

Politics of Ethics: A Moral Identity for EU Citizens¹

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Law has played a special role in the EU context. Through the law Europe started to exert its political and economic role and has been aiming in the last years at be(com)ing a constitutional entity. Law has been the main tool for the construction of Europe²: this means that, “compared to national political systems, the European political system focuses more on enacting rules than intervening financially in the economy”³. This privileged position of legal tools has been reinforced (at least in principle) in the shift from the European Economic Community, based mainly on the free movement of goods, labour, capital and services in a common market, to the European Union as a political entity framed by a Constitution and a corpus of fundamental human rights. Legal rules have operated as the main way to harmonize markets in Member States. But, in the passage from economic to political Europe, the roles of the law have been increasingly strengthened and widened, and law itself has become a privileged way to build Europe as a polity and Europeans as citizens.

The transformations that law is undergoing in order to respond both to the new cognitive and regulatory challenges communicate the feeling that the word “law” is no longer adequate enough to explain how normativity is evolving in the EU context nowadays. New normative discourses were invented to cope with challenging situations where either legal procedures do not proceed fast enough, or a common strongly normative position cannot be easily reached, or new entities and identities need to be shaped. In all these situations a va-

¹ A version of this paper has been already published: “Politics of Ethics and the EU Citizenship”, *Politeia* 2006, XXII, 83, pp. 101-113.

² T. Christiansen, K.E. Jørgensen and A. Wiener, “The social construction of Europe”, *Journal of European Public Policy* 1999, 6, 4 Special Issue, pp. 528-544.

³ Commission of the European Communities, Commission Staff Working Document, White Paper on Governance, “Enhancing democracy in the European Union”, Work Programme, Brussels, 11 October 2000, SEC(2000) 1547/7 final, p. 8.

riety of forms of normativity, weakly prescriptive or even seemingly descriptive tools have emerged in the process of deconstructing, rethinking or replacing law⁴.

In this landscape ethics has increasingly become a major tool to deal with normativity in these different ways. Ethics has been introduced in the European Union context, originally in the field of biotechnology, to bring society closer to European institutions and to build an identity for European citizens. This attempt to use ethics to “represent” civic participation has turned out to be more symbolic than real. In fact, ethics has been applied effectively as a strategy for bio-politics, contributing to the construction of a normative identity for EU citizens on how they should think of themselves and act.

This paper provides some hints –from a STS, constructivist perspective—⁵ at how “this thing called ethics” has become a valuable political resource for purposes other than those alleged— namely, the relevance of moral values to the European decision-making process. These further purposes encompass the willingness to go beyond the original economic foundation and to shape the EU political and epistemic identity. Through ethics European citizens have not only been evoked, they have also been provided a well-defined moral identity. This identity is visible in the regulation of human body materials, with the legal invention of the “citizen-donor”. Moreover, citizens’ mandatory moral identity is used to legitimize the market in its biotechnological use of the body and to exclude any control of it by citizens themselves. In this perspective ethics has always been played as a “politics of ethics”.

FROM BIOETHICS TO POLITICAL ETHICS

The renewed interest in applied ethics and the official birth of bioethics in the late Sixties have been explained in various ways. According to ethicists and historians of

⁴ M. Pollack, “Theorizing the European Union: International Organization, Domestic Polity, or Experiment in New Governance?” (2005) *Annual Review of Political Science* 8: 357-98; K. Abbott, R. Keohane, AM Slaughter, and D Snidal, “The Concept of Legalization” (2000) 3 *International Organization* 54; K. Abbott and D Snidal. “Hard and Soft Law in International Governance” (2000) 3 *International Organization* 54: 421-422.

⁵ D.M.Trubek, P. Cottrell, and M.Nance, “ ‘Soft Law’ , ‘Hard Law’ , and European Integration: Toward a Theory of Hybridity”, *Jean Monnet Working Paper 02/05*, NYU School of Law, New York 2005: “Unlike positivism and materialism, which take the world as it is, constructivism sees the world as a project under construction, as becoming rather than being. (...) At bottom, constructivism concerns the issue of human consciousness: the role it plays in international relations, and the implications for the logic and methods of social inquiry of taking it seriously. Constructivists hold the view that the building blocks of international reality are ideational as well as material; that ideational factors have normative as well as instrumental dimensions; that they express not only individual but also collective intentionality; and that the meaning and significance of ideational factors are not independent of time and place. From an epistemological standpoint, the constructivist approach is not interested in how things *are*, but in how they *became* what they are. Thus, whereas rationalist approaches treat identity and interests of actors as exogenously given or inferred from a given material structure, constructivists ask how actors come to acquire their current identity and interests, and seek to demonstrate how interests are not objectively derived but rather are “socially constructed and dependent on historically bounded social roles occupied by knowledgeable actors” (p. 14).

ethics⁶ the main reason for this search for moral principles has its roots in the problem of human subjects research and in the rise of biotechnical medicine⁷.

What happened after a relatively short period of discussion dealing with the opportunity either to regulate or to leave bioethical issues open belongs to the history of bioethics and the law⁸.

These genealogies of the ethical discourse seem to indicate that the need for a more intense and open dialogue between science and society lies at the core of the bioethical/ethical movement: the need to ground the self-referential ethics of science in a socially agreed vision of values and choices. However, despite these origins, (bio)ethics –its statute and its role– has become a strange borderline entity in the contemporary normative landscape.

The creation of ethics committees and commissions as a seemingly innovative method of decision-making both for single cases⁹ and for general opinions on scientific issues transformed the ongoing pluralist and interdisciplinary dialogue that was at the core of ethics to the bureaucratized mechanisms of expert advice derived from scientific committees' procedures.

More specifically, an ambiguous relation exists between ethics and the law. This ambiguity depends on the fact, on the one hand, that moral discourse has been developed historically primarily as a matter of individual decision and not as a collective, deliberative procedure; and, on the other hand, that traditional moral judgment does not imply specialized knowledge, while bioethical questions seemed loaded with sophisticated scientific expertise.

The attempt to introduce ethics at an institutional level has led, at least in the EU context, to an even more complex situation. Bioethics and ethics have become valuable political resources in EU normative discourse for purposes other than those alleged –the relevance of moral values to the decision-making process. Science has shared this political role with ethics, since the ethical dimension has been introduced in the European normative discourse both as a warrant and as a limit to scientific and technological power – when technoscience began to reveal its close contacts with the market — and as a means to suggest that a closer link to society was established.

An apparent politics of values has been highly advertised indeed as a distinctive ele-

⁶ N.S. Jecker, A.R. Jonsen, R.A. Pearlman, *Bioethics. An Introduction to the History, Methods, and Practice*, Jones and Bartlett Publishers, Sudbury Ma. 1997; M.L. Tina Stevens, *Bioethics in America. Origins and Cultural Politics*, Johns Hopkins University Press, Baltimore 2000.

⁷ In the US the growing interest in the social implications of science at the end of World War II was associated with the discussion of science policy concerning the role that social sciences might play as a form of awareness public accountability of science for the natural scientists community (U.S. Congress, Office of Technology Assessment, *The Regulatory Environment for Science —A Technical Memorandum*, OTA-TM-SET-34, Washington, DC: U.S. Government Printing Office, February 1986).

⁸ S. Jasanoff, *Science at the Bar*, Harvard University Press, Cambridge Ma 1995.

⁹ S.S. Ellenberg, T.R. Fleming, D.L. DeMets, *Data Monitoring Committees in Clinical Trials : A Practical Perspective (Statistics in Practice)*, John Wiley & Sons, London 2002.

ment around which the political European Community could and should be built. Meanwhile, ethics has also served other political goals in a far less noticed way. So-called “ethical aspects” have been accurately shaped, displayed or hidden, to be used as an effective political instrument aimed at de-politicising some sensitive issues. Namely, ethics has become a self-legitimate way to make politics and law albeit without the usual warrants required by legal systems to protect citizens from State powers.

From time to time, ethics has been used by EU institutions in order to neutralize political issues, to introduce norms outside the traditional process of law-making, to evoke society without involving it, to pretend to have democratic concerns where solely experts’ procedures were taking place, to control citizens’ behaviour and directly intervene in their bodies through norms where scientific and ethical statements merge, and to exempt the market from ethical criticism. Engaging in ethical discourse as a supposedly participatory dialogue, EU institutions have *de facto* performed a biopolitics, endorsing individual and community values to establish freely which ethics and whose values count or do not count in European politics.

ETHICS AS A SUBSTITUTE FOR POLITICS: CREATING-REPRESENTING CITIZENS

In recent years EU institutions have displayed their awareness about the main role that ethics has played as a political element, presenting it as a matter of open and shared choice. EU institutions (and primarily the Commission) seem to be willing to talk about themselves in a self-reflexive way, proposing their narrative about the origins of ethics.

In order to create a recognizable space and a public status for ethics, numerous websites¹⁰ describe its rise, presenting it as a general political factor in the shift from the ECSC Treaty in 1953 to the Single Market in 1991, to the Treaty of Maastricht in 1993 when “a new phase of the European integration began: to build an ever-closer European Union”.

The official politics of ethics started in 1991 –through the appointment of the Group of Advisers on the Ethical Implications of Biotechnology (GAEIB)– with the decision to incorporate ethics in the decision-making process, at the beginning, in relation to biotechnology, and later, to all areas of application of science and technology¹¹. In the words of

¹⁰ In the interval between the draft of this text and its final revision, the DG Research website dealing with ethics was redesigned. In this deep revision several expressions were modified. This makes the European politics of ethics even more intriguing, since an apparent politics of words is restlessly taking place. The references to the previous and now extinct sites are shown here to document the untraceable history of the online European ethical language.

¹¹ As the *Commission Decision on the renewal of the mandate of the European Group on Ethics in Science and New Technologies*, 11 May 2005, (2005/383/EC), Official Journal of the European Union L 127/19, 20/5/2005 explains, “(1) In November 1991, the European Commission decided to incorporate ethics into the decision-making process for Community research and technological development policies by setting up the Group of Advisers on the Ethical Implications of Biotechnology (GAEIB). (2) The Commission decided on 16 December 1997 to replace the GAEIB by the European Group on Ethics in Science and New Technologies (EGE) extending the Group’s mandate to cover all areas of the application of science and technology.”

the Commission, GAEIB represented – even though only supposed to turn “an ear” to all interested groups —¹² the interests of European society and the respect for the fundamental rights of every European citizen.

“That is the role of the Group of Advisers on the Ethical Implications of Biotechnology. In setting it up the European Commission has highlighted its desire to integrate Europe's science and technology in a manner that serves the interests of European society and respects the fundamental rights of every European citizen. (...) European integration must mean more than establishing a single market; progress in science and technology must be given a human, social and ethical dimension, otherwise European citizenship cannot be established”¹³.

Ethics has thus become essential to establish the idea of “European citizenship.” Having entered the European arena as a basic element in regulating both citizens’ lives and researchers’ behaviours in relation to biotechnology, ethics has become an important legitimizing factor in the construction of a political European Community –the shift from a primarily economic to a political organization passed through it.

“In the spirit of this economic approach most legislative powers were allocated in the core fields of necessary market regulations. Ethics and cultural values, by nature, are predominantly regulated on the national level. They follow the principle of subsidiarity. However, while seeking for harmonized market conditions, European directives necessarily touch on the issue of ethics”¹⁴.

It seems that “ethics and cultural values” should not be subject to European legislation. But this is not due to the fact that they are per se a questionable field for legally binding norms. Instead, the main reason is shown by the priority held by national legislation. But this priority has to yield when the superior interest of harmonizing the market gives precedence to European regulation.

In a few lines the reader becomes aware that ethics has to be a matter of legislative competence; that this competence may be national or supranational; that “necessarily” European directives deal with ethics; and that ethics is directly related to the economic field.

It is worth noting that no definition of ethics is given (which ethics?, ethics applied to which fields?, whose ethics?). Moreover, ethics comes together with cultural values, two other undefined words. The broad expression suggests that everything in peoples’ daily life, in their history, every behaviour may become part of this enlarged perspective.

Why moral values are proposed as a stronger advertisement than just law for European citizenship can be easily guessed. Values are a metaphoric reference to the civil society,

¹² http://ec.europa.eu/european_group_ethics/archive/1991_1997/bilan_en.htm.

¹³ *Ib.*

¹⁴ Cf. European Commission, Research, Science and Society, http://europa.eu.int/comm/research/science-society/ethics/research-e-legislation_en.html (accessed on October 2005).

to historical heritage, to rooted communities, to a non-bureaucratic but spontaneous level of organization. Talking of ethics and allowing ethical values to be part of the decision-making process, European institutions suggest they represent society as a whole and present themselves as a political community, or even a polity¹⁵.

Even more, values express the substantial content of the law that modernity has discarded and detached from its positive form. Re-implanting values in the pale procedural image of law conveys the impression that something like a Europe by “natural law” is taking place, that Europe exists not just because of treaties but because of deeper meanings.

The willingness to use ethics as a manifestation of indirect involvement of the public in the decision-making process and as a symbolic move toward a qualitatively different vision of the European Community seems to put an emphasis on the role of civil society in building a broader political community. But ethics is only symbolically evoked for democratic involvement and is not implemented accordingly. Even though it is declared that “[t]he Commission aims to promote responsible research in Europe and to keep the rapidly advancing progress in science in harmony with the ethical values of all Europeans”¹⁶, the identification of these values is not linked to any sort of public consultation but is the precise task of an appointed expert committee¹⁷.

The identification and the definition of the ethical issues are the tasks of ethics experts and, in fact, the activity of the scientific/ethical committee is recognized as expert advice. As to the public, they must just be kept properly informed.

The assumption that ethics is a form of representation of citizens and the weak awareness that ethics and law cannot easily be reduced to each other, neither in their content nor in their procedural requirements, has gone so far that some impressive Freudian slips can be found in the EU language. Expressions such as “legislation on ethics”¹⁸ and also “ethical legislation”¹⁹ are indeed signs that ethical values are becoming a matter of semantic, if not institutional confusion.

These expressions were used until November 2005 when the new websites of a promptly self-reflexive Europe switched to: “Ethics: Democratic fundamentals”²⁰. With a

¹⁵ S. Jasanoff, *Designs on Nature: Science and Democracy in Europe and the United States*, Princeton University Press, Princeton NJ 2005, p. 89.

¹⁶ http://europa.eu.int/comm/research/science-society/ethics/legislation_en.html (accessed on October 2005).

¹⁷ *Ib.*: “to identify and define the ethical issues raised by biotechnology; to assess, from the ethical viewpoint, the impact of the Community's activities in the field of biotechnology; to advise the Commission, in the exercise of its powers, on the ethical aspects of biotechnology and to ensure that the general public is kept properly informed.”

¹⁸ Cf. Commission of the European Communities, *Science & Society in Europe*, http://europa.eu.int/comm/research/science-society/ethics/research-e-legislation_en.html (accessed on October 2005).

¹⁹ Commission of the European Communities, *Science & Society*, http://europa.eu.int/comm/research/science-society/ethics/legislation_en.html (accessed on October 2005).

²⁰ http://ec.europa.eu/research/science-society/page_en.cfm?id=2995

sudden change that realistically shows the European identity in flux, so-called European values are now more plausibly connected to the Charter of Fundamental Rights²¹.

COMMISSIONING ETHICS: RULE-MAKING BEYOND THE RULE OF LAW?

The problem of commitology has been widely explored both at the theoretical²² and at the institutional level²³. But the issue is not solved and it bears a heavy weight on the representative nature of ethical committees.

From the point of view of States under the rule of law – as Europe is, finding and founding its unity on the normative level — the problematic character of all committees is made even worse here by the fact that one main reason to use ethics committees has been the agility of their procedures compared to the legal ones. In this sense it is interesting that an important character of the GAEIB was envisaged in its “dynamism”: “Its openness and dynamism are the best response to the accelerating pace of development in the relationship between science, technology and the key values of society”²⁴.

The recent Commission Decision on the renewal of the European Group on Ethics in Science and New Technologies (EGE) mandate in 2005 seems to weaken the openness but, indeed, strengthens the dynamism.

After having defined that the EGE members are experts appointed *ad personam* to whom apply the rules on expert knowledge²⁵, the document explains how the EGE functions. Article 4.3 affirms the non-public character of EGE work, whose sessions are private. The participation of a limited, selected public is allowed only during round tables (one for each opinion delivered), aimed at promoting dialogue and improving transparency²⁶.

Other elements reveal the real nature of this bureaucratized version of the ethical discourse. Article 4.5 suggests that when “not unanimously” taken, decisions shall also contain dissenting opinions, but it leaves to internal regulation the adoption of decision rules.

²¹ *Ib.*: “Europe’s democratic societies should offer the necessary safeguards and channels of dialogue to ensure that the development and application of science and technology respects certain fundamental values. The EU’s 450 million or so citizens have just such a common ethical framework that binds them together as Europeans: the Charter of Fundamental Rights”.

²² See for instance B. Wynne, “Expert Discourse of Risk and Ethics on Genetically Manipulated Organisms: the Weaving of Public Alienation”, *Notizie di Politeia* 2001, XVII, 62, pp. 51-76.

²³ Through the reform of the system of committees serving the European Commission: see *Council Decision 1999/468/EC of 28 June 1999 (a new ‘commitology decision’ repealing Decision 87/373/EEC) laid down the procedures for the exercise of the implementing powers conferred on the Commission*.

²⁴ http://ec.europa.eu/european_group_ethics/archive/1991_1997/bilan_en.htm.

²⁵ *Décision de la Commission du 11 mai 2005 relative au renouvellement du mandat du groupe européen d’éthique des sciences et des nouvelles technologies (Le texte en langue française est le seul faisant foi)*. The following quotations are taken from the English version: *Commission Decision of 11 May 2005 on the renewal of the mandate of the European Group on Ethics in Science and New Technologies (2005/383/EC)*, Whereas (5): “The Communication from the Commission on the collection and use of expert advice by the Commission”.

²⁶ *Commission Decision on the renewal (2005/383/EC)*, cit., Art. 4.5: “will organize a public round table in order to promote dialogue and improve transparency for each opinion that it produces”.

Whereas (4) reinforces the idea that ethics is a lighter and faster version of law, and that it requires “new working methods in order to respond to more rapid science and technology developments in a timely manner”²⁷.

In its White Paper on European Governance²⁸ the European Commission (EC) has made clear that legal rules need to be complemented with a broad variety of policy tools and non-legislative instruments. This assertion seems to imply that the rule of law, as it has been imagined in the construction of the modern State under the rule of law, is not a flexible-enough form of regulation. The legislative process, with its rigidity, well established forms, limited capacity to organize broader participation, and its slow pace, needs to be fixed. “The Union,” it is said, “must renew the Community method by following a *less top-down* approach and ...when legislating, the Union needs to find ways of *speeding up* the legislative process”²⁹. Conciseness has become the most desirable feature of law, namely a “‘primary’ legislation limited to essential elements (basic rights and obligations, conditions to implement them)”³⁰.

Accordingly, law finds itself at the centre of a major process of revision and deconstruction as the main instrument to control/legitimize political power.

In the ongoing discussion about the so-called law-lag – the chronic delay affecting the pace of the law compared to the pace of techno-science— frequently evoked by European Directives dealing with science and technology, the informal features of ethics combined with the logic of expert decisions represent the easiest way to introduce rules beyond the rule of law.

In redefining and refining the right place for law, other more handy, flexible and speedy normative instruments are introduced. These substitute instruments, however, are not always likely to grant the same degree of legitimization and legal warrants. Due to the urge to “speed-up and simplify” the legal processes, the reshaping of the law, indeed necessary, has become, at least in some cases, more a deterministic deconstruction of the law according to techno-scientific and economic “needs” than a reflexive rethinking of rule-making.

THE CASE FOR THE “GOOD-AND-SAFE” EUROPEAN CITIZEN-DONOR

Through ethics Europe is creating its own idea of citizenship and its own citizens. These citizens are not only evoked, but they are also provided a well defined, desirable moral identity.

²⁷ Ibid., Whereas (4): “The EGE requires new working methods in order to respond to more rapid science and technology developments in a timely manner and requires new competences in order to address a greater range of science and technology applications”.

²⁸ Commission of the European Communities, *European Governance. A White Paper*, Brussels, 25.7.2001, COM(2001) 428 final.

²⁹ Ibid., p. 5.

³⁰ Ibid., p. 20.

In constructing their own epistemology, European institutions have stated in numerous documents the unwillingness to separate science from ethics as the most apparent feature of their identity and epistemology³¹. The general (normative) idea that inspires provisions ranging from biotechnology to biomedicine, to consumer protection and to animal welfare is that ethics is part of sound science. It is not clear whether this statement is made with regard to the inner morality of science, the necessity of an external, social control on scientific applications, or both. But the ethical gaze on scientific issues has become a well recognizable element of European law-making.

This European epistemology of “ethically-related science” has been expressed in numerous legally-binding documents. An important example is Directive 2001/20/EC on good clinical practice which states at Article 1.2. (Scope):

“Good clinical practice is a set of internationally recognized *ethical and scientific quality requirements* which must be observed for designing, conducting, recording and reporting clinical trials that involve the participation of human subjects. Compliance with this good practice provides assurance that *the rights, safety and well-being* of trial subjects are protected, and that *the results of the clinical trials are credible*” [emphasis added]³².

The quality of research and trials relies necessarily on both good science and ethics, and compliance with these standards is a measure for both the respect for rights and the credibility of results. This tendency to merge science and ethics and to shift from descriptive to prescriptive language is not used only to control the behaviour of scientists and researchers –who are asked to comply with the ethical requirements for research activities– but also to assess and normalize citizens’ behaviour. A normative citizens’ identity has been inscribed in and prescribed by the regulation of human body materials (HBMs) –namely of the European citizens’ bodies, more and more requested by the market– through the legal invention of the reliable “good-and safe citizen-donor”.

This new view of citizens is introduced by the legislation on the procurement of human biological materials. The regulatory framework for human cells and tissues has been shaped for many years now by institutions inside both the EU and the Council of Europe (COE). The two principles of free donation and prohibition of financial gain from the human body have been received by the 1996 COE Convention on Biomedicine and Human Rights and amplified in subsequent recommendations³³, while the EU Directives

³¹ M. Tallacchini, “Epistemology of the European Identity”, *The Journal of Biolaw & Business* 2002, Supplement Series Bioethix 2002, pp. 60-66.

³² Directive 2001/20/EC of the European Parliament and of the Council of 4 April 2001 on the approximation of the laws, regulations and administrative provisions of the Member States relating to the implementation of good clinical practice in the conduct of clinical trials on medicinal products for human use, OJ, 1/5/2001.

³³ Council of Europe, *Committee of Ministers, Recommendation Rec(2006)4 of the Committee of Ministers to member states on research on biological materials of human origin* (Adopted by the Committee of Ministers on 15 March 2006 at the 958th meeting of the Ministers’ Deputies): “Article 7 – Prohibition of financial gain - Biological materials should not, as such, give rise to financial gain”.

on Good Clinical Practice³⁴ and on the patentability of biotechnological inventions³⁵ declare the non-marketability of the human body (at least as to private individuals).

In 2004 the EU published Directive 2004/23/EC on setting standards of quality and safety for the donation, procurement, testing, processing, preservation, storage and distribution of human tissues and cells. The Directive applies to almost all human cells and tissues, as well as to reproductive cells (eggs, sperm), fetal tissues and cells, and adult and embryonic stem cells³⁶.

Though the title refers solely to scientific-technical requirements, and the EU here seems to stick to its well established identity of harmonizer of the market, the Directive contains one of the most impressive ethical statements that can be found in its legislative production. Without any reference to a shared public vision of the subject, a well defined philosophy of the (born)³⁷ human body is normatively declared at Whereas (18). After having said (Whereas 3) that the awareness that "...we are all potential donors..." has to be promoted at both national and Community levels (in order to help "European citizens decide to become donors during their lifetime"), the text so follows:

"As a matter of principle, tissue and cell application programs should be founded on the philosophy of voluntary and unpaid donation, anonymity of both donor and recipient, altruism of the donor and solidarity between donor and recipient. Member States are urged to take steps to encourage a strong public and non-profit sector involvement in the provision of tissue and cell application services and the related research and development"³⁸.

A sharp contrast may be seen between the philosophical approach and the urgency presented to States to implement this philosophy. But in the following lines it becomes apparent that this principled philosophy of (compulsory) "altruism and solidarity" is mandatory only for citizens. In fact Whereas (6) explains that the Directive does not apply to "[t]issues and cells intended to be used for industrially manufactured products,"

³⁴ *Directive 2001/20/EC*, cit.

³⁵ *Directive 98/44/EC of the European Parliament and of the Council of 6 July 1998 on the legal protection of biotechnological inventions*, OJL 213, 30/7/1998.

³⁶ *Directive 2004/23/EC of the European Parliament and of the Council of 31 March 2004 on setting standards of quality and safety for the donation, procurement, testing, processing, preservation, storage and distribution of human tissues and cells*, L 102/48 Official Journal of the European Union, 7 April 2004.

³⁷ Another interesting point in this continuous shift from scientific to ethical language regards the definition of individual and person. Even though Directive 2004/23/EC deals with body cells and tissues and prescribes the ethical behaviour in their donation and procurement, the human body is described only at its "cellular and tissue level" and no definition of the whole body is given. In fact this definition is allocated to Member States. While all cells and tissues are regulated under Directive 2004/23/EC, the acknowledgment of individuality and personhood to the whole foetal or embryonic "body" is discussed not directly as a matter of ethics, but as a matter of nationality, with which the Directive "should not interfere" (Whereas 12). The choice of the adequate scientific level of description, body parts instead of body wholes, and the choice of the adequate legislative levels are the mechanisms used to neutralise the ethical issues involved.

³⁸ *Directive 2004/23/EC*, Whereas (3): "It is necessary to promote information and awareness campaigns at national and European level on the donation of tissues, cells and organs based on the theme 'we are all potential donors'."

namely to industry, and that the matter is regulated (except for donation) by other legal provisions³⁹.

A strong ethical vision of European citizens is legally implemented as result of the institutional philosophy endorsed by the EU. This ethical vision is not only encouraged and enforced, but, in the above mentioned context of quality and safety standards of biological materials, is also proposed as an indicator of safety that concerns both the tissues and the tissue donors. “Voluntary and unpaid” donations are not presented just as a requirement for a more equitable society but as a direct factor of safety:

“Voluntary and unpaid tissue and cell donations are a factor which may contribute to high safety standards for tissues and cells and therefore to the protection of human health”⁴⁰.

It is hard to say whether the provision shows concern about combating the illegal trafficking of organs and tissues, or if it is aimed at granting industry free access to human tissues. However, in order to discourage the sale of body tissues and cells, the imperative of free donation is proposed as a direct element of safety and public health protection. Who is willing to sell his/her tissues, the Directive implicitly states, is a threat to society. “Normal” citizens will be those who behave at the same time “ethically and safely”. But this “science-based ethics” -- where ‘safe’ becomes a synonym for ‘moral,’ the ethics of behaving safely — is introduced through a seemingly neutral and descriptive language that simply shows the statistical correlation between “free” solidarity and health safety.

A recent Directive dealing with the safety aspects of donation (Directive 2006/17/EC)⁴¹ makes it clear that donors evaluation is performed by collecting and recording all “relevant medical and behavioural information,” and that “in order to acquire the appropriate information, different relevant sources must be used,” including interviews with third parties (Annex IV, 1.2).

MANUFACTURING ETHICS TO LEGITIMIZE THE MARKET

A triangular relationship among ethics, science, and the market emerges from the analysis of the European politics of ethics. Ethics should have limited economic interests in the field of biotechnology, as the GAEIB recalls in one of its opinions:

³⁹ *Ib.*: Whereas (6): “Tissues and cells intended to be used for industrially manufactured products, including medical devices, should be covered by this Directive only as far as donation, procurement and testing are concerned, where the processing, preservation, storage and distribution are regulated by other Community legislation”.

⁴⁰ *Ib.*, Whereas (19).

⁴¹ *Commission Directive 2006/17/EC of 8 February 2006 implementing Directive 2004/23/EC of the European Parliament and of the Council as regards certain technical requirements for the donation, procurement and testing of human tissues and cells.*

“The affirmation of the citizen's rights in the European Union implies that the economic advantages derived from biotechnological developments should in no way affect the respect of ethical requirements”⁴².

But the way ethics has entered the normative framework of biotechnology reveals how ethical values have been used to draw the boundaries between citizens and industry, between civil life and economic interests. The distinction between natural and artificial entities as the threshold of patentability is an example of these boundaries.

Patents are one of the first fields where the European Community and the Council of Europe have acknowledged their different competences about ethics. When the COE Convention on Human Rights and Biomedicine⁴³ was released in 1997, the European Parliament and Council Directive on the legal protection of biotechnological inventions (98/44/EC)⁴⁴ was still under the process of approval, but despite the fact that ethical concerns about patenting life were a strong obstacle to the approval of the European Directive, the COE decided to ignore the relevance of patent matters to bioethics. Accordingly, commenting on the relation between the Oviedo Convention and the proposed Directive 98/44/EC about the prohibition of getting financial gain from the human body, the Explanatory Report on the Convention adopted the following position:

“The question of patents was not considered in connection with this provision (marketability of body materials); accordingly the latter was not intended to apply to the question of the patentability of biotechnological inventions”⁴⁵.

This statement clearly reflects the reciprocal intention of EU and COE not to challenge the other's legal status and competences. Avoiding dealing with patents on living matter while discussing the non-marketable legal qualification of the human body was a way not to see “the elephant in the room”.

But the effects of this distinction have played a precise role in the subsequent story of patents and of the separation between what is natural and what is artificial. Isolation and purification⁴⁶ have been constructed as the defining elements of biotech patents, but

⁴² GAEIB, Opinion No 8 of 25 September 1996: *The patenting of inventions involving elements of human origin*, Requested by the Commission in April 1996. Rapporteurs: Professor Gilbert Hottois and Professor Dietmar Mieth.

⁴³ *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)*, adopted by the Ministers Committee the 19th of November 1996 and open to signature in Oviedo the 4th of April 1997.

⁴⁴ In 1988 a Proposal of Directive was presented for the first time to the Parliament by the European Commission, and again a revised version in 1995 (COM/95/661). The Parliament approved the Directive in May 1998.

⁴⁵ *Explanatory Report to the Convention on Human Rights and Biomedicine* (Strasbourg, May 1997, DIR/JUR (97) 5), Art.21, P.134; and also Art.21, P. 132: “(...) this Article does not prohibit the sale of a medical device incorporating human tissue which has been subjected to a manufacturing process as long as the tissue is not sold as such”.

⁴⁶ *Directive 98/44/EC*, Article 5.2: “An element isolated from the human body or otherwise produced by means of a technical process, 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”.

they have also contributed to accurate distinctions between what is ethically relevant or irrelevant.

Two of the major documents on the legal status of the body in the European context agreed on a vision where the human body is at the same time unsalable (for individuals) and marketable (for industry), thus both ethically relevant and irrelevant.

Well before Directive 2004/23/EC stated that human biological materials intended to be used by industry are not subject to the philosophy of solidarity and gratuity, this distinction of competences alone had already prepared the terrain for the contemporary ontology of body materials. COE is still the authority for values, EU governs the market.

Reciprocating in acknowledging each other's position, the Convention takes it for granted that biological entities may be patentable, and the Directive calls for respect for the fundamental human rights to dignity and integrity⁴⁷.

Through the identification of their different institutional tasks and languages (an interesting story of "Whereas" and "Bearing in mind"), EU and COE have contributed to neutralizing the political space between what is given for free and what is paid. And it is ethics that draws the boundaries, seemingly de-politicizing the necessary choice.

The same distinction has been replicated inside the EU institutions in order to account for the separation between natural and bio-artificial human body. While Directive 2004/23/EC restrains its application to the acts of donation and procurement of human tissues and cells, and Directive 2006/17/EC deals with the safety aspects of donation, the competence to define the legal threshold between natural and manufactured tissues has been given to DG Enterprise⁴⁸.

In its Proposal for a Regulation on advanced therapies, namely gene therapy, somatic cell therapy and human tissue engineering⁴⁹, the Commission DG Enterprise has widened as much as possible the domain of the market. The definitory feature adopted as the indicator of the degree of artificiality of tissues and cells is their "destination to the market," whether the tissues are produced as standardized products for a limited number of patients or for a single patient (only with the exclusion of "products which are both prepared in full and used in a single hospital, in accordance with a medical prescription for an individual patient")⁵⁰. The philosophy of voluntary and unpaid donation, that is repeatedly af-

⁴⁷ Only the *Explanatory Report to the Convention* refers to the *Proposal for a European Parliament and Council Directive on the legal protection of biotechnological inventions*, COM (95)0661 - C4-0063/96 - 95/0350(COD)). The preliminary version of the Directive makes reference to the Convention, while the final text quotes only Art.1 of TRIP's Agreement (*Trade-Related Aspects of Intellectual Property Rights*, GATT 1994, WTO 1995) and the *Convention on Biological Diversity* (Rio de Janeiro, 5.6.1992).

⁴⁸ <http://ec.europa.eu/enterprise/pharmaceuticals/advtherapies/index.htm>.

⁴⁹ Commission of the European Communities, *Proposal for a Regulation of the European Parliament and of the Council on advanced therapy medicinal products and amending Directive 2001/83/EC and Regulation (EC) No 726/2004*, 16.11.2005, COM(2005) 567 final.

⁵⁰ *Ib.*, Article 28: "Any advanced therapy medicinal product (...) which is both prepared in full and used in a hospital, in accordance with a medical prescription for an individual patient".

firmed together with its explicit public safety implication (Whereas 14, Art. 3.5)⁵¹, and in the Explanatory Memorandum is, significantly, followed immediately by the comment dealing with “competitiveness aspects” (3.6)⁵².

All ethical issues about human tissues have been purified and have vanished through the isolation of the ethical moment in the context of donation, through the political use of ethics to exclude citizens from decisions concerning the market, and through the political decision to put the regulatory task in the hands of DG Enterprise and Industry.

Europe is sticking to its perpetual movement between community and commodity. In a vicious circle, the politics of ethics, built up to promote the creation of the political Europe, has become the most compliant instrument to serve the needs of the economic Europe.

⁵¹ *Ib.*, Explanatory Memorandum, 3.5, and Whereas (14): “As a matter of principle, human cells or tissues contained in advanced therapy medicinal products should be procured from voluntary and unpaid donation. Voluntary and unpaid tissue and cell donations are a factor which may contribute to high safety standards for tissues and cells and therefore to the protection of human health”.

⁵² Such as: a harmonised data protection period; the possibility to be designated as an orphan medicinal product; the possibility of an accelerated assessment procedure; the option to get conditional marketing authorisations or marketing authorisations in exceptional circumstances (*Ib.*, Explanatory Memorandum, 3.6).