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BIOMEDICINE AND EU LAW: UNLIKELY ENCOUNTERS?

Stéphanie Henneva-Vauche



**EUROPEAN UNIVERSITY INSTITUTE, FLORENCE**  
**ROBERT SCHUMAN CENTRE FOR ADVANCED STUDIES**

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**STÉPHANIE HENNETTE-VAUCHEZ**

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## **Abstract**

Over the last decade, a significant body of biomedical law has emerged within EU law. In so far as the EU has long been portrayed as aiming mostly if not only at economic integration, it is surprising at face value to see issues such as human embryonic stem cell research or trade in oocytes even reach the EU's political and legal agenda. Although it is possible to argue that the puzzle waters down when one considers not only that EU has in fact always been open to "non-market" values on the one hand but also that biomedical issues have themselves undergone radical transformations recently, as one commonly speaks now of "Tissue Economies", these elements do not seem to suffice for explaining the development of a body of biomedical law within EU law. It is argued here that many of the legal technicalities that sustain the view that the EU does not have any straightforward competences in the field have been balanced by the specifically "polity-building" dimension of "Ethics" (and here bioethics). In other words, the research presented here establishes several manners in which "Ethics" have been instrumental in the EU law making process, thus bridging EU law and biomedicine and simultaneously enabling the EU to assert itself as polity.

## **Keywords**

European Union - Bioethics - Biomedical Law





## Introduction

One crucial feature of biomedical issues is that ever since they have acquired public salience<sup>1</sup>, they have been phrased in dramatic terms: no less than human identity and the destiny of humanity have been said to be at stake. This is what French sociologist Memmi calls the *montée en généralité* of bioethical narratives that has ensured their extended social reach and resonance (Memmi, 1996). Her analysis is confirmed by the recent study by Gottweis, Salter and Waldby who accordingly note the importance in many a national setting of the process through which an issue such as that of embryonic research (including the use of human embryonic stem cells) becomes the issue about “future of humanity and the state of the [German] nation” (Gottweis, Salter, Waldby, 2009: 111). This is also what Bauer and Gaskell point at when they consider biotechnology to have functioned as a “sounding board” in many European countries: “once elicited, debates rarely stuck simply to the technology itself: they came to inhere in much broader societal discourses” (Bauer & Gaskell, 2002: 39). One thing seems clear, then: biomedical issues raise “fundamental”, “societal” issues.

It is then only logical that the fundamental rights have “framed the discourse”<sup>2</sup> over biomedical issues. This begs a question when it comes to the specific approaches EU law has of biomedical issues. EU law undisputedly is one of the legal fora in which biomedical law is currently strongly growing. However, traditional narratives of European law insist on its economic integrationist dimension and its teleological horizon: the completion of the internal market. In other words, fundamental rights usually do not appear to be a basic grammar of EU law. Since biomedical issues certainly have not been constructed as pertaining to market values, one can wonder: how then have they come to appear on the predominantly economic European Community’s agenda? How did EU law and biomedicine even meet?

While addressing that question, the present article makes two major claims. The first is that some elements of evolving contexts of both biomedical issues and European law have favored their encounter; these elements can be ordered into two parallel stories. The first one is about the manner in which EU law arguably opened up to non-market values; the second one insists on the changes that have recently altered the very context in which biomedical issues rise and have led to the fact that they need now be addressed in terms of “tissue economies” (Waldby & Mitchell, 2006). However, these remain parallel stories and their actual bridging still needs to be explained. The second claim of the article is that “ethics” –and, in particular, *bioethics*- have constituted a determining factor in the connection between EU law and biomedicine. It is argued that ethics’ progressive pervasiveness within norms of EU law as well as their instrumental function in the (re)definition of democratic governance in Europe throughout the 1990s have made the advent of EU biomedical possible and have given strength to the “science and technology studies”-inspired notion that the regulation of biotechnologies has actually become a way for Europe to constitute itself as a polity.

### I. The parallel evolutions of EU law and biomedical issues’ narratives

The story of the European community as a primarily economic community is too well-known to be again dwelled on. By contrast, the fact that EU law has also engaged with non-market values remains acknowledged in an often diffuse or imprecise fashion and its main illustrations and explanations thus deserve to be recalled (I.1.). By greater contrast still, the impact of the changing context within which biomedical issues have come to be framed and the shift in the cognitive tools that are actually useful

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<sup>1</sup> On the history of biotechnology acquiring public salience, see Bauer & Gaskell (2002) as well as Bud (1993) who insists on the 1970s wedding between « green » biotechnologies and (human) genetic engineering as the igniting factor for the issue to become prominent as a matter of public concern.

<sup>2</sup> An expression coined by T. Hervey & J. McHale on the wider subject of health law; see Hervey, McHale (2004: 66).

and relevant for reflecting upon them is still largely underestimated. Para-philosophical interrogations drawing on Aldous Huxley's *Brave New World* with the tools of Hans Jonas' "heuristic of fear" (1984) still resonate throughout the biomedical debate, much of which continues to strive to find foundational principles from which concrete answers could be derived (Rendtorff & Kemp, 2000). However, such perspectives increasingly appear to be outdated or ill-adapted to the globalization of the context in which biomedical issues need to be addressed; some essential features of these very contemporary evolutions of the nature and structure of biomedical issues will be sketched out (I.2.). It will then be argued that both these stories of evolutions (one relating to EU law, the other to biomedical issues) are interestingly read in parallel for they contribute to explaining the encounters between the two –even if they do not suffice to account for the actual emergence of an actual body of EU biomedical law (I.3).

### ***I.1. EU law and non-market values***

How have biomedical issues appeared on the European agenda? To this overly naïve question, there certainly is an answer that takes stock of the complex nature of EU law and distances itself from the 'all-market'-inspired caricature. In fact, although it is not its prominent feature, EU law does encompass and pertain to non-market values even to the extent that in fact, "internal market legislation is always also about something else" (de Witte, 2006: 76). The inclusion of non-market values within EU law operates in different ways. First, they are a relevant and legitimate component of several policies for which the Community has received sector-specific competences over the years, such as culture (art. 167TFEU<sup>3</sup>, ex art.151EC), the environment (art. 192TFEU, ex-art.175) or health (art. 168TFEU, ex-art.152)... Second, they can be incorporated, to a significant extent, in internal market legislation. This has been true both historically and in present times. Historically, internal market legislation has indeed incorporated such values; B. de Witte lists: environmental policy, biodegradability standards for detergents, the lead content of petrol or more generally social policy and employee's rights in the event of transfers of undertakings (de Witte, 2006, 65). This, actually, should not come as a surprise as it is generally acknowledged that *before* the Single European Act the very concept of the internal market was coined as 'unlimited' and thus potentially encompassing other preoccupations (Barents, 1993). Later on, and despite its tentative domestication of the ever-expanding remit of the internal market, the SEA did not put an end to possibilities of integrating such values in EU legislation. It even made preoccupations such as the rights of employees or the protection of health explicitly relevant issues for internal market legislation throughout their inclusion in then article 100a [now 114TFEU]. And the institutional shift from unanimity to majority voting in the Council on internal market affairs as well as the strengthening of the European Parliament in decision-making processes not only "allowed the building of a 'regulatory majority' against the opposition of one or more States" (de Witte, 2006: 68) but also turned the European Parliament into the "champion of diffuse interests" such as those of environmental and consumer protection of gender equality (Pollack, 1997).

Obviously these factors were all but weakened by the further developments under the Maastricht and Amsterdam treaties; and the development of sector-specific competences these treaties operated has not hampered the then-existing possibilities of internal market legislation on non-market values. Granted, the existence of a sector-specific legal base for harmonization did lead the European Court of Justice, be it the case, to require that the corresponding measure be based on it. However, this is only true as long as the center of gravity of the measure is viewed as environment-, culture- or say health-related (see the *Titanium Dioxide*<sup>4</sup> and the *Commission v. Council*<sup>5</sup> cases). In other words, ex-art. 95

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<sup>3</sup> Numbers indicated refer to the Treaty on the Functioning of the European Union as amended by the Treaty of Lisbon.

<sup>4</sup> ECJ, 11 June 1991, Case C-300/89, *Commission v. Council*, ERC [1991]-I, 2867.

<sup>5</sup> ECJ, 17 March 1993, Case C-155/91, *Commission v. Council*, ERC [1993]-I, 939.

[now art. 114TFEU] measures can still be accepted in those fields in which the Community has acquired specific competences as long as their main *raison d'être* is related to the internal market. The notorious *Tobacco Advertising* saga exemplifies both this reasoning put forth by the ECJ and its uncertainties. In its first judgment in this case, the ECJ did indeed invalidate the then-art. 95 grounded total ban on tobacco advertising on the grounds that what it was really pursuing was a public health aim and thus met with the art. then-152.4.c. prohibition of harmonization measures in the field<sup>6</sup>. However, after a revised version of the directive was adopted that better justified the internal market implications of the prohibitory policy in the field of tobacco advertising, the ECJ upheld it<sup>7</sup>.

Additionally, the ever-growing normative weight of fundamental rights within EU law can be seen as another sign of its openness to non-market values. As is well-known, the ECJ has developed a fundamental rights doctrine according to which EU acts and Member State acts alike ought to comply with fundamental rights of the European legal order either when implementing<sup>8</sup> or derogating<sup>9</sup> from EU law. To be sure, the ECJ's fundamental rights case-law has not gone uncriticized<sup>10</sup>. It is however undisputed that fundamental rights are now largely binding under EU law –and this will probably only deepen in the future as the Lisbon Treaty has made the EU Charter of Fundamental a fully authentic source of EU law. Fundamental rights are crucial bases for the blossoming of non-market values within EU law such as for instance the dignity of man, the freedom of arts and sciences or the prohibition of all forms of discrimination. And such values in turn, when framed as fundamental rights, give an “ethical tone” to the polity they stem from. As Plomer and Favale argue: “EU health policy... has had to respond to political pressure to situate the legislation within an ethical frame. This has been achieved through the incorporation of the largely open-ended and indeterminate norms contained in overlapping and disjointed EU human rights instruments which in turn guide the flexible and more specific ethical constraints contained in legislative texts” (Favale & Plomer, 2009: 111). Finally, it should be noted that fundamental rights are increasingly invoked by market actors. “The language and logic of fundamental human rights has infiltrated the economic and commercial sphere” (Harding, Kohl and Salmon, 2008:1), thus also maybe accounting for issues readily framed in rights language –such as biomedical issues- to be attracted into the sphere of influence of European law.

In other words, EU law is not hermetic to non-market values and this may well be a first route to be explored when trying to map the ways in which biomedical issues have reached the European Community's agenda.

## ***1.2. The economy of biomedical issues***

But other routes also need to be explored, especially since biomedical issues' shape and nature have been undergoing radical changes over the last decade in relation to the now undisputable globalization of the circulation of substances of human origin. This in turn may well account for the greater relevance of economics-oriented systems of regulation (such as the one offered by EU law). Reference has been made to the notion of ‘tissue economy’ that now exists at a worldwide scale (Waldby & Mitchell, 2006). This economy is foremost a political economy: one in which the actual forms of tissue circulation have implications on the forms of the polity<sup>11</sup>. But it also is an economy of

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<sup>6</sup> ECJ, 3 April 2000, Case C-376/98, *Germany v. Parliament and Council*, ERC [2000]-I, 2247.

<sup>7</sup> ECJ, 12 December 2006, Case C-380/03, *Germany v. Parliament and Council*, ERC [2006]-I, 11573.

<sup>8</sup> ECJ, Case C-5/88, *Hubert Wachauf v Bundesamt für Ernährung und Forstwirtschaft* ECR [1989] 2609.

<sup>9</sup> ECJ, C-260/89, 18 June 1991, *Elliniki Radiophonian Tiléorassi*, ECR I-2925.

<sup>10</sup> The literature is quite wide on this topic and includes the debate between Coppell & O'Neill (1992) and Weiler and Lockhart (1995).

<sup>11</sup> This dimension of the concept of ‘tissue economies’ is linked by Waldby and Mitchell to the works of Richard Titmuss (see notably Titmuss, 1970) who has insisted on the social implications of the choice of coining blood as a gift or a commodity in the two systems of blood donation regulation he observed (Britain and the United States), the former

circulation and retribution, regardless of the persistent but at times deceiving insistence of many legal narratives on the fact that substances of human origin may not lead to remuneration. As it has been convincingly argued, it is precisely the ambiguity of many of the central legal concepts on which biomedical law was built, including non-marketability of substances of human origin, informed consent and the like, that has actually allowed the transformation (as opposed to the impediment) of *gifts* (donation) into *property* (acquisition), thus designing a situation in which “while persons have no property rights in their own body parts, it is possible for a second party to establish property rights in tissues once they have left the donor’s body” (Waldby & Mitchell, 2006: 71). Blood is no longer a simple and stable product circulating only from donor to recipient: it is fractioned, transformed, interests multiple users and plays a crucial part in the pharmaceutical industry (Hermitte, 1996). Stem cells (and other biological materials) are now stored in *Banks* (Bellivier & Noiville, 2009) such as in Great-Britain and Spain and venture capital plays an important role in the globalized world of stem cell research (Gottweis, Salter & Waldby, 2009). Most of what still appeared as hospital waste until recently has been turned into *biovalue* (Waldby & Mitchell, 2006: 88)... In other words, substances of human origin circulate as products between a variegated set of actors; their circulation designs areas of exchange that strongly resemble markets and they generate investments and profits. And this circulation really is worldwide: stem cell lines are imported and exported throughout the globe, Indian and Ukrainian fertility clinics are experiencing a significant boom in demand, academic researchers as well as biotechnology companies routinely change national settings in order to find themselves subjected to the most beneficial regulatory environment...

In the face of such radical evolutions, one might well critically look back at the kind of concepts and paradigms that have historically governed regulatory narratives in the field of biomedicine: are they still relevant and appropriate? Aren’t rights such as privacy and dignity much better suited to Hollywood stars in the management of the amount of information they want to make public about their recourse to surrogate motherhood than to the anonymous Indian midwife who is considering to act as a surrogate for the second time in order to provide her son not only with shelter but also education? Isn’t the whole idea of reproductive *rights* flawed when ethnographic studies tend to underlie that ‘choice’ for that matter is often but a mirage (Murphy, 2009a: 195)? How viable are legislative options in the field of reproductive medicine that rely on publicly controlled and subsidized systems (such as in France for instance) or the exclusion of profit (such as in the British approach to surrogate motherhood) when privately driven markets develop at a rapid pace where oocytes donation or surrogate motherhoods contracts provide women with significant revenues? Not to mention the threat that the reality of contemporary tissue economies poses to other founding concepts of bioethics, such as anonymity (confronted with the common practice for intentional couples to maintain relationships with the gestational mother after surrogacy contracts), autonomy (unevenly built into biomedical law throughout the world as restrictive legislations on abortion, assisted reproduction or even the right to refuse medical treatment sometimes strongly jeopardize it) and non-marketability (as said, although it seems for the most part preserved as far as the primary donor goes, there is no doubt as to its inappropriateness with regards to further steps of circulation). These are elements of context who considerably contribute to the increased visibility and even legitimacy of market-oriented approaches to biomedical issues. Consider the shift between the outcries that surrounded E. Landes and R. Posner’s piece on a market for babies in 1978 (Landes & Posner, 1978) and the policy proposal voiced in 2008 by the British Economic and Social Research Council according to which incentivisation measures needed to attract organ donors in greater numbers could include “the provision of vouchers, for example, to obtain white or electronic goods (e.g. iPods, music CDs or DVDs etc.)” (ESRC 2008: 7). Principled positions may well be seen to be more challenged by pragmatic modes of reasoning today than in earlier times. Subsequently, and as far as the search for the

(Contd.) \_\_\_\_\_

option favoring the notions of social solidarity, social cohesion and a general ethos of welfare that the latter turns it back to.

appropriate legal regulatory tools goes, “human rights”<sup>12</sup> probably no longer is the only and comprehensive relevant paradigm under which to usefully reflect upon biomedical issues. Such an admission is crucial not only because it is a necessary step for looking at and reacting to the backwards ‘revolution’ (Murphy, 2009b: 15) that is strengthening in the field of biomedicine in the forms of what Brownsword has coined as a “dignitarian alliance” (Brownsword, 2005) but also because it can potentially serve as an explanation for the recent development of biomedical law in unlikely fora such as the EU.

### ***1.3. A body of EU biomedical law***

Greater openness of EU law on the one hand, evolutions in the very nature of biomedical issues that justify complementing the traditional fundamental rights approach<sup>13</sup> by one that is susceptible of adapting better to the now undisputedly economy-oriented dimension of biomedical issues on the other hand: these form potentially viable explanations for the emergence of a body of biomedical law at the EU level. For indeed, such a body of law now exists. Some authors strongly argue that “the unprecedented expansion of EU controls on biological materials under the aegis of the expanding remit of the EU on public health has caused major reshaping of the regulatory landscape of the life-sciences in the Member States” (Favale & Plomer, 2009: 90). To be sure, this emerging body of law is very diverse and heterogeneous and thus rather grudging to traditional academic taxonomies. It is in part direct and in part indirect; and it is sometimes soft and others hard.

Some norms of EU law do indeed directly aim at biomedical issues. It is the case of most of the directives and regulations in the field, such as the directives on the protection of biomedical inventions<sup>14</sup>, on clinical trials<sup>15</sup>, on Blood<sup>16</sup>, Tissues<sup>17</sup> and Organs<sup>18</sup> quality and safety requirements, or such as the recently adopted Regulation on advanced therapy medicinal products<sup>19</sup>. It is also the case for a number of soft law acts, such as the many resolutions the European Parliament has put forth in the field on topics like *in vitro* embryos<sup>20</sup>, cloning<sup>21</sup>, trade in oocytes<sup>22</sup> etc. Other parts of this body of biomedical law at the EU level only indirectly deal with biomedical issues. This is the case for instance of the EU’s research policy as defined in the five years long framework programmes, in which topics such as embryonic research and cloning have become prominent. It is also the case throughout patent law, for “by making patents available within certain types of gene technology, and not others, regulatory bodies are capable if not to forbid certain types of research activity, at least to provide a strong steer to what actually happens on the ground” (Harvey & Black, 2005: 33). Despite its arguable lack of coherence, there thus is a growing body of biomedical law at the EU level that

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<sup>12</sup> Or fundamental rights; we will not differentiate between the two for the purposes of this article.

<sup>13</sup> Because of many factors and not least because of their once linkage to a third generation of human rights, biomedical issues have long been perceived as (exclusively) fundamental rights issues. See for instance P. Sturma (2006): 369: “a human rights approach is not the only possible way of dealing with the problem, but it has the advantage of combining law and ethics”.

<sup>14</sup> Directive 98/44/EU of 6 July 1998, OJ L 213 of 30 July 1998.

<sup>15</sup> Directive 2001/20/EU of 4 April 2001, OJ L 121/34 of 1 May 2001.

<sup>16</sup> Directive 2002/98/EU of 27 January 2003, OJ L 33/30 of 8 February 2003.

<sup>17</sup> Directive 2004/23/EU of 31 March 2004, OJ L 102/48 of 7 April 2004.

<sup>18</sup> COM(2008)818final of 8 December 2008.

<sup>19</sup> Regulation (EU) 1394/2007 of the European Parliament and the Council, OJ L 2007 324/121.

<sup>20</sup> Res. of 16 March 1989 on ethical and legal issues relating the genetics (doc A2-327/88) and Res. of 16 March 1989 on artificial insemination in vivo and in vitro (doc. A2-372/88).

<sup>21</sup> Res. of 7 September 2000 on the cloning of human beings (OJ C 135/263 of 7 May 2001) –note that this resolution follows five other on similar topics that had been adopted by the EP between 1989 and 2000.

<sup>22</sup> Res. of 10 March 2005 on planned eggs trade, P6\_TA(2005)0074.

could if at all be ascertained by a pastiche of T. Hervey's pragmatic method for convincing her readers that such a thing EU health law did exist (Harvey, 2002: 69)<sup>23</sup>.

But these two stories of parallel evolutions undergone by EU law on the one hand and biomedical issues on the other hand should be taken cautiously with regards to their explanatory value when it comes to accounting for the appearance of a body of EU biomedical law, for they are not straightforward. EU law's encompassing non-market values –and thus its ability to deal with biomedical issues- is not plain and simple and the case can be made for such values to however remain ancillary to Community law's core functions, structure and institutional mechanisms (I.3.1). Conversely, the fact that biomedical issues nowadays ought to be thought within the general framework of tissue economies should not deceivingly lead us into the belief that economics-oriented legal categories are necessarily better suited as regulatory tools than older fundamental rights ones (I.3.2) –if only, because the view according to which a clear-cut divide exists between ethics and economics –rights and the market, fundamental rights and fundamental freedoms- can be challenged (Hennette-Vauchez, 2009; Morgan 2007).

### I.3.1. Non-Market Values in EU law: to what extent?

The fact that there are no obstacles of constitutional nature for EU law to take into account non-market values should not overshadow the notwithstanding strong 'regulatory gap thesis' according to which positive integration (re-regulation through the setting of positive standards) remains a more hazardous (and thus, unlikely) task within the community than negative integration (deregulation through the abolition of trade barriers) (Scharpf, 1999). The mere possibility of non-market values to be incorporated in EU law does not guarantee that they actually are taken into account. Indeed, and despite the fact that cautious authors call against readings that oversimplify them (de Witte, 2006: 62), prominent rulings by the ECJ such as the abovementioned *Tobacco Advertising* ones do appear to maintain values such as health protection in an inferior position when compared to market ones (Hervey & McHale, 2004:104). Not to mention the fact that in many of the cases in which sector-specific competences have been awarded to the EU, they do in principle preclude harmonization (as in the case of culture of education or public health) or only authorize it as a narrowly defined derogation (as in the case of health in so far as the quality and safety of substances of human origin is at stake). Furthermore, the case has been made for fundamental rights to similarly remain ancillary to fundamental freedoms in European law, even in its most recent post-*Schmidberger* state. In the words of J. Heliskoski: "Fundamental rights are... to be treated as just one ground among others which may or may not qualify as exceptions to the Treaty freedoms... It is the fundamental economic freedoms that provide the basic paradigm. There is... an a priori perspective to the judicial decision-taking by the Court, a perspective with the fundamental freedoms as the leading rule to which other grounds may or may not qualify as exceptions... It might be argued that the structure of the reasoning adopted by the Court is inherent in the legal and political system of the Union as it stands at present or that it is only the most natural reading of the Treaty which produces such a perspective. This is not the case. What we are witnessing here is an instance of the Court of justice constituting the relevant normative field in a particular kind of language, that is the language of fundamental economic freedoms" (Heliskoski, 2003: 441). Other lines of reasoning lead to similar conclusions (see also Coppel & O'Neill, 1992). In fact, ever since the *Wachauf* case, fundamental rights have been defined as rights susceptible of being altered by the community logic: "The fundamental rights recognized by the Court

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<sup>23</sup> « Diane Blood relies on free movement of rights in Community law to seek fertility treatment in Belgium. A Community body –the Committee for Proprietary Medicinal Products- recommends that Viagra be approved for marketing across Europe. The European Commission responds to food-related threats to public health, such as BSE, by proposing a European Food Agency. The Commission proposes the prohibition of tobacco advertising across the EU. These events, along with many other of a less high profile, illustrate how the European Union is playing an increasing role in the determination of both individual and collective health entitlements. It might be said that the EU is developing a health policy".

are not absolute, however, but must be considered in relation to their social function. Consequently, restrictions may be imposed on the exercise of those rights, *in particular in the context of a common organization of a market*, provided that those restrictions in fact correspond to objectives of general interest pursued by the Community and do not constitute, with regard to the aim pursued, a disproportionate and intolerable interference, impairing the very substance of those rights”<sup>24</sup>. Despite the fact that the *Schmidberger* ruling<sup>25</sup> has generally been praised for its indication that fundamental rights could however prevail over fundamental freedoms (Morijn, 2006), this seems to be a short-sighted view for even in *Schmidberger*, fundamental rights are constructed as mere potential *restrictions* or *derogations* to (hypothetically superior) fundamental (economic) freedoms –and not as competing (equal) norms<sup>26</sup>. As C. Brown puts it: “It could be said that, as a matter of principle, it should not be for those who are invoking protection of their human rights in effect to have to justify themselves. Using the language of prima facie breach or restriction of economic rights suggests that, even if the restriction is ultimately justified, it remains something which is at its heart “wrong”, but tolerated. This sits rather uneasily with the State’s usually paramount constitutional obligation to protect human rights” (Brown, 2003: 1508). In other words, *Schmidberger* alone does not clear all suspicion of a tendential bias of the Court (and thence of the very doctrine of fundamental rights in EU law) in favor of fundamental (economic freedoms). These elements converge in underlying the fact that even though non-market values are not alien to EU law, they do not enjoy a status, centrality and legitimacy comparable to those of market values. Hence their very existence within EU law may well be called upon for explaining the emergence of a body of EU biomedical law, but that would most likely also make the case for a marginal and potentially weak body of biomedical law.

### I.3.2. Legal regulation of biomedical issues: under which paradigm?

Last but not least in terms of tentatively framing the general *problématique* of the encounters between EU law and biomedical issues, it must be recalled that regardless of the paramount importance of the changes biomedical issues are undergoing (the growing strengthening of ‘tissue economies’), it does not mechanically follow that economics-oriented legal categories are satisfactorily equipped for overcoming the shortcomings or increased inappropriateness of a previously essentially fundamental rights-oriented attempt at domesticating biomedical issues through law. Actually, it could be argued that *any kind* of legal device is a poor or at least uneasy answer to biomedical issues, to the extent that legal regulations are always very difficult to craft in those domains because of the extreme sensitivity of moral pluralism that only makes accommodation with majoritarian democratic rule-making more hazardous. This is why legislative proposals to authorize therapeutic cloning were filed in the French parliament as early as months after it had been outlawed by the 2004 bioethics legislation, and why the 2004 assisted reproduction law in Italy was shortly after followed by attempts to obtain its abrogation by referendum... What legislation achieves on those matters is at best compromise, not consensus. Hence the questions are never really settled: there is no closure, no harmony after compromise (Franklin, 1995: 244); and there is no reason to believe that these difficulties would vanish or even only be tempered by a shift from a national to an international (European) level of legal regulation. Leads rather points to the contrary, notably because of two arguably contradictory aspects of the new tissue economies framework: its global dimension on the one hand, and its nation-state-enhancing effect on the other.

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<sup>24</sup> ECJ, 13 July 1989, C-5/88 *Hubert Wachauf v Bundesamt für Ernährung und Forstwirtschaft*, ECR [1989] 2609 [emphasis added].

<sup>25</sup> ECJ, 12 June 2003, C-112/00, *Eugen Schmidberger v. Republic of Austria*, ECR [2003]-I, 5659.

<sup>26</sup> A different view is put forth in C. Kombos (2006: 448) “The Court could not attribute a higher status to freedoms against rights for reasons of legitimacy and for safeguarding the prestige of the ECJ. Moreover, the rights of could not be given an absolute priority over freedoms because the implications for the effectiveness of EU law would have been too serious... The logical conclusion is that the ECJ balanced rights and freedoms in a neutral way whereby it omitted to locate them hierarchically”.

As to the former aspect, it is indeed in ever-growing proportions that people (researchers as well as tentative patients), capital, substances of human origin themselves as well as associated biomedical services circulate across borders and in fact across continents. As to the latter, it has convincingly been argued that the globalization of biomedicine confirms doubts that have been expressed *vis à vis* “the reduction in government spending and state activity anticipated in much of the globalization literature” (Gottweis, Salter & Waldby, 2009: 28). Rather, it has given support to views similar to those supported by Cerny as to the emergence of the “competition state” who pursues “increased marketization in order to make economic activities located within the national territory, or which otherwise contribute to national wealth, more competitive in international and transnational terms” (Cerny, 1997: 259). States are effectively strongly involved in funding and coordination of partnerships between public and private sectors, defining the rules for retrieval, storage and access to substances of human origin etc., to the extent that their role in these tissue economies is *enhanced* rather than watered down.

Obviously, these two realities are hardly favorable to swift and effective legal regulation in the field. First because the challenges of legal regulation of such axiologically sensitive issues are not only daunting as such but also dramatically increased when the level of regulation is supranational. Let us recall the pathetic failure of the to-be Universal convention on the prohibition of cloning: a working group had been launched on the subject matter by the United Nations General Assembly at the end of 2004 but the strength of dissent amongst the represented States made the position of those who wished the text to oppose *all* forms of cloning literally irreconcilable with that of those wishing to ban reproductive cloning only. As a result, the foreseen convention was downgraded to being a mere (non-binding) declaration while its core provision sought to dissimulate the failure of achieving consensus behind its highly ambiguous formulation (the prohibition pertains to “all forms of human cloning inasmuch as they are incompatible with human dignity and the protection of human life”; Res. A/RES/59/280). But similar criticism can also be directed at other attempts to craft legal norms at the international level in the field –such as the so-called Oviedo convention of the Council of Europe<sup>27</sup> whose art. 18 serves as an emblem of the sheer impossibility of reaching a consensus on another issue, that of embryonic research, thus resulting in a provision not deciding on the issue one the one hand (“Where the law allows research on embryos *in vitro*, it shall ensure adequate protection of the embryo”) and keeping some States such as Great-Britain, Belgium or Sweden who have made therapeutic cloning legal from ratifying it on the other hand (“The creation of human embryos for research purposes is prohibited”). In other words, it can be pragmatically stated that international norms in the field are but the painstaking expression of minimum common denominators<sup>28</sup> –a result quite at odds with the whole ambition of such endeavors that in principle would rather aim at generating demanding *ad hoc* principles than watered down minimal standards accompanied by opt-out mechanisms.

In addition, these issues only gain in intensity when transposed at the level of the EU for at least two reasons. First because the actual political likelihood of agreements is only lowered by the relatively greater strength of EU law compared to any other body of international law. Indeed, if non-binding declarations such as the UN one or even the Oviedo convention have met with such difficulties, one can easily imagine that they would not even have come to existence at the EU level given the normative value of EU law (primacy, direct applicability...) that will only encourage States to be even more cautious. This is actually confirmed by the stance of countries like Ireland or Malta demanding specific protocols to European treaties guaranteeing that they may not affect national

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<sup>27</sup> Convention for the protection of human rights and dignity of the human being with regard to the application of biology and medicine: convention on human rights and biomedicine, 4 April 1997.

<sup>28</sup> For this problem, see A. Plomer (2005).



legislation on abortion<sup>29</sup>. Second because EU law is at any rate governed by the constitutional principle of conferred competences that *a priori* precludes the community from interfering in domains in which it has not been awarded explicit competences. Since by all accounts “the community was primarily conceived as an ‘economic community’” (Vos, 1999: 1) this would account for the impossibility of EU law in many (non-market oriented) fields –biomedical issues among others. To be sure, as it has been recalled earlier, this strict and rigid reading of the doctrine of conferred competences does not match reality; and there has been a number of means for EU institutions and Member States to overcome it: a broad interpretation of the notion of ‘internal market’, a great reliance of the implied competences doctrine (see both the ECJ’s case law<sup>30</sup> and the recourse to ex-art. 308EC [now art.352TFEU]<sup>31</sup>)... These are ways that have secured some space within EU law for non-market values alongside the “traditional” internal market objectives. However, the grounds for action in fields such as biomedicine, because of their being situated outside the original core of the European (economic) integration project, remain more uncertain than say, those for anti-trust legislation or agricultural policy. In addition, one should bear in mind the fact that regardless of the issue of EU institutions’ competences, Member States themselves remain instrumental in EU actions. The view that EU law “comes from Brussels” is partly flawed if it is omitted that Member States themselves are present in Brussels<sup>32</sup>. Yet in the particularly tense, moving and uncertain field of biomedicine, this remaining role of the States may well be an additional element increasing the unlikelihood of EU law in the field, for there might be great reluctance towards the sole idea of transferring competences to a supranational level of regulation of such heated, politically sensitive and identity-defining issues. As H. Nys puts it: “there are undoubtedly certain vexed themes in medical law –such as abortion and euthanasia- where the ideas of various Member States –but also within the States- are so far apart due to religious, philosophical, ethical and other reasons that a common European regulation *would be simply unthinkable*” (Nys, 2001: 325). Not to mention the fact that at any rate, because of the multilevel system of governance that actually characterizes much of EU law, it would probably be flawed to try allocating competences in the field of biomedicine either to the EU or to the States.

From the outset, and as these lengthy and convoluted developments already announce, the very settings of EU law and biomedical issues’ encounters are thus complex to sketch. EU law and biomedical issues are both, in their own capacities, undergoing significant changes that could well favor their coincidence and thus account for the growing interest and increasing action of the EU in the field of biomedicine. However, these changes are neither straightforward nor univocal enough for sufficing to explain this rather new body of EU law. At best, they could be viewed as the (pre)conditions of possibility for EU biomedical law to come to existence, thus leaving open the question of the actual determining factor that would, by hypothesis, have bridged EU law and biomedicine. In order to answer the question of what has in fact bridged EU law and biomedicine, a thorough analysis of a definite corpus of EU law in the field has been carried out. The method used to define its scope and boundaries has been very empirical; bottom-up. EU legal acts (be they directives, EP resolutions, research policy decisions, EGE opinions....) in the field of biomedicine have been

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<sup>29</sup> See protocol n°7 annexed to Malta accession treaty of 2003 or protocol 17 annexed to the Maastricht treaty of 1992 regarding Ireland, cited by Hervey & McHale, 2004: 401-402.

<sup>30</sup> ECJ, 9 July 1987, C-281, 283, 284, 285 and 287/85 *Germany v. Commission*, 1987 [ECR] 3203.

<sup>31</sup> « If action by the community should prove necessary to attain, in the course of the operation of the common market, one of the objectives of the community and this Treaty has not provided the necessary powers, the Council shall, acting unanimously on a proposal from the Commission, and after consulting the European Parliament, take the appropriate measures »; this provision has often been viewed as a catch-all provision. See for instance J.H. Weiler (1991): 2403 underlying that with a broad interpretation of the provision “it would become virtually impossible to find an activity which could not be brought within the objective of the Treaty”.

<sup>32</sup> In a similar vein but not restricted to underlying this fact with regards to the legislative process, see P. Craig’s presentation at the “The ECJ and the autonomy of Member States” conference, European University Institute, 20-21 April 2009.

constituted into a corpus to be analyzed. The analyses presented here draw from in-depth studies of this corpus and as far as possible, of the conditions of their elaboration.

## II. The appearance of EU biomedical law as fuelled by “Ethics” as a governance instrument

The research has led to the hypothesis according to which “ethics” (*bioethics*) have played an instrumental role in the emergence and contemporary development of biomedical law at the level of the EU<sup>33</sup>. At different stages and under different guises, the injection of “ethics” in the normative process has indeed been the condition of possibility of EU biomedical law. This has occurred in three main ways (II.1). Over the past fifteen years, ethics have played an ever-growing role in the legislative process, sometimes substantially, sometimes in a procedural fashion, and more recently under the guise of new modes of governance. Indeed, ethics may well be said to have significantly contributed to the (re)definition of democratic governance –governance itself having to do with the way Europe constructs itself as a polity, thus accounting for the “science and technology studies”-inspired notion that bioethics constitute a polity-making regulatory field (Jasanoff, 2005). In other words, it will be argued here that a look at EU biomedical law helps understand not only an emerging and ill-known body of law, but also some ways in which the European polity is actually evolving (II.2).

### II.1. The penetration of (bio)ethics in EU law

The relationship between law and ethics is complex. For a long time, Western societies thought that “ethics” were a way out of the challenges (or even at times, conundrums) caused by the perceived need of regulation of biomedical issues. Ethics –and even more so *bioethics*- have thus tended to appear as a sort of “third way” between impossible hard and insufficient soft law, between moral pluralism and the idea of core common values. Under the guise of “secular moral reasoning”, ethics did appear, well into the 1980s, as a means of overcoming “moral fragmentation that characterizes postmodernity” (Engelhardt, 1986: 421) as well as of identifying foundational or “middle-level principles” (Beauchamp & Childress, 1979) on the basis of which regulatory consensus could blossom. In fact, ethics committees multiplied at the time and were presented and thought of as means of securing a deliberative, consensual and pluralistic mode of rule-making (Moreno, 1994). These times may well be said to have gone by: while many Western societies now wave a reasonable farewell to the myth of regulatory consensus<sup>34</sup> (bioethics committees are now rather thought of as experts’ committees to which opinions are asked more than as consensus laboratories), they generally acknowledge that the playing field is rather one of increasingly agonistic regulatory *biopolitics* (Hennette-Vaucher, 2009a, 2009b). However, by a sort of *ruse de la raison pratique*, great expectations continue to be placed in ethics. It is now expected that where they were supposed yesterday to positively produce consensus, ethics should now negatively provide with means of overcoming disensus. In other words, ethics paradoxically seem to be even more utilized as a technique now than before, despite the fact that their usefulness in terms of crafting regulatory *substance* is more or less accepted to be non-existing. It is their *formal* or functional qualities (mostly, containing political conflict outside the law-making process) that have become their most interesting feature.

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<sup>33</sup> A similar idea was already put forth in the 1990s (albeit on a narrower scale) by C. Landfried on the basis of her analysis of the EU’s handling of green biotechnology issues (mainly GMOs); see C. Landfried (1987) 256: “social and ethical criteria are beginning to play an important role in European decision-making processes, and thus European governance structures may be argued to be more than a technocratic regime and to do more than merely promote economic rationality and negative integration”.

<sup>34</sup> See also Brownsword (2005).

The role of ethics in EU law confirms this technological (as opposed to ontological) function of ethics in the lawmaking process. As far as legislation goes, ethics can be said to alternatively operate one of the three following tasks: i) transform vague and open-ended notions in possible common grounds between opposing views and thus enable compromise ii) act as a mode of deliberation external to the lawmaking process itself and thus either postpone or distract the heat of political conflict (and thus enable compromise) iii) justify a renewed approach to lawmaking such as the recourse to new modes of governance (and thus enable higher likelihood of compromise). Examples drawn from the abovementioned corpus will exemplify these alternative roles of ethics in EU biomedical lawmaking processes. A general presentation of the corpus is needed *beforehand* though, in order to show that despite its heterogeneity, it is always as a response to political conflict that ethics have been called into the legislative process.

The directives that are part of the corpus that has been constituted for the purpose of the present research differ greatly by several aspects. For a start, their chronology is not tight, for it extends over two decades. They were thus logically drafted, discussed and adopted in rather different contexts. While the first proposal for the Patents directive was published in 1988, the latest one pertaining to the quality and safety for Organs dates of December 2008. The Patents directive only came into being after an earlier version had been rejected by the European Parliament in 1995 *for reasons that could not have been foreseen* by the Commission at the stage of its initial proposal in 1988. Indeed, by the mid-1990s, the debate over the patenting of living materials was dominated by the questions raised by the Harvard oncomouse and Craig Venter's express sequenced tags affairs<sup>35</sup>. However, none of those could have been even thought of in the mid- and late 1980s, when the proposal was being drafted by the Commission and patents had not yet really been massively applied to animal –and even less so human living entities. In this particular case then, context was putting severe strains on the Community's endeavor to legislate, and States were cacophonously and simultaneously trying to make up their national minds and coherently react to the Community initiative. Things were almost reverse for the Blood directive. As it has convincingly been argued, in this case it is because of a strong desire of Member States who were struggling with AIDS contamination scandals that advantage was taken of ex-art. 152.4.aEC's sector-specific harmonization competence [now art. 168TFEU] in order to shift the political burden to the European level (Farrell, 2005). Community legislation here is thus rather to be seen as a response to national demand than as a European initiative.

On a more technical standpoint, these directives also differ in legal basis. While some of them are grounded in art. 114 TFEU's [ex-art. 95EC] internal market legislation procedures and thus strive to smoothen the functioning of the market by remedying to the diversity in national legislations (Patents directive, Clinical Trials directive), others are based on art. 168.4.a's [ex-art. 152.4.a] specific harmonization competence (Blood, Tissues and Organs directives). Apart from the abovementioned fact that the ECJ in principle requires specific harmonization competences such as art. 168 [ex-art. 152] ones to be used when they exist (unless the given measure can also be said to pursue internal market objectives), it must be said that recourse to art. 114 [ex-art. 95] legislation is strategically avoided when possible by EU institutions because of the fact that such a mode of regulating politically and ethically sensitive questions is tricky (Hervey & McHale, 2004: 80). This has to do with the fact that the divide between general and specific harmonization grounds is hardly clear-cut<sup>36</sup>.

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<sup>35</sup> The Harvard oncomouse was a mouse on which experimentation had been carried out and for which a patent was awarded by the US Patents Office but initially denied by the European one (and finally granted on appeal). It is one of the major cases over which the law of patenting living material has been debated. Another one is linked to the claim by Craig Venter, whose was responsible for the US National Institute of Health's participation to the human genome project, that « sequence expressed tags », that is gene sequences identified in their structure but not in their function, be patented. Although his claims were rejected, this launched the debate over the patentability of genetic sequences.

<sup>36</sup> See for instance Hervey & McHale's appreciation of the Clinical Trials Directive being grounded in art. 95: "the Commission has sought to frame its regulatory proposals within this provision, even though the CTD contains many

However, all these directives have in common the fact that they caused intense and heated political controversy. The Patents directive is often referred to in this respect, for not only did it take ten years for it to actually come to existence, it was also subsequently challenged before the ECJ by unhappy Member States, only to then meet with strong reluctance in terms of transposition –several actions for failure to act being launched by the Commission. But the 1998 directive is not isolated in this respect. Both the Blood and the Tissue directive were controversial and necessitated adjustments and compromises. The Clinical Trials directive’s gestational period too, superseded the decade (Sprumont, 1999: 33): the need to propose a directive was mentioned by the Commission in a discussion paper as early as 1991, even though a proposal was actually only published in September 1997<sup>37</sup>. These delays can arguably be explained by the political nature of the problems caused by these texts, disagreement in all likelihood being a cause for lengthy crafting, adoption and implantation processes.

Beyond this chronological similarity, these texts all share the fact that not only were the debates that led to their adoption politically very heated, but also each time “ethics” were a significant element of the conflict. In fact, the opposing views in all the corresponding lawmaking processes were always structured in a binary fashion<sup>38</sup>: “ethics” versus “competitiveness”<sup>39</sup>. For instance in the debate over the Patents directive, the “ethical” view that human material needed be withdrawn from the reach of potential patents clashed with the argument drawing on the necessity for Europe to unify patent legislation and create a regulatory safe environment in order to attract capital and investors in an industrially and financially promising domain. During the Clinical Trials directive discussions, the procedural guarantees and standards of ethical clinical trials were opposed (and tentatively downplayed) by lobbies representing the pharmaceutical industry whose main aim was to obtain greater uniformity in pre-marketization trials as it is synonymous with decreased costs and scale economies (Liddell, 2006). Over the Blood directive negotiations, the reality of blood and blood products’ circulation across Europe (and indeed the world) clashed with the continued attachment of some Member States to the “ethical” gift model (Titmuss, 1970) of voluntary unpaid donation (Farrell, 2006). And shortly after, the debates around what was to become the Tissues directives served as a means for those actors (from Christian Democrats to green groups) who were simultaneously losing ground in a parallel regulatory enterprise (the crafting of the EU’s research policy) to try obtaining, on “ethical” grounds, the exclusion of embryos and embryonic stem cells from the circulation model that was being elaborated (Farrell, 2005 and 2009).

Interestingly, each time, “ethics” also proved to ensure, in one way or another, a way out of political conflict. More precisely, the evidently axiological dimension of the political debates that were taken place has each time led to an increased reliance on the capacity of “ethics” to provide the

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elements that are only tangentially related to the internal market, in particular its provisions concerning ethical principles” (Hervey & McHale, 2004: 249, n67).

<sup>37</sup> OJ, 1997 C 306/10.

<sup>38</sup> As such, the debate at the European level only echoes the wider societal debate over biotechnologies, as described notably by Bauer & Gaskell (2002 : 40) : « two different stories about biotechnologies. Industry emphasized commercial applications including large-scale fermenting and deliberate release. Exaggerations of future promises were commonplace as companies tried to attract venture capital, despite the fact that very few of them had an actual product. On the other hand, environmentalists put forward not only risk arguments –whether or not they were substantiated- and abstract ethical considerations, but also concrete and serious doubts about the track record of the chemical and agro-industry and the financial entanglement of senior researchers with start-up companies”.

<sup>39</sup> Competitiveness early on is the keyword for the EU’s interest in biotechnology ; see notably the first communication of the Commission on the subject: COM(1983)672final, *Biotechnology: the Community’s Role* which is the result of reflections carried out since the late 1970s by the Bio-Society Unit within the FAST Programme. See later significant steps: COM (1986) *A Community Framework for the Regulation of Biotechnology* and SEC(91)629final, 19 April 1991: *Promoting the Competitive Environment for the Industrial Activities Based on biotechnology within the Community*. By all accounts, only the latter document explicitly takes into account the wider stakes of ethics, safety etc. over competitiveness –which has not meant that the goal of competitiveness was watered down. On the contrary, the Life Sciences Strategy (OJ 2003 C39-9) considers biotechnology to be central to the EU’s objective to be ‘the most competitive and dynamic, knowledge-based economy in the world’ (Lisbon Council, cited by M. Lee, 2008, 9).

regulatory process with solutions. As Jasanoff puts it: “policymakers were tempted to characterize all these as conflicts over values... If policy conflicts could be attributed to divergent values, then a logical response for national as well as the European superstate was to ask for better analysis and management of such value differences –in short, for more expertise in ethics” (Jasanoff, 2005: 89). Let us take three examples of the manner in which “more expertise in ethics” has indeed proven to be a condition for successful legislation at the EU level.

### II.1.1. Direct incorporation of “ethics” in EU legal acts

The 1998 directive, as it is often recalled, is the ending point of debates over “one of the most controversial proposals ever tabled by the Commission” (Smith, 1996: 136). The differences between the original Commission proposal<sup>40</sup> and the first Common Position of the European Parliament and the Council<sup>41</sup> are telling in this respect, in so far as the latter expressed concerns in the application of patents to human living material and the human body that the former completely ignored. Conciliation between such strongly competing views failed<sup>42</sup> and ultimately, the Commission had no other choice but to present a new proposal in December 1995<sup>43</sup>. The major inputs of the legislative process notably include a number of “ethical” recitals similar to rec. 16: “whereas patent law must be applied so as to respect the fundamental principles safeguarding the dignity and integrity of the person” and “ethical” provisions such as art. 5 ruling that “the human body, at the various stages of its formation and development, and the simple discovery of one of its elements, including the sequence or partial sequence of a gene, cannot constitute patentable inventions” (even though “an element isolated from the human body... including the sequence or partial sequence of a gene, may constitute a patentable invention, even if the structure of that element is identical to that of a natural element”). These are the results of important parliamentary amendments that have led to a painstakingly reached agreement between those who wanted a clear ethical principle withdrawing the human body as such from the reach of patent law and those who wished to secure what they considered to be the *acquis* of patent law<sup>44</sup>, namely the possibility of patenting gene sequences that were known in both their structure and functions regardless of the fact they existed at the *état de nature*. In a similar vein, art. 6 of the directive lists a number of exclusions of patentability concerning human cloning processes, the use of human embryos for industrial processes, as well as any invention that would contravene *ordre public* or morality. To be sure, whereas such general clauses did exist prior to the directive in patent law<sup>45</sup>, their being complemented by the specific bans on cloning of industrial use of embryos is also a result from the ethical turn in the EU legislative process we are describing. In other words, this directive has been viewed as an instance of direct incorporation of ethics within EU law –this incorporation being novel with respect to the initial proposal and instrumental to the lawmaking process successively coming to an end. Henceforth, from the Patents directive onwards, it no longer was possible for “politicians to claim that they [were] deciding upon technical questions which [were] in reality political” (Landfried, 1997: 259) –a trick that has been demonstrated to be foundational in the GMOs legislation of the 1990s (Brosset, 2003).

This incorporation of “ethical” principles within EU legislation has thus been one manifestation of the role of ethics in Community lawmaking that the 1998 directive has been both a lever and a melting pot for –even when, as was the case for the Blood and Tissue directives, they were initially thought of

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<sup>40</sup> OJ C 10 of 13 jan. 1988.

<sup>41</sup> Common position 4/94 OJ C101 of 9 April 1994 : 65

<sup>42</sup> Following the EP’s Rothley Report (CP Report 14-0029/95), a conciliation procedure was launched but this resulted in a dead end.

<sup>43</sup> COM(1995)661

<sup>44</sup> See in particular the Relaxine decision of 1994 by the European Patent Office: Case V-0008/94 of 8 Dec. 1994: .

<sup>45</sup> See for instance the TRIPS agreement, or the Munich convention.

as “technical” responses to health threats<sup>46</sup> or when, as was the case for the Clinical Trials directive, they essentially aimed at smoothening the internal market<sup>47</sup>. Examples are multiple. The Tissue directive’s article 12 reads: “Member States shall endeavor to ensure voluntary and unpaid donations of tissues and cells”, thus voicing an exhortation of those Member States who took the gift paradigm to be an ethical position<sup>48</sup>. It further continues by ruling that when compensation is provided for donors, it is to be strictly limited “to making good of the expenses and inconveniences related to the donation”. And although the main aim of the Clinical Trials directive is to define institutions in charge of supervising and authorizing them, it also endorses some substantial views in terms of the criteria that ought to guide them, such as the notion that a balance between “the foreseeable risks and benefits” and “the anticipated benefit for the individual trial subject and other present and future patients” is a valid ethical evaluation criterion, or that minors and incapacitated adults may be involved in clinical trials provided a set of procedural requirements expected to substitute for their actual consent are met<sup>49</sup>. As a matter of fact, such substantial options are vehemently discussed in the literature pertaining to bioethics in general, and the case could well be made, from an ethical perspective, *against* them –hence the relevance of reading some provisions of the directive as actual ethical choices. Not to mention the fact that the directive’s very first article defines the notion of “good clinical practices” as conforming to a set of “internationally recognized *ethical* and scientific quality requirements”. To be sure, these examples of ethical provisions of EU directives in the field of biomedicine differ in strength and precision<sup>50</sup>; our point however is only to show that they are more and more common.

Additionally, direct incorporation of ethical principles is not to be found in EU legislation only but also for instance in the decisions grounding the Community’s research policy. The decision founding

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<sup>46</sup> Commission Staff Working Document accompanying the White Paper, *Together for health: a strategic approach for the EU 2008-2013*, COM(2007)630final, 16. However, it could be claimed that “a question is technical only where the technique or means chosen are neutral with respect to the purpose of the action. A choice of means in the field of biotechnology... is nonetheless not neutral with respect to a given objective, where the purpose is not merely progress in research, but also the protection of human health and the environment”: Landfried (1997: 257-8).

<sup>47</sup> See Consultation Paper issued by the UK Department of Health: “the primary purpose of the directive... is to simplify and harmonize the administrative provisions... creating conditions conducive to an effective coordination of such trials... and to facilitate the internal market in medicinal products”, cited by W. May Kong (2004: 176).

<sup>48</sup> See in a similar fashion the conflicts over the Blood directive negotiation as analyzed by Farrell (2006: 172-3): “political conflict... centered on the extent to which recognition should be given in regulatory terms to the preferred method for sourcing the Community blood supply... While explicitly acknowledging voluntary, unpaid donation as the preferred method for sourcing... in the directive would have been in line with EU blood policy, any mandatory requirement to do so would have adversely affected the commercial interests of the international blood industry, as well as presenting a significant dilemma for those Member States governments who has diverse sourcing arrangements in place in relation to their national blood supplies”. As a result, the directive takes an aspirational one the issue, encouraging States to take all necessary measures in order to ensure that blood comes from voluntary unpaid sources.

<sup>49</sup> Not to mention the fact that the directive’s article 3 insistence on informed consent defined as a decision which is taken “freely after being duly informed of its nature significance, implications and risks” is hardly a convincing attempt at dissimulating all the ambiguities and in fact discrepancies in the interpretation of such words that are given across Member States. On this topic, see Nys (2001: 324: “informed consent might be a generally accepted principle, but... it is interpreted so differently that one wonders whether it can still be called an ‘acquis communautaire’”), Hennette-Vauchez (2004).

<sup>50</sup> Favale & Plomer analyze them according to a tri-partite matrix: “At one end of the spectrum [EU directives] introduce EU-wide ethically motivated but essentially scientific technical, uniform standards which are fixed and are strictly obligatory. At the other end of the spectrum norm or value based “ethics” driven regulation in transnational contexts sets standards and norms in an open-ended aspirational flexible form allowing for a high degree of variability in the interpretation and determination of specific rules or norms in order to accommodate a plurality and diversity of ethical perspectives. In between strict, measurable uniform standards and aspirational open-ended norms/values, a middle third way involves a mix of mandatory but loosely constrained open-ended flexible ethical norms” (Favale & Plomer, 2009: 103). Examples of aspirational open-ended norms can be found for instance in both the Blood and the Tissue directive in the form of exhortations to Member States to favor voluntary unpaid donations but without making them obligatory.

FP6 reads as follows: “fundamental ethical principles are to be respected. These include the principles reflected in the Charter of fundamental rights of the EU”, thus expressing a general abiding of the EU by ethics in research. More specifically, as it has been argued above, many of the decisions that have been made regarding the eligibility criterion for funding under the last FPs are the direct consequences of ethical evaluations –such as for instance the exclusion of “research aiming at human cloning for reproductive purposes” and “research activities intended to create human embryos solely for the purpose of research or for the purpose of stem cell procurement” [therapeutic cloning]<sup>51</sup>. In fact, “the conflict between the cultures of science and industry, on the one hand, and some parts of civil society, on the other, was formalized (and to a degree normalized) through the referencing of ‘ethics’ as a suitable and legitimate vehicle for the conduct of continuing political bargaining” during FP6 negotiations (Salter, 2004:8).

Finally, attention must be paid to the European Group on Ethics’ role. To be sure, the EGE only delivers opinions that as such are not legally binding in the same manner as directives or art. 182 TFEU [ex-166 EC] decisions. However, the EGE can be said to play at least two important roles in ascertaining the position of ethics within EU biomedical law. A first one would be a preparatory work, for it so happens that most of the positions endorsed or defined by the EGE as “ethical” have eventually been put forth by EU institutions. This has been true for subjects such as the patentability of genetic sequences provided their function is known or the admissibility of research on embryonic stem cells. In that perspective, it could be argued that the EGE’s role is instrumental in that it *a priori* legitimizes the positions it coins as “ethical”. A second role is related to what can be perceived as an unduly extensive understanding the EGE might have of its own office. Pretty much the same way some national ethics committees have been found to readily recourse to the juridical language in order to increase their decisions’ authoritativeness (Galloux, 1993), the EGE does at times contribute to blurring the frontier between law and ethics and some of its opinions’ provisions do have a very normatively binding tone<sup>52</sup>. Sometimes this is not just a matter of tone but of outright prescriptive character of pieces of EGE opinions. This is particularly conspicuous in the EGE’s opinion n°22 on the ethical review of hESC FP7 research projects. As it has been recalled above, the funding by the EU of hESC research has been a very tense question over the past two FP adoption processes and although FP6 and FP7 have eventually managed to be launched, “the compromise reached is a limited political compromise founded on the recognition and respect for the diversity of legal and moral culture in Europe, rather than an ethically coherent policy founded on a common European understanding of the precise scope of application of the principle of human dignity” (Plomer, 2008: 850). It is thus a highly controversial background against which the EGE was asked by president Barroso to come up with criteria for the ethical review of research projects. Nonetheless, the EGE took a very incisive stance, actually adding to the debate instead of merely trying to strike a balance between those arguments that were already in presence. Its recommendations as to the fact that toxicity tests should not be carried out on embryos but on animals, or the ones requiring very detailed consent requirements, create “novel and higher ethical bars on hESC research which go against... the evolution of agreed policy” (Plomer 2008: 856) regardless of their soundness on merits which it is by no means this article’s aim to dwell

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<sup>51</sup> Decision 1513/2002/EU of the European Parliament and of the Council of 27 June 2002 concerning the 6<sup>th</sup> framework programme of the European Community for research and technological development. Similar provisions have survived in FP 7, see Decision 1982/2006/EU of the European Parliament and of the Council of 18 December 2006 concerning the 7<sup>th</sup> framework programme of the European Community for Research and technological development (2007-2013), *OJ*, 2006 L412/1.

<sup>52</sup> As Plomer (2008:845-46) puts it: “the linguistic expressions for the headings [of EGE opinions]... give an air of ‘quasi-legislative’ proceedings to the publications. Yet, while this ‘semantic’ structuring does indeed assist in highlighting the sources relied upon by the EGE, it is also potentially misleading because, unlike the syllogistic form of reasoning which may be applicable in legal contexts, the EGE’s opinions have historically drawn on a mixture of ethical principles and fundamental (legal) principles...The danger lies in the blurring of normative ethical and legal orders in areas which are already potentially highly charged, as conclusions could impliedly be read as being substantively necessitated or at least consistent with law”.

upon. Suffice it to say here that these recommendations by the EGE rest on criteria that were not only priorly absent from EU law but are also more stringent than what the negotiations over FP7 could have allowed one to predict.

As such, these instances of direct incorporation of “ethical” principles within EU biomedical law are interesting in so far as they contradict the otherwise generally accepted notion that “moral integration” is to remain alien to the European integration process, if only because of the principle of subsidiarity that commands moral (ethical) options to remain a matter of national decision making. As a matter of fact, when asked to deliver an opinion at the peak of the inter-institutional conflict over the Patents directive, the European Group on Ethics underlined the fact that “the appropriate place to address and resolve some of the [ethical] considerations seems to be the recitals of the directive”<sup>53</sup>, thus expressing the view that it was better to keep a hands-off approach to “ethics” within (hard) EU law. In a similar vein, Research Commissioner Philippe Busquin insisted, when presenting in 2003 the Report he had commissioned on stem cell research, that it “was not about establishing EU legislation on ethical questions [because] regulating on ethical matters is the competence of Member States”<sup>54</sup>. And the Commission more widely has developed the concept of ethical subsidiarity that it readily puts forth in answers to questions by MEPs and in other occasions. Such a doctrine however, as we have seen, has not impeded ethical considerations to appear within the actual body of directives in the field of biomedicine –both before and after strong institutional declarations of deference to ethical subsidiarity. Therefore, it can be argued that more than anything, it is used in a strategic manner: it is silenced when it proves useful to directly incorporate ethics in EU law and voiced again when it does not.

#### II.1.2. Ethics as a means of externalizing political conflict during EU lawmaking processes

The elaboration of the Tissues directives points at another role of ethics in EU lawmaking, one in which institutional community actors try to externalize the ethical debates from the legislative process, in order hopefully to mediate (Farrell, 2009: 46) and/or water down the political conflict. Basically, the partial chronological overlap between the lawmaking processes of both the Tissues directive and the FP6 decision did both of them much harm: the question of the legitimacy of embryonic stem cell research was a permanent interference of one debate over the other. While legislation would have had to approach the issue from a principled perspective (should embryonic research be authorized?), its containment within negotiations over the EU’s research policy notably simplified it (should embryonic research be funded?). Unsurprisingly, the second route was taken; and “ethics” played an instrumental role in allowing for this to happen, for they enabled to expunge the legislative process from the question.

A first step in this direction was the publication by the commission of a staff working paper<sup>55</sup> focusing on the stakes of research on embryonic stem cells as the core question of the political debate and thus aiming at attracting it outside the institutional / political arena of lawmaking. A second one was the organization of an inter-institutional seminar on the subject matter. These attempts can be seen as a means of acknowledging the importance of ethical considerations while at the same time maintaining them outside of the legislative process itself. To be sure, their eventual success was highly dependent on this specific context that allowed the Commission to bail out by saying that the issue of hESC research was going to be dealt with within the debates over the EU’s research policy and were thus to be kept away from the legislative process over the Tissues directive.

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<sup>53</sup> EGE, Opinion n°3 of 30 Sept. 1993 on ethical questions arising from the commission proposal for a Council directive on legal protection for biotechnological inventions.

<sup>54</sup> Cited by Hervey & Black (2005:11). The Report itself echoes Busquin’s views on the matter, see: “each Member State retains its full prerogative to legislate on ethical matters” (European Commission, 2003: 12).

<sup>55</sup> European Commission, *Report on Human Embryonic Stem Cell Research* SEC(2003)441.



More often still, this externalization process occurs under the guise of asking the European Group on Ethics to produce an opinion. This has been common practice since the very first legislative incursions in the field of biotechnologies in the early 1990s<sup>56</sup> and has repeatedly received confirmation during negotiations over directives<sup>57</sup> or research framework programmes<sup>58</sup>. This however points at the at times ambiguous status of the European Group on Ethics within the EU's institutional landscape. In fact, the very conditions in which the EGE came to existence<sup>59</sup> confirm this originally partly cynical conception of ethics within the EU. Its creation was announced by the Commission in its 1991 communication on Biotechnology<sup>60</sup> because "ethical issues need to be narrowly construed or the public debate will continue to be ill-defined". In other words, it would be flawed or overly naïve to see the EGE as an institution grounded in neo-Kantian ideals of 'pure reason'. The manner in which the EGE was created and its mandate was defined is in fact very much in line with the suggestions made by the Senior Advisors Group on Biotechnology (an association of leading pharmaceutical industrials<sup>61</sup>) as to the strategic interest there was of complementing policy framed in terms of competitiveness (Homeyer, 2002: 182ss). And at least initially, the EGE was organically quite dependent from the Commission, a situation that some say has impacted its early shy (referring to the social and political implications of BST, the EGE argues that "such problems go beyond [its] terms of reference") or weak (often the EGE "basically supports" the Commission's views) opinions. In other words, some occurrences of EU institutions asking the EGE to produce an opinion on the midst of political debate over the place "ethics" should occupy within EU legislation may well be viewed as political maneuvers aimed at ensuring the lawmaking process's success –rather than any genuine belief in (let alone achievement of) the possibility of truly European ethical standards.

### II.1.3. Ethics in the guise of new modes of governance

Finally the recently published proposal for an Organs directive embarks upon yet another ethical route: that of new modes of governance (NMGs). In its 2007 communication<sup>62</sup>, the Commission indicated its desire to recourse to the Open Method of Coordination in the field. Indeed, consultations meetings have been taking place involving a variety of stakeholders and have led to the publication of a second communication<sup>63</sup> that very much reflects this NMG approach, for the Commission presents the foreseeable actions to be taken as aiming at the "identification and development of common objectives and guidelines, jointly agreed indicators and benchmarks, and identification and sharing of best practices". Soon after, a proper directive proposal was published<sup>64</sup>. The question might be asked : have EU institutions drawn a lesson from their former legislative experiences in the field of biomedicine that has led them to use NMGs as an upstream ethical guarantee ? Since NMGs are often associated with soft(er) normativity and perceived as allowing for more diversity, they might have appeared as

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<sup>56</sup> See for instance Opinion n°5 of 5 May 1995 on Ethical Aspects of the Labeling of Foods Derived From Modern Biotechnology.

<sup>57</sup> Cf. the above mentioned opinion n°3 of 30 Sept. 1993 on ethical questions arising from the Commission proposal for a Council directive for legal protection of biotechnological inventions.

<sup>58</sup> See Opinion n°10 of 11 Dec. 1997 on Ethical Aspects of the 5<sup>th</sup> Research Framework Programme.

<sup>59</sup> Actually, the EGE initially was called the Group of Advisers on the Ethical Implications of Biotechnology (GAIEB). Created in 1991 for two years, it was composed of 6 members –a number that grew to 9 in 1993. In 1997 the GAIEB was replaced by the EGE (12 members with a term of office of 3 years and even 15 members as of 2005).

<sup>60</sup> SEC(91)629final, 19 April 1991: *Promoting the Competitive Environment for the Industrial Activities Based on biotechnology within the Community*

<sup>61</sup> An association established in June 1989 by Ferruzzi, Hoechst, ICI, Monsanto, Rhone Poulenc, Sandoz and Unilever, under the auspices of the European Council of Chemical Manufacturers' Federation (Homeyer, 2002: 172)

<sup>62</sup> COM(2007)275final.

<sup>63</sup> COM (2008)819/3final.

<sup>64</sup> COM(2008)818final.

trump cards susceptible of silencing (or at least watering down) foreseeable political conflict (over such issues as presumed consent of the dead to donation, limitative definitions of living donors, etc.).

Moreover, NMGs have appeared in the field of EU biomedical law before the 2008 Organs directive proposal. Previous directives such as the Blood and Tissue ones had already been coined as « framework » directives, a qualification close to the NMGs paradigm (Farrell, 2005)<sup>65</sup>. In a similar vein, the EU's minimal harmonization competence as defined by art. 168.4.aTFEU [ex-art. 152.4.a] has readily been referred to as an example of “new approach” legislation, that is legislation limited to setting standards required to protect essential health and safety interests but still allowing for significant discretion of national authorities (Farrell, 2006: 169) –then again, an NMG-resembling melody, regardless of the fact that some authors insist that flexibility, framework approaches and the like are not so “new” (Scott & Trubek, 2002: 2)<sup>66</sup>.

These examples are striking because they give support to the hypothesis that “ethics”, respect for national diversity and NMGs are interrelated. As it is, much of the teeming literature on NMGs insists that they allow for greater participation and expression of the multiple levels of government in the EU, as well as on the fact that they aim at coordinating more than at uniformizing. It is also argued they have developed as a response to the increasing complexity of issues on the agenda and as a means to secure the legitimacy of EU policy making (Scott and Trubek, 2002: 5-8). The recent report by the European Parliament's Committee on Environment, Public Health and Food Safety on the directive proposal on Organs safety strikingly echoes the potentially intricate relationship between ethics, NMGs and diversity: “The directive respects core principles of subsidiarity as well as the differences between the Member States”<sup>67</sup>. Moreover, the report's general tone is rather positive and the proposed amendments rather marginal in their impact on the proposal's general economy, thus allowing for the EU institutions to finally hope for one rather peaceful legislative process in the field of biomedicine.

## **II.2. Ethics and (new) democratic governance**

What is very interesting in the observation of an increased attention paid within EU legislation to ethical considerations is that it does not (only) have to do with the subject matter –biomedical issues. Indeed, the case can be made for “ethics” to have contributed ever since the beginning of the 1990s to (re)defining democratic governance at the European level<sup>68</sup>. As a matter of fact, this is explicit in the famous White Paper on governance à propos which Commission president Delors said that it aimed at putting forth a “strategy of making ethics an integral part of governance” –governance thereby implying increased “openness, participation, effectiveness and coherence” (EU, 2001: 8, 19). For that reason, it can be said that “Bioethics must remain at the heart of the European decision-making process. It is becoming part and parcel of the democratic process in Europe” –as Noelle Lenoir, former president of the European group on ethics, put it (Lenoir, 2006: 5). Such analyses are not uncommon. Mark Cantley, an early and central actor of the EU's interest in biotechnologies in general also indicates that “it is difficult to separate the history of biotechnology regulations in Europe from the evolution of the Community institutions themselves” (Cantley, 1995: 610). There thus seem to be

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<sup>65</sup> See for instance the framework Water directive: 2000/60/EU, OJ L327 (2000): 1.

<sup>66</sup> In fact, in this paper, J. Scott and D. Trubek distinguish between « old, new governance » (NOG) tools that rely on flexibility, comitology and participation of civil society, and « New Governance » whose main features are : partnership, social dialogue or the open method of coordination.

<sup>67</sup> European Parliament, Committee on the Environment, Public Health and Food Safety, Draft Report PR\798376EN\6ENdoc. on the proposal for a directive in standards of quality and safety of human organs intended for transplantation, by Miroslaw Mikolasik available at : [http://www.europarl.europa.eu/meetdocs/2009\\_2014/documents/envi/pr/798/798376/798376en.pdf](http://www.europarl.europa.eu/meetdocs/2009_2014/documents/envi/pr/798/798376/798376en.pdf) (visited May 3, 2010).

<sup>68</sup> See also the insistence of R. Brownsword on the importance of new technologies for European law and scholarship (Brownsword, 2008: 24-5).

parallels and simultaneity between the emergence of “(bio)ethics” and that of a quest for good governance methods within the European polity.

This inevitably begs the question of the links between good governance objectives in general and the (more recent) infatuation of both EU law actors and scholars with NMGs. As is well known, NMGs generally stand for flexibility and participation, and are opposed to traditional legalistic modes of regulation through control and command (the “classic community method”). And the case has been made for biomedicine to be (both on an *ought* and an *is* mode) a propitious field for regulation through NMGs rather than traditional legal tools. Many directives in the field have been analyzed as “new approach” directives of a NMG-type. It has been argued that because they illustrate “a Community competence [limited] to the taking of minimum harmonization measures in relation to standard setting... while at the same time giving Member States the flexibility to impose higher standards in line with national priorities” (Farrel, 2006: 169), they are best described as examples of “‘new approach’ harmonization [that] involves the determination at the EU level only of a floor of minimum standards required to protect essential health and safety interests [whereas] Member States remain free to set higher regulatory standards” (Hervey & McHale, 2004: 59).

However, it is argued that the relationship between NMGs and EU regulation in the field of biomedicine is not one of necessity. If some pieces of regulation in the field have unquestionably stemmed from NMGs (let us think notably of the foreseeable Organs directive), it is only the result of a (strategic) choice of institutional actors. In other words, there is no correlation between the sensitivity of issues in the field of biomedicine and a particular (here, “new”) mode of governance. It is worth making the claim clearly, for much of the literature implicitly links NMGs and biomedical issues on the assumption that because of their nature, the latter necessarily call for “flexible” methods of regulation. In fact, this unexpressed assumption may well account for some inconsistencies that can be met in the legal commentary of many a piece of EU biomedical law. Let us take for example the generally shared view that directives such as the Blood or the Tissue directives are “framework” directives. First, it remains unclear how this qualification actually situates them in the modes of governance taxonomy, for ambiguities remains towards a label that is often linked to NMGs (Scott & De Búrca, 2006) albeit being defined as a typical example of minimum harmonization –in which case it is best described as a ‘new approach’ than a ‘new governance’ tool. Not to mention the fact that the label itself may well be said to be void of any clear meaning –a view shared for instance by S. Prechal who notes that: “during the 1990s... a new term became fashionable: the framework directive. This is an unknown instrument in the typology of the EU Treaty and it is, in fact, not clear what exactly it refers to. One of the characteristics of a framework directive seems to be that it lays down only basic and general principles... However, much depends on how this framework is further completed. Quite a few directives known as ‘framework directives’ are implemented further through so-called ‘daughter directives’ or ‘individual directives’ which may be rather detailed” (Prechal, 2005: 15). Interestingly, both the Clinical Trials and the Blood directives have indeed been followed by further texts<sup>69</sup>, thus illustrating Prechal’s point as far as doubting the heuristic value of the very concept of framework directives. In other words, a critical stance ought to be taken towards equating hypotheses in which the EU secures the possibility for Member States to maintain or adopt further (typically, more stringent) rules with NMGs. Flexibility is not always an indication of NMGs; it has existed for long in EU law and under many guises (de Witte, Hanf, Vos, 2001) and it is not alien to “traditional” harmonization methods.

There is another reason for which it seems relevant to insist on the merely coincidental dimension of encounters between EU regulations in the field of biomedicine and NMGs. Much of the “new

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<sup>69</sup> Directive 2006/86/EU of 24 Oct. 2006, OJ L 294/32 of 25 Oct. 2006; and Directive 2005/85/EU of 8 April 2005 laying down principles and detailed guidelines for good clinical practice as regards investigational medicinal products for human use, as well as the requirements for authorization of the manufacturing or importation of such products, OJ L91/13 of 9 April 2005.

governance” literature insists on the fact that “traditional” law has become an inappropriate regulatory device in a number of fields, mostly because of its “substantial” nature that proves helpless when mere procedural mechanisms are needed. Teubner’s work notably is often referred to in support of the argument that the number one task of regulation nowadays is to design conflict resolution devices more than substantial norms. If this truly is a common denominator to NMGs however, then there is a strong case for underlying how often EU biomedical regulation is very far away from that image. Indeed, as it has tentatively been demonstrated in the present contribution, much of EU regulation in the field is rather substantial: incapacitated adults *can* take part in clinical trials; cloning (be it reproductive or therapeutic) *cannot* be funded through the EU’s research policy; the human body nor elements thereof *may not* as such constitute patentable inventions but adequately isolated and characterized genetic sequences *may*...

It would then be possible to make the case for NMGs to have appeared as a means of dealing with the “destabilization” of law by new technologies (Flear, 2009: 6). Complexity, uncertainty and risk (both ascertained and unforeseeable) are common features of the conditions under which regulation in the field of biomedicine is bound to take place. This could well account for a tendency to let go of “command and control” mechanisms. Similarly, fragile legitimacy of legal answers, especially at a supranational level, to some questions raised by biomedicine might have triggered the development of NMGs in the field. But this then begs the question of their assessment in that respect: have they effectively proved to deal better with the issues at stake? Do we even have enough hindsight to determine whether the “colonizing of deliberation by the ethical discourse” in the field of, say, biomedicine, has not been too quick to be satisfactorily evaluated (Jasanoff, 2006). Working on the role of “ethics” in the regulatory policy of GMOs, B. Wynne actually reached a rather negative conclusion. In his view, the dominant discourse of ethical concerns has mostly resulted in less transparency in the political deliberation and legal regulation of technology. Either it renders the human and ethical commitments of the larger policy culture invisible as matters of private choice or it defines them in scientific terms that then lead to erecting knowledge into the ultimate justification for policy choices –and consequently, to explaining opposition by ignorance (Wynne, 2001: 446-447).

Jasanoff also notably makes the case for not looking only at the legitimizing function of ethics but also at “their quiet participation in the politics of European identity-building” (2005: 90). Such analyses are worth underlying for they strongly echo the “science and technology studies”-inspired notion that while regulating science (here, biomedical issues), politics (here, Europe) actually engender themselves. This has to do with the co-production hypothesis notably put forth by Sheila Jasanoff (2004) that law and science co-produce the social world<sup>70</sup> –and its application to the European polity: “The rise of ethics on the European agenda is a response to these concerns and is closely tied to EU policymaking for the life sciences” (Jasanoff, 2005: 89). Such an imbrication between Europe’s self-constitution as a polity and the history of regulation in the field of biotechnology in general and biomedicine in particular can be explained: “in contrast to most other policies, which had already been fully developed at the national level before they were ‘Europeanized’, the EU has been strongly involved in biotechnology regulation from the very beginning. Starting in 1976, EU biotechnology legislation evolved from a first, unsuccessful proposal for a directive to harmonize emerging national safety regulations for rDNA research into a

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<sup>70</sup> See Jasanoff refers to the manner in which « knowledge-making is incorporated into practices of state-making, or of governance more broadly” (2004: 3) and as far as Europe and the regulation of biotechnology go, she writes “Like 19<sup>th</sup> century Nation States, the EU has found it necessary to specify the problems it wants to solve in order to legitimate its political existence”. In this respect, Jasanoff insists that STS pay more attention to law in general; see Jasanoff (2008: 781) for “accounts of the development of science are incomplete without taking on board the shaping influence of legal imperatives and imaginations, and of necessity the work of legal practitioners and institutions”. These approaches can be compared to the idea developed by G. Majone according to which regulation is always put in place in order to make exist what it regulates (Majone, 1989).

comprehensive set of cross-sectoral horizontal directives and vertical product sector legislation” (Homeyer, 2002: 1).

On this basis, it could be hypothesized that a two-ways self-reinforcing movement then occurred. On the one hand, Europe as a polity needed a greater rationale than competitiveness with Japan or the United States to successfully deal with biotechnological issues. This had been the cruel lesson of the Patents directive experience; and “ethics”, in that respect, would provide some grandeur to EU (biomedical) law. But how would the move to “ethics” be justified? By the triggering of a genuine interest among European citizens for biomedical and biotechnological issues. It is probably not coincidental that the early 1990s witnessed the emergence of several means by which the Community has tried to equip itself with tools aimed at grasping and analyzing public perceptions of life sciences. As of 1991, questions relating to biomedical issues came to be included in the periodical Eurobarometer questionnaires<sup>71</sup>; and a significant part of the BRIDGE Programme (1990-94) foresaw the financing of studies on the socio-economic impact of biotechnologies as well as on public acceptance studies<sup>72</sup> (Smith, 1996: 44-45). On the other hand, these very means by which fostering such interest could be achieved (some have evoked the creation of a biocitizenship) were at the same time an instrumental factor in the strengthening of Europe as a polity. As Jasanoff puts it: “defining policy in opposition to competition from abroad is not a surefire recipe for placating constituents at home, as politicians in the globalizing world have discovered to their sorrow. In policy as in politics, there is no substitute for a committed domestic constituency satisfied with the handling of immediately recognizable local problems” (Jasanoff, 2005: 85). Hence the need for representations of public opinion on such subjects: “these instruments are not merely objective tools of policy and politics. They are ontological ordering devices: in sampling European opinion they help to constitute the very thing that they seek to represent” (Jasanoff, 2005: 85).

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<sup>71</sup> Eurobarometer 95.1 Biotechnology and genetic engineering : What Europeans think in 1991 and Eurobarometer 39.1 with the same title in 1992.

<sup>72</sup> CEC, Biotechnology 1992-1994 Catalogue of socio-economic studies, 1995, EUR 16511 et OJ L 361 du 31.12.1994. See for an example : L. Lemkov (1993).

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**Author contacts:**

**Stéphanie Hennette-Vachez**

Professor of Law (University Paris Est Créteil)

Marie Curie Fellow

European University Institute, RSCAS

Villa Malafasca

Via Boccaccio, 151

I-50014 San Domenico di Fiesole (FI)

Email: [Stephanie.Hennette-Vachez@eui.eu](mailto:Stephanie.Hennette-Vachez@eui.eu)

