to ascribe to prenatal human life. The EU Court’s flagrant disregard of the long established jurisprudence of the European Court of Human Rights and the imposition on the whole of Europe of a ‘unified’ view of the embryo instead, illustrates the potential for the EU to encroach on the autonomy of Member States in ways which also involve a retreat from fundamental human rights in Europe.
The Court’s record of bias

The Brüstle ruling is not an isolated example of questionable decision-making by the Court. The Court has sometimes been described as little more than a ‘rubber stamp’ for the Commission (Chalmers, 2012). According to Chalmers, there is not a single instance in the jurisprudence of the EU Court in the past 35 years where the Court has struck down a Directive on grounds that it violates some fundamental right (Chalmers, 2012). Arguably, the adoption of the EU Charter of Fundamental Rights of the European Union, which has “the same legal value as the Treaties” (Article 6 TEU), has provided the EU Court with a new and potentially far reaching legal platform from which to expand its own problematic jurisdiction. This is liable to be (mis)used by the Court to interfere with and limit the autonomy of Member States in contested fields through its interpretation of open-ended fundamental principles, originally intended to accommodate and respect a diversity of moral and religious viewpoints in Europe. The Charter has already been cited in over 300 cases heard by the Court (O’Neill, 2012). The Court itself has made it clear in a number of cases that it does not see the text of the Charter as confining its reasoning and will instead maintain its “dynamic” approach, with the express rights set out in the Charter being seen as the starting point of any consideration of EU law (O’Neill, 2012).

EU law scholars have keenly endorsed the potential for the Charter to provide an ‘enhanced’ level of human rights protection over the baseline provided by the ECHR (i.e. de Burca), although the Charter is not supposed to displace the European Convention on Human Rights. Article 52(3) of the Charter requires that those Charter rights which correspond to rights already guaranteed by the ECHR be given the same meaning and scope as, and no lesser degree of protection than, that provided under the ECHR. There is also an undoubted pressure for convergence and deference of the EU Court to the European Court of Human Rights in the Lisbon Treaty requirement that the EU should accede to the ECHR and the limitation on the EU Court’s jurisdiction over fundamental rights to matters concerning EU law. Nonetheless, the potential for disjunction and displacement of the longstanding human rights jurisprudence of the ECtHR is also manifest in the number of rights enumerated under each instrument (38 Articles in the EU Charter compared to 18 Articles in the ECHR) and the limited competence and expertise of the EU Court judges as regards protection of fundamental rights.
Judicial Politics, Judicial Competence and the Need for Reform

The adoption of the EU Charter arguably mirrors and scales up to a supranational level the historical rise in European States of a form of national constitutionalism in Western Europe since 1945 and elsewhere since 1989 based on the US model (Gardbaum, 2001, 2013). The features of this model involve granting fundamental rights higher legal status than legislation, entrenching these rights against legislative amendment or repeal and enforcing their higher legal status by means of judicial power (Gardbaum, 2001). The Achilles’ heel in all models vesting ultimate responsibility on judges to settle constitutional disputes concerns the competence and democratic legitimacy of judge-made decisions. These concerns are conspicuously amplified in the case of the European Union, where the Court enjoys “unparalleled transnational powers” whilst lacking a robust credibility and legitimacy in terms of its composition and working methods as evidenced below.

Judicial competence and judicial independence are critical to lend credibility and legitimacy to the potentially disruptive role of such a court in democratic systems. The current Court suffers from serious deficiencies on both counts. As regards judicial competence, the Court is made up of 27 judges, one for each member state. Out of the 27 judges, almost two thirds (17) have no prior experience of appellate courts. Eight of the ten judges who have experience at appellate court level come from the post 2004 accession countries and only two from other EU countries with a longer history of democracy.

Until the Lisbon Treaty, the judges were nominated by States and their appointment formally made by the Council of Ministers (viz. cabinet members representing governments). There were no formal requirements regarding the procedures for national selection of candidates. This remains the case to date, notwithstanding the introduction of a modest judicial oversight mechanism in the form of a seven-person advisory panel established by Article 255 TFEU, to give an opinion on the suitability of candidates for appointment to the Court. The panel is made up of “... persons chosen from among former members of the Court of Justice and the General Court, members of national supreme courts and lawyers of recognised competence, one of whom shall be proposed by the European Parliament.” The operating rules of the panel which were adopted by the Council (Article 255 TFEU) allow the panel to interview new candidates nominated by Member States (for two hours). The deliberations of the panel take place
behind closed doors, although the panel produces a yearly report. The Council of Ministers is not under any duty to follow the opinion of the panel.

Whilst Article 252 TFEU provides that judicial appointees must be “persons whose independence is beyond doubt and who possess the qualifications for appointment to the highest judicial offices in their respective countries or who are jurisprudents of recognised competence”, the system of appointment palpably carries a serious risk that judges may be nominated for political reasons rather than legal competence. The risk is significantly heightened by the fact that States may only submit one candidate. (something regretted in the first annual report of the panel in 2011). By contrast, States must provide a choice of three candidates for the European Court of Human Rights. Furthermore, the panel does not have the power to take into account the need of the Court for particular areas of expertise when scrutinizing individual candidates. Hence, the composition of the Court is ultimately dictated by the political vagaries of national systems through a process described by Lord Mance, a member of the panel as one of ‘random selection’ (Mance, 2011). Aside from deficits in competence and independence, it has also been noted that women are underrepresented in the Court by contrast to the ECtHR, which has with some success taken steps to redress the balance (Mance, at 21).

**Conclusion**

Our analysis suggests that judicial overreach in decisions such as the Brüstle ruling is not mere accident. The underlying causes of such overreach point to the fact that the institutions of the European Union in their current form have features which involve substantial losses of sovereignty and autonomy for its Member States, as well as a substantial democratic deficit in the make-up of its key institutions, including the Court. Even if the Union is not formally a Federal State, it is nonetheless a quasi-federal structure in virtue of the principles of supremacy and direct effect of EU law. Whether it is desirable that it should become a unitary Federal State obviously depends on what the federalist dream entails. Whatever form the growing constitutionalization of the EU takes in the future, longstanding concerns about democratic deficit will need to be addressed. Our paper builds on a new call for closer scrutiny of the Court and the further threat it poses to the democratic ideal and illustrates how the field of biotechnology provides a theatre for these tensions to erupt.